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NOTE

Please be advised that this book of contributed papers only contains those papers submitted in support of the posters presented at the International Conference on Effective Nuclear Regulatory Systems: Sustaining Improvements Globally, held from 11 – 15 April 2016 in Vienna, Austria.

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NEW NPP CONSTRUCTION EXPERIENCE IN FINLAND

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Abstract

The paper discusses the experiences of the new nuclear power plant construction projects. The topics include the licensing and regulatory oversight process, completion of the design prior to construction, experience and know how of the participating organisations, quality management in a nuclear construction project, safety culture aspects in a nuclear construction project, and the role and importance of regulator’s oversight. Finland has recent experience of new nuclear power plant construction, one plant unit being under construction close to commissioning phase and one plant unit in construction license phase.

1. INTRODUCTION

The licensing process of a new nuclear facility in Finland is shown in Fig. 1. Currently there is one nuclear power plant unit under construction in Finland, i.e., Olkiluoto unit 3 which is EPR type pressurised water reactor. Olkiluoto unit 3 received a construction licence in 2005 and the licensee is planning to submit an operating licence application in April 2016. New licence applicant (Fennovoima) submitted a construction licence application in June 2015. Fennovoima has a plant contract with Rosatom to build an AES-2006 type pressurised water reactor. There are also two operating plant units in Olkiluoto site (boiling water reactors, BWRs) and two operating plant units in Loviisa site (pressurised water reactors, VVERs). These operating plants were commissioned in the end of 1970’s and licensees are carrying out modernisations. All existing plant sites have final disposal facilities for low and intermediate level radioactive waste. Spent fuel final disposal company Posiva received a construction licence for a spent fuel final repository in November 2015 as a first this type of a facility in the world. Currently ongoing large oversight projects at nuclear facilities in Finland are shown in Fig. 2.
2. REGULATORY FRAMEWORK IN THE COUNTRY OF CONSTRUCTION

Each nation is solely responsible for the safety of its nuclear installations. Therefore, there are also national practices on how nuclear power plants are licensed.
and how the safety and quality of these plants are verified during construction and operation.

Differences in licensing, regulations and regulatory practices may have an impact on the design of the plant and how it is licenced. There may be differences in how the detailed design has to be documented and how and when it needs to be submitted for approval to the regulator. To avoid surprises due to differences, it is beneficial for the owner and plant vendor to familiarize themselves early enough on the national practices and regulations. In addition, the owner and the plant vendor have to understand what are the national safety goals and safety requirements that the plant has to fulfil and what they mean to the detailed design of the plant. These have to be clarified and explicitly defined by the owner in terms of design criteria in the bidding documentation to avoid difficulties in the future steps of the project. It is recommendable to discuss those design criteria also with the regulator in connection with the bidding process before signing the contract.

In the Finnish regulatory system, the licensee has to submit the design and working documentation of safety significant systems, structures and components to the regulator for approval. Regulator’s approval of the documentation for most safety significant structures and pressure equipment is required prior to start of construction or manufacturing. Also the pressure equipment manufacturers, and inspection and testing organisations have to be approved by the regulator prior to start of manufacturing, inspections and tests, respectively. In addition, when reviewing the working documentation the regulator may define witness or hold point type of inspections. These inspections are conducted before, during and after construction or manufacturing to verify that the component is being manufactured as described in the documentation.

3. COMPLETION OF THE DESIGN PRIOR CONSTRUCTION

One of the most important factors in new build projects is the adequate maturity of detailed design of the plant and its’ systems, structures and components at the time when civil construction is to be started. Based on the experience in Finland, special emphasis should be put on the time and effort needed to incorporate new conceptual design features into the detailed design of the plant.

The amount of work needed to complete the detailed design is large and the design work may involve both in-house (vendor) and subcontracted engineering staff. Furthermore, design of a first of a kind plant may be much more iterative

1 For example concreting plans, technical description of pressure vessel manufacturing, welding procedures, inspection plans, etc.
process than redesigning a plant that has already been built.\textsuperscript{2} In this context, the management of the design process becomes very important. It is beneficial to all stakeholders to ensure the availability of qualified and experienced engineering resources and mature design management processes before start of the detailed design. This is needed to ensure a once through review and approval of the design and working documentation, i.e., to avoid iteration and rotation of documents between the involved parties.

4. MANAGEMENT OF DESIGN IN A CONSTRUCTION PROJECT

Subcontractors may engineer significant parts of the detailed design of the plant’s systems, structures and components. Since the nuclear industry is widely globalised and also the vendors can be multinational, the detailed design of the plant can be done by several organisations and in different locations.

Both the wide use of subcontractors and the global nature of vendor organisations highlight the importance of proper design management processes. This includes written description of design configuration and change management processes, together with a transparent and traceable requirement management. Design management process should ensure adequate communication between civil, process, electrical and I&C engineers. One should also ensure that safety and risk experts are directly involved in the design review process. They should verify that for example the principles of redundancy, separation, and diversity are consistently applied in all disciplines including both safety and their support systems.

One important factor for avoiding misunderstandings and for managing the interfaces between the design levels and the different organisations that work on the plant, system and component level designs is provision of explicit design and implementation requirements.\textsuperscript{3} Explicit requirements will also ensure that the design of structures and components meet the requirements set by the system and the plant level. It is not possible for the licensee and regulator to approve the documentation if it is not explicit. This causes additional updates of the documentation and extra work for all organisations.

\textsuperscript{2} Even though the plant has been built somewhere else, there is anyhow some redesign that needs to be done due to site specific aspects, due to different subcontractors, and due to different owner and regulatory requirements in a country of construction.

\textsuperscript{3} Design and working documentation shall not contain implicit expressions such as “mainly”, “in principle”, “in general”, “and/or” “whenever possible” etc.
5. EXPERIENCE AND KNOW HOW OF THE LICENSEE AND THE VENDOR, MANAGEMENT OF SUBCONTRACTORS

Licensee’s and vendor’s key persons (e.g. project directors, people responsible for safety and design of the plant, Quality Assurance and Quality Control) shall have experience in nuclear power construction or operation. This is the key to the success. Right experience ensures that nuclear specific issues are known and timely identified and right amount of attention, resources and time is allocated to the important areas. In particular for pilot projects, the team should have people with experience from previous pilot projects.

Regulator should verify that the licensee has adequate human resources for the project from the beginning. Resources should include e.g. staff needed to oversee the activities of the vendor and staff needed to review and approve of the plant’s design. Licensee’s need of resources varies during the project and hence it should conduct staff planning covering the entire project. Staff planning is important especially in a small country if more than one nuclear power project is starting or ongoing. The use of consultants in lieu of licensee’s own staff should be planned and justified. When balancing the use of consultants and own staff it should be taken into account that the design, construction and commissioning phases are most useful for the licensee to build up the know-how and experience which is needed to operate the plant safely.

The subcontractor selection criteria and approval process should be clearly defined and agreed between the vendor and the licensee. Licensee may want to consider setting restrictions to the length of the subcontractor chain (e.g. vendor’s subcontractor may not order work from another subcontractor unless agreed prior contracting). It should be understood by the licensee and the vendor that subcontractors with limited or no nuclear experience require special attention with regards to training and guidance prior to start of activities and oversight during manufacturing and construction. In addition, contracts between the vendor and its subcontractors shall be clear especially in nuclear specific issues (e.g. quality assurance and quality control requirements differing from conventional industry). The understanding and implementation of these requirements shall be audited prior to start of activities and verified when the activities are ongoing.

As well as new design features, also new and advanced manufacturing and construction technologies may require additional time and effort to be qualified for the purpose. Areas where new technologies will be applied should be identified in the beginning of the project to be able to pay attention and allocate adequate time for the qualification process.

6. ROLE OF QUALITY MANAGEMENT

Requirements for Quality Assurance (QA) and Control (QC) are very specific to safety critical applications like nuclear power plants. In general, the conventional
industry is nowadays quite familiar with the international quality standards like ISO. It has to be noted that ISO and other conventional standards alone are not enough for safety significant activities in a nuclear power project. What is enough shall be clarified, defined and agreed between the regulator, the licensee and the vendor from the very first days of the project. This means for example that quality requirements to be applied in different safety classes are clearly defined and agreed before subcontracting and procurement starts so that they can be clearly written in contracts and specifications.

One specific example is the definition and process for a non conformance. Raising and reporting a non conformance shall follow a uniform and effective process throughout the project. The criteria for a non conforming performance or a product, classification principles and roles and responsibilities to report and resolve a non conformance shall be clear.

7. LICENSEE’S RESPONSIBILITY IN TURN KEY CONTRACT

From regulator’s point of view, licensee is always responsible for safety independently of the contract type. Licensee has to control and oversee everything that has to do with safety of the plant, with a graded approach. With a turn key contract the licensee has contracted a vendor for example to design, build and commission the nuclear power plant.

Turn key contract type highlights the importance of clear and explicit requirements for the design, manufacturing, construction, installation and commissioning of the plant. Experience has shown that it is not always simple for the licensee to interfere the project when the work is in progress and requirements for the work are not explicitly defined. Even turn key projects are manageable, but in addition to explicit requirements a necessary prerequisite is systematic, transparent and traceable requirement management process applied together with strong, competent and safety oriented QA/QC personnel who are able to verify compliance with the requirements.

8. SAFETY CULTURE IN A CONSTRUCTION PROJECT

Construction of a nuclear power plant does not differ from an operating nuclear power plant from safety culture point of view. Safety and quality must have higher priority than costs and schedule. This message has to be very clear and transmitted from the licensee and vendor management to all participating organisations and to all levels of the organisations from day one. Management’s acts and decisions in the project have to be consistent with the message.

In order to ensure that safety and quality has the highest priority in every day activities throughout the project, everyone has to understand the safety significance of the work one is responsible for. Understanding is essential to promote personal responsibility for safety and quality. This is a challenge in a construction project.
where thousands of people are involved and many of them have no previous experience or knowledge on nuclear power plants.

The level of safety culture is tested whenever problem situations are encountered. One of the outcomes of good safety culture is that safety and quality problems are openly raised, discussed, reported and resolved. The ways and routes to raise them have to be made known to the workers. Atmosphere to report safety and quality issues has to be open, free of punishment and encouraged by the foremen. When a safety issue has been raised by a worker, foreman or someone else has to give feedback to the person and inform whether the issue was significant or not and how it was resolved.

9. REGULATORY ISSUES IN NEW CONSTRUCTION

The experience has shown the importance of stringent regulatory approach and inspections. These are needed to verify that the performance of the licensee, the vendor and the subcontractors meet the expectations and that the equipment and structures meet the specifications set by the design. Prerequisite is that regulatory body is competent, independent, has strong powers and enforcement tools.

New plant projects raise always a lot of media interest both nationally and internationally. Therefore it is important that regulator is prepared to interact with media. One of the essential factors is that regulatory decisions are transparent and can be published either pro-actively or when asked by media, other organisations or members of the public.

10. CONCLUSIONS

Starting new NPP construction project is very demanding because much of the earlier experience and resources have been lost from the nuclear industry. Therefore, adequate time has to be allocated to good preparation of the project before the actual construction start. This includes e.g. building competent organizations, complete design incorporating possible new design features, qualified new manufacturing and construction technologies, ensuring availability of qualified designers, constructors and manufacturers to implement the project, and resolving potential regulatory uncertainties.

Construction of a nuclear power plant is a complex project. It for example includes different technical disciplines within various stakeholders, a number of subcontractors, and workers from different countries. It is evident that challenges will be met in a nuclear power plant construction project. Therefore close monitoring and oversight both by the licensee and the regulatory body is necessary to ensure achievement of specified quality, i.e. meeting the technical standards and criteria that the vendor has specified and that have been approved as part of licensing and design documents.
REGULATORY EXPERIENCES FROM EFFECTIVE STEP-WISE IMPLEMENTATION OF THE SPENT NUCLEAR FUEL DISPOSAL IN FINLAND

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Abstract

Finland is one of the foremost countries in the world in developing a disposal solution for spent nuclear fuel (SNF). The Construction License Application (CLA) for the Olkiluoto SNF encapsulation and disposal facility was submitted by Posiva, the implementer, to the authorities at the end of 2012 and the Government granted construction license in November 2015. STUK, as the independent safety regulator, submitted its safety evaluation and statement to the Finnish Government in February 2015. STUK’s main conclusion was that proposed Encapsulation plant and disposal facility for spent nuclear fuel can be constructed to be safe.

1. INTRODUCTION

Finland began planning and preparing for nuclear waste management measures in the 1970s, during the procurement and construction phase of the first nuclear power plants. In 1983, the Finnish Government made a policy decision on the principles and schedules of nuclear waste management. Accordingly, disposal facilities for the low and intermediate level operational waste generated at Olkiluoto and Loviisa were taken in use in the 1990s. In 2000, the Government adopted a favourable Decision-in-Principle (DiP) accepting the concept of a deep disposal facility for spent fuel from the Finnish nuclear power plants in Olkiluoto and Loviisa. This DiP was confirmed by the Parliament in 2001. A construction licence application for the encapsulation and disposal facility was submitted to the Government in 2012.

STUK, as the independent safety regulator, has been performing stepwise review of developing safety case and R&D needed to demonstrate safety of spent nuclear fuel (SNF) disposal. STUK strategy has also been that safety regulation is developed coincide with the development of disposal. This approach has enabled to include experiences and growing knowledge timely into safety regulation.

STUK also decided to participate actively in pre-siting and pre-license phase. Active participation has included pro-active public communication and step-wise
evaluation of site characterisation work and development of safety case. Based on our experiences active participation and communication with implementer has been one of the key factors in regulatory work to enable effective progress in disposal development and licensing.

The Finnish government granted in 12th November 2015 Posiva license to construct SNF encapsulation plant and disposal facility in Olkiluoto. License is for 6500 tU SNF originating from Olkiluoto 1-3 and Loviisa 1-2 reactor units. Before encapsulation and disposal process begins, Government has to issue a operating license. Operating license application is expected to be submitted in early 2020’s and disposal is planned to start 2023.

2. FINNISH SPENT NUCLEAR FUEL MANAGEMENT POLICY AND STRATEGY

The Finnish Government decided on the principles of arranging nuclear waste management as early as 1978, in the early stages of nuclear power utilisation in Finland. In the management of low and intermediate level operational waste, the Government aimed for domestic measures, as they were considered the easiest to implement. In the management of spent fuel, permanent exportation or exportation for reprocessing were considered as primary options.

According to the 1978 decision of the Finnish Government, each producer of nuclear waste – in practice the nuclear power companies – is responsible for the management of spent fuel and other radioactive waste generated in connection with their operations and for the costs incurred. Nuclear waste management includes handling, storage and disposal of the waste and decommissioning of the nuclear facilities. The 1978 decision laid also down the principles and responsibilities for R&D planning and regulatory oversight. Since 1988, the waste management responsibility and regulatory process has been laid down by the Nuclear Energy Act (990/1987).

In 1983, the Finnish Government made a general decision on the objectives and schedules of the research, investigation and planning activities concerning nuclear waste management at the existing nuclear power plant units. This general decision presented two basic options for the management of spent fuel. The first option involved centralised international disposal solutions and contract arrangements that would have allowed reprocessing waste or spent fuel, as such, to be irrevocably located abroad. In the other option, power companies had to prepare for disposal of spent fuel in Finland, meeting safety and environmental protection standards. The disposal measures were to begin around 2020. Before that, the companies had to survey and select the disposal site by the end of 2000 and be prepared to present plans for the disposal facility and encapsulation plant required for the construction licence. The schedule for construction plans was adjusted in 2003, requiring the plans to be presented by the end of 2012.
From late 1970’s until 1996 Finland had dual strategy for SNF management. Spent fuel from Loviisa NPP was exported to Soviet Union and later to Russia for reprocessing. Basis of agreement was that also waste from reprocessing stayed in Soviet Union/Russia. TVO, licensee on Olkiluoto NPP’s, started to prepare plans for SNF disposal in Finland. In 1994, a significant amendment was made to the Nuclear Energy Act. Nuclear waste generated in connection with or as a result of the use of nuclear energy in Finland shall be handled, stored and permanently disposed of in Finland. As a result of this policy decision, SNF from Loviisa NPP could not be exported anymore to Russia and NPP owners established Posiva to continue development of a joint disposal facility according to strategy established in Government 1983 decision.

3. STEPWISE PROGRESS AND LICENSING

The licensing procedure for a disposal facility has several steps that are similar to all nuclear facilities in Finland and are defined in Nuclear Energy Act [1] and Degree [2]. These licensing steps are (Figure 1):

— Decision-in-Principle (DiP) is required for a nuclear facility having considerable general significance. This is essentially a political decision: the government decides if the planned project is in line with the overall good of society. The decision can be applied for one or more sites, the host municipality has a veto right and the parliament has the choice of ratifying or not ratifying the decision.

— Construction License is granted by the Government and authorizes the construction of the facility. The actual construction is regulated by STUK and includes several review and approval steps, hold points and viewpoints.

— Operating License is granted by the Government and authorizes the operation of the facility for a certain period. The operating license is needed for example before nuclear waste can be introduced in encapsulation plant or disposal facility.
3.1. Regulatory activities during site selection and disposal concept development

The first comprehensive documentation about KBS-3 concept was produced in Sweden 1983. In Finland the disposal concept evolution was followed also by STUK. At that time STUK’s work mostly concentrated to follow review and assessment done by the Swedish regulators. Above mentioned Government decision from 1983 required stepwise submittal of site characterization summaries for regulatory review and assessment. The implementer, first TVO and later Posiva, prepared safety cases concentrating on siting issues in 1985, 1992 and 1996. Safety cases were used to support screening process in siting. STUK made regulatory review of these safety cases.

An important element of regulatory oversight for SNF disposal development has been review and assessment of R&D programmes produced by licensees with waste management obligation. Legislation has required waste producers to submit to responsible ministry their plans for nuclear waste management. STUK has been involved in regulatory process by reviewing the plans from safety perspective. During site characterization and pre-license phase reviewing these R&D-plans has been the main method for STUK to follow overall progress in SNF disposal development.

3.2. STUK’s preliminary safety appraisal regarding Decision-in-Principle

The first licensing step towards a disposal facility for SNF is Decision-in-Principle (DiP). For Posiva’s disposal facility, this first step was reached at the end
of 1999 when Posiva submitted the application for a Decision-in-Principle [3] for a spent fuel disposal facility in the Olkiluoto. At this step the Government shall consider whether "the project is in line with the overall good of society". In particular, the Government shall pay attention to the need of the facility, to its effects on the environment and to the suitability of the proposed site. For the Government's decision, STUK has to make a preliminary safety evaluation of the facility, the proposed host municipality has a veto-right and they shall state their acceptance or rejection for siting the facility. And finally the positive DiP decision by the Government has still to be ratified by the Parliament.

Posiva submitted its DiP application in May 1999, together with the environmental impact assessment (EIA) report. The Ministry of Trade and Industry requested STUK to submit its preliminary safety evaluation of the DiP application by the end of 1999. STUK had engaged already in year 1998 international team of external experts to support STUK’s own safety evaluation work. STUK's safety review included aspect like retrievability, completeness of scenarios, consideration of human intrusion, treatment of uncertainties, consistency of models and input data and long-term performance of engineered barriers. After STUK’s positive safety appraisal and approval by the host municipality, the positive DiP was made by the government in late 2000 which was ratified by the Parliament in early 2001. In addition to the permit to proceed with the project, it gave also Posiva the authorization to start to construct an underground rock characterization facility at the proposed site, to the depth of actual planned disposal, as required by safety regulation.

The DiP issued in 2000 for a disposal facility applies to the spent fuel generated by the operations of the four nuclear power plant units currently in use in Finland, totaling a maximum of approximately 4,000 tons of uranium (tU) of spent fuel. For Olkiluoto 3 plant unit, separate DiP was issued to enlarge disposal with 2,500 tU of spent fuel.

3.3. Regulatory activities during pre-license phase

3.3.1. Regulatory oversight of underground rock characterization facility

After the DiPs on 2001 and 2002, STUK started work aiming for the readiness to review the construction license. One of the major activities was the regulatory oversight of the construction work of the underground rock characterization facility (URCF), Onkalo. STUK planned and executed the regulatory oversight of the URCF in similar manner as it would do for nuclear facility due to the fact that Posiva’s plan is to use the constructed URCF as part of the disposal facility in the future.

The safety of the future disposal facility in Olkiluoto is based on ensuring the integrity of the containment of the disposed waste for a long period of time and effective retardation of radioactive nuclides. The purpose of STUK’s regulatory
oversight of URCF is primarily to ensure that the design and construction are carried out in such a manner that the geo-environment retains its favorable characteristics and conditions. The regulatory approach for the oversight of the construction included review and assessment of the documentation and onsite inspections which included construction inspection program focusing on Posiva’s management system, operations and activities, inspections on the readiness of Posiva to begin excavations and work phases and inspections concerning construction work on site. Construction of URCF started 2004.

3.3.2. Review and assessment of the R&D work and draft documentation

Besides the oversight of the construction work of the URCF, STUK followed closely Posiva’s R&D work based on the R&D program published every third year and reviewed the draft post closure safety case documentation published by Posiva before year 2012. The aim of the step-wise review, close follow-up and regular meetings with Posiva was to identify the safety relevant issues and especially key safety concerns already before Posiva finalizes and submits the construction license application. During the license application preparatory phase STUK had a process for collecting and updating the position of key safety concerns with regular dialogue between STUK and Posiva. However after a while it was acknowledged that addressing single safety concerns did not in many cases lead to better overall understanding of safety and sometimes the linkage to safety was not very clear. From this experience a need for more structured review and assessment process for the construction license application review was seen necessary.

In 2003 the Ministry of Employment and Economy required Posiva to submit preliminary (draft) license documentation by the end of 2009. The reasoning was to have a regulatory review of the status of construction license application development. STUK reviewed the draft safety case and delivered the results to Posiva during 2010. This was an unique possibility for STUK to test review process, review organization and to obtain overall status of safety case development.

3.3.3. Increasing regulatory resources and competence

In addition to the activities related to Posiva, STUK also developed it’s own resources and competence to prepare itself for the construction license review. In 2006 STUK management made a strategic plan to increase waste management resources before Posiva submits the CLA. Plan was followed and the amount of people working mainly for the waste management regulations was almost tripled during next six years. STUK made also framework contracts with 13 external experts to support STUK during in the review of CLA.
3.3.4. **Updating the regulatory guidance**

STUK decided to reform the regulatory guidance for nuclear facilities (YVL-guides) in 2005. The original plan was to publish the new guidance several years before Posiva was going to submit the construction license but there were some delays in the project and the estimate was to publish the guidance in 2011. This was postponed again by couple of years because of the Fukushima accident. The lessons learned from that were included in the YVL guides published in the end of 2013.

New guides were released after the submittal of the CLA for the SNF encapsulation and disposal facility. Despite of this, the CLA was written based on the new guidance. This was possible because most of the guides were in the final draft stage already in 2010 and STUK agreed with Posiva that Posiva would use the draft guidance for the CLA documentation. Some of the last minute changes in the YVL-guides caused some extra work both for Posiva and STUK but as a whole it was considered worthwhile that the safety of the new facility is reviewed against the latest regulations.

3.3.5. **Planning the review of the construction license review**

STUK set up a project for the regulatory licensing of the spent nuclear fuel disposal facility in 2011. Project was divided in four main phases: 1. Preparatory phase, 2. construction license phase, 3. construction phase including commissioning and 4. operating license phase.

In the preparatory phase STUK made a overall plan for the whole project and more detailed plan for the CLA review phase which describes the review process, organization, time schedule and resources for the license application review. The main element of the CLA review phase was of course the review of the extensive safety documentation. The assessment of safety requirement fulfillment and implementer organizations readiness for construction activities was supported with STUK inspection program for pre-construction phase.

The regulatory assessment of safety is, of course, done against regulatory safety requirements. In the pre-licensing stage STUK’s approach was initially safety issue oriented and a bottoms-up assessment. However for having a more regulatory requirement oriented and safety related review basis for the detailed CLA review and assessment, STUK started the development of the so called review plan during the preparatory phase. This review plan contains a collection of earlier regulatory observations and expectations for the construction license application that were derived from and linked to regulatory safety requirements given in the government decree on the safety of disposal of nuclear waste [4] and YVL-guides. The review plan was used as guidance both for internal and external participating in STUK’s review. It was also the basis for the structure of STUK’s safety evaluation report.
3.4. Regulatory review and assessment of the construction license application

STUK’s task in the license application process is to review and assess the fulfillment of all applicable radiation and nuclear safety requirements. STUK shall also prepare a statement and safety evaluation report for the Government. In the statement STUK has the possibility to highlight issues that need further attention or propose license conditions.

During the first quarter of 2013 STUK performed the first initial review for the CLA. The aim of the initial phase, sometimes compared to docketing, was to check that the license application contained all main elements requested in STUK YVL guides. The conclusion from the initial review was that Posiva had delivered most of the documentation required and STUK continues the review. STUK also required Posiva to deliver to STUK the missing parts of the documentation and to update some parts which were considered to be on too general level.

The detailed review and assessment phase started on the second quarter of 2013. During this phase STUK made approximately 30 requests for additional information in areas where further information or clarification was needed. STUK accepted main documents e.g. PSAR [5] and post-closure safety [6] and submitted statement and safety evaluation report [7] to the Government in early 2015.

STUK’s main conclusion was that the planned encapsulation plant and disposal facility can be built to be safe. Also there is sufficient reliability that there will be no detrimental radiation effects to the public or environment neither during the operational period nor after decommissioning and closure of the facility. In the statement to the government STUK raised areas that need further development before specific construction step or before submittal of operating license application. These areas are related for example to process for selecting suitable disposal tunnel location, further R&D and assessment of engineered barrier system performance and development in post-closure scenario analysis and presentation of post-closure safety case. These areas have been further specified in PSAR and post-closure safety case decisions that STUK has send directly to Posiva.

3.4.1. Inspection program during the CLA review

The assessment of safety requirement fulfillment and implementer organizations readiness for construction activities was supported with STUK inspection program for pre-construction phase. The inspection program will be later broadened for construction inspection program, for encapsulation plant and disposal facility construction oversight.

The objective of the inspections performed by STUK during the pre-construction phase was to support the review and decision making process by verifying the license applicant’s management system, processes and procedures and also technical issues described in the license application documentation. Through these inspections STUK got a more comprehensive view of the status of the
applicant’s activities and progress of its development work. STUK focused the inspections on the license applicant and the organizations responsible for the nuclear facility’s design and any organizations involved in the project whose work can be deemed to have major implications on safety. STUK’s inspections covered all the main processes and major parts of sub-processes defined in the license applicant’s management system. During the CLA review 17 inspections were performed.

3.4.2. Resources used for the CLA review

For the review and assessment of the CLA, in-house expertise was used both from nuclear waste and material regulations and nuclear reactor regulations. Important parts of the safety case focus on the post-closure safety and the related safety assessments are wide and needed to be carefully assessed in a timely manner. For this reason STUK signed agreements with Technical Research Centre of Finland (VTT) and several international experts for supporting its review and to conduct independent modeling. The total number of experts participating in STUK’s CLA review was approximately 90 persons and altogether 27 person years was used for the review.

3.5. Planning for the regulatory oversight of the construction

Government granted the construction license to Posiva in November 2015 and Posiva’s plan is to start the construction activities during the second half of 2016. Planning of the regulatory oversight of the construction period is based on the regulatory requirements and experiences from the oversight of the URCF construction and CLA review. Detailed planning started right after STUK finished the CLA review.

During the construction period STUK will have oversight over the detailed design, construction, fabrication and pre-operational testing, which will be followed by the review of the operating license application. As described STUK’s review and assessment of CLA raised several safety related topics, where STUK needs to follow Posiva’s further work before operating license application will be submitted. STUK will also conduct a construction inspection program during the construction period which focuses on the management system, processes, procedures and technical issues.

YVL-guides on nuclear waste management will be updated based on the experiences received from the CLA review. Regulatory requirements need also some supplements to fully cover construction and manufacturing of the systems, structures and components of the encapsulation plant and disposal facility. STUK’s internal guidance will also be updated for the construction period.
4. CONCLUSIONS

STUK reviewed the construction license application for the encapsulation plant and disposal facility during the years 2013-2014 and gave its statement and safety evaluation report in February 2015. Main conclusion was that the proposed facilities can be built to be safe. For the review STUK carried out comprehensive preparations which included close monitoring of Posiva’s activities, review of preliminary safety documentation, planned increase of STUK’s own competence and resources and preparation of internal project and review guidance.

To reach this point in SNF disposal facility project, more than 30 years of parallel development of the repository project and the regulatory approach to SNF management was needed. Key features in the Finnish waste management framework supporting the long term project are:

— A clear licensing process.
  • Long term political commitment to resolve the nuclear waste issue;
  • National strategy and discipline in implementation;
  • Stepwise licensing and implementation including veto-right for the local community regarding hosting the waste facility;
  • Timely and focused communication to public.
— Early establishment of a national framework.
  • Well defined liabilities and roles;
  • Early on established funding system.
— Active regulatory work.
  • Development of a regulatory approach parallel with R&D and in analogy with nuclear power plant safety regulations;
  • Regular regulatory follow-up of progress in the SNF disposal program.

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Abstract

In Canada, the Fukushima Daiichi accident triggered not only a review of the safety of existing Nuclear Power Plants (NPPs), but also a review of the Canadian regulatory framework of NPPs. To that effect, in addition to the action plan to improve the safety of NPPs following Fukushima accident, a comprehensive review of the regulatory framework was initiated.

Drawing from the Canadian Nuclear Safety Commission Task Force Report, this paper will review the lessons learned from the event with respect to the regulatory framework. The paper will also provide the status and rationale for the improvements in regulatory requirements, such as improvements in severe accident management, emergency management, deterministic safety analysis and probabilistic safety assessment, design requirements for new NPP and periodic safety review requirements. The paper will also highlight issues and challenges facing Canadian industry during the implementation of these regulatory improvements. The topic of multi-unit probabilistic site assessments, as well as the development of Safety Goals will be discussed. The impact of all these improvements and their relation to the Vienna Declaration of Nuclear Safety will also be presented.

1. INTRODUCTION

When the magnitude 9 earthquake and ensuing Tsunami occurred on the east coast of Japan on March 11, 2011, the world watched the tragedy unfold and as part of it, the nuclear accident at the Fukushima Daiichi Nuclear Power Plant. The tsunami had disabled the backup emergency systems, and the operators were powerless in stopping the accident sequence that led to multiple core melts and radioactive releases.

Following this major event, the nuclear community responded by reviewing the strength and robustness of their nuclear plants. The European countries performed stress tests, the US Nuclear Regulatory Commission (USNRC) performed
a Near Term Task Force and the Canadian Nuclear Safety Commission staff embarked on a task force to review lessons learned from Fukushima Daiichi accident.

In addition to the review of the robustness and defence in depth of the nuclear plants, the Canadian task force also undertook a thorough examination of its regulatory framework in order to assess how it covered the lessons learned from Fukushima and, if gaps were identified, to recommend further actions. Before covering these aspects in more detail, a brief explanation of the Regulatory Framework situation at the time the accident happened is given below.

2. REGULATORY FRAMEWORK CONTEXT

The CNSC’s regulatory framework is comprised of the Nuclear Safety and Control Act, which govern the regulation of Canada’s nuclear industry, regulations, regulatory documents and licences. Fig. 1 shows the hierarchy of these instruments in the Canadian Nuclear Regulatory Framework. All these instruments describe the requirements that nuclear facilities must follow in order to be compliant with regulations and requirements. The CNSC’s processes also cover inspections, verifications and enforcement as part of its compliance program. This paper will not discuss the compliance aspects but rather the requirements identified in the various regulatory documents such as the Act, Regulations, Regulatory Documents and licences conditions.

![FIG.1. Canadian Nuclear Regulatory Framework](image)

The Canadian Nuclear Framework has evolved over the years. In 2009, The CNSC started a review to reform of its Regulatory Framework to ensure that its suite of regulatory documents were up to date, well defined, and supported by guidance as necessary [1]. Later on, the CNSC improved upon the Regulatory Framework Structure by establishing a system which facilitates stakeholder access to regulatory framework elements, and improve the clarity of the overall regulatory framework for
licenses and applicants using the 14 Safety and Control areas used in Canadian licensing process [4].

Another important aspect of the present Canadian Nuclear Regulatory Framework is that it is a transparent process with involvement from stakeholders. The process itself calls for multiple commenting periods from interested stakeholders on regulatory documents. In addition the CNSC’s process allows for discussion papers to be published to elicit comments and suggestions from interested stakeholders at the conceptual level prior to drafting the regulations or document.

When the Fukushima Daiichi accident happened, the regulatory framework reform was in progress, with some major documents being in the middle of their review. For instance, the important document on Design of New Nuclear Power Plant [2] was being reviewed and updated. As explained below, this review was enhanced to also cover the lessons learned from Fukushima.

3. THE CANADIAN REGULATORY FRAMEWORK “STRESS TEST” FOLLOWING FUKUSHIMA DAIICHI ACCIDENT

As part of the Canadian Task Force review [3], an important aspect was the review of the regulatory framework [5]. All the regulatory framework type of documents were reviewed, from the Nuclear Safety and Control Act through licence conditions.

The first conclusion of the review was that no amendments were necessary to the Nuclear Safety and Control Act and the General Regulations. However some amendments were suggested for the Class 1 Nuclear Facilities Regulations and the Radiation Protection Regulations. It was suggested that the Class 1 Nuclear Facilities Regulations be amended to require submission of off-site emergency plans. For the Radiation Protection Regulations, it was suggested that additional guidance be proposed for emergency doses limits and criteria for return to work for emergency workers post-emergency.

It should be mentioned also, that the existing regulatory framework at the time already provided the capacity to trigger an early regulatory intervention following the Fukushima accident; the General Nuclear Safety and Control Regulations provided the mechanism whereby the CNSC requested NPP licensees (and other nuclear facility licensees) to review their safety cases in the light of the lessons learned from the Fukushima accident. Subsection 12(2) of those regulations places an obligation on licensees to respond to a request from the Commission, or from a person who is authorized by the Commission, to “conduct a test, analysis, inventory or inspection in respect of the licensed activity or to review or to modify a design, to modify equipment, to modify procedures, or to install a new system or new equipment.”

The CNSC internal review of the regulatory framework however concluded that some specific CNSC regulatory documents should be updated on a priority
basis, specifically recommending updating selected design-basis and beyond-design-basis requirements to address:

- external hazards and associated methodologies for assessment of magnitudes probabilistic safety assessments for multi units plants
- complementary design features for prevention and mitigation of severe accidents passive safety features
- fuel transfer and storage
- design features that would facilitate accident management.

Due to the overall breadth and scope of these recommendations, CNSC staff also streamlined the existing process for updating or appending regulatory document to propose focussed amendments to address these recommendations.

The Fukushima omnibus amendments project, covered updates to the following Regulatory Documents:

- Probabilistic Safety Assessment (PSA) for Nuclear Power Plants (S-294)
- Developing Environmental Protection Policies, Programs and Procedures at Class I Nuclear Facilities and Uranium Mines and Mills (S-296 and G-296)
- Severe Accident Management Programs for Nuclear Reactors (G-306)
- Deterministic Safety Analysis for Small Reactor Facilities (RD-308)
- Safety Analysis for Nuclear Power Plants (RD-310)

Other CNSC regulatory document projects that were underway were further updated to address key lessons from Fukushima, include the following:

- REGDOC-2.5.2, Design of Reactor Facilities: Nuclear Power Plants (formerly RD-337)
- REGDOC-1.1.1, Site Suitability (for nuclear power plants and small reactor facilities - formerly, Site Evaluation for New Nuclear Power Plants (RD-346))
- A new dedicated regulatory document on accident management
- A strengthened suite of emergency preparedness regulatory documents

The Fukushima Omnibus amendments constitute a good example of a flexible and adaptive regulatory process. The Omnibus streamlined the review of the regulatory documents with specific attention to the lessons learned from Fukushima. The recommendations from the Task Force were taken into account to propose amendments to the five documents mentioned above. In some of these, minor administrative changes were also incorporated, however the principal changes consisted of recommendations from the lessons learned from Fukushima. The normal regulatory document process was modified to allow prompt and concise
amendments proposal and documentation. The review process however was not modified; hence stakeholders had the same review time for the omnibus amendments than the normal process dictates.

The omnibus amendments covered primarily the following issues:

— station boundary monitoring
— objectives of probabilistic safety assessment
— external hazards/events and methodologies for assessment of magnitudes (severe accidents)
— multiple unit accidents and events
— extended station black-out, and prolonged loss of coolant, power, and equipment/instrumentation availability (or sustainability)
— assessment of potential cliff-edges and margins
— irradiated fuel bays/spent fuel pool events or accidents considerations for nuclear facilities other than NPPs

The resulting regulatory documents as described in Table 1 were presented to the Commission and were approved:

<table>
<thead>
<tr>
<th>Current Regulatory Document</th>
<th>Previous Regulatory Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ REGDOC-2.3.2, Accident Management: Severe Accident Management Programs</td>
<td>G-306, Severe Accident Management Programs for Nuclear Reactors</td>
</tr>
<tr>
<td>➢ REGDOC-2.4.1, Deterministic Safety Analysis</td>
<td>RD-308, Deterministic Safety Analysis for Small Reactor Facilities</td>
</tr>
</tbody>
</table>

In addition, other Regulatory Framework initiatives following Fukushima were initiated, albeit not in the same integrated manner as the omnibus. These initiatives were to:

— Develop a regulatory document on accident management (REGDOC 2.3.2)
— Strengthen the suite of emergency preparedness regulatory documents (REGDOC 2.10.1) Review applicable Canadian Standards Association (CSA) standards;
— CNSC has been in discussion with CSA group to support their review of CSA’s nuclear standards to take into account the lessons from Fukushima. In particular, the CSA standard on nuclear emergency management is developed (N1600)
  • Introduce Periodic Safety Reviews; for Periodic Safety Reviews (PSR)
  • REGDOC 2.3.3 was introduced to prescribed requirements
    This document is in line with IAEA framework for PSR.

4. IMPROVEMENTS TO REGULATORY FRAMEWORK, CHALLENGES AND VIENNA DECLARATION OF NUCLEAR SAFETY

The open and transparent process that CNSC follows for regulatory improvements includes many opportunities for stakeholders to comment on proposed regulatory documents. One of the major comments arising from this process was consideration of multi units and irradiated fuel bay in the Probabilistic Safety Assessment (PSA). The concern was that there is no methodology currently established to perform these assessments. CNSC staff recognized this fact, but nevertheless considered that these requirements were mandated following the Fukushima accident.

Another corollary finding from the stakeholders was that the current Safety Goals used to assess how a plant meets the nuclear safety objective, involves risk metrics measured on a per unit basis and not on the whole site. In addition, clarity was needed on to which risk the Safety Goals were supposed to assess, such as the whole list of risk arising from internal and external events or only internal events.

It was recognized that these important issues were a concern internationally, as there is no international consensus on the aspects of whole site PSA, risk aggregations and Site Safety Goals. CNSC therefore organized an international workshop [6] to discuss these issues. The workshop was very well attended and fostered research into these topics. CNSC staff has established a working group to review Safety Goals in light of these discussions. The Canadian industry has also been mandated to develop a whole site PSA pilot project for the Pickering Nuclear Station methodology to be presented to the CNSC in 2017.

The Vienna Declaration of Nuclear Safety (VDNS) [7] came into effect in February 2015 and Canada, as party of the Convention of Nuclear Safety, recognizes its importance. The VDNS stipulates that:

(a) New nuclear power plants are to be designed, sited, and constructed, consistent with the objective of preventing accidents in the
commissioning and operation and, should an accident occur, mitigating possible releases of radionuclides causing long-term off-site contamination and avoiding early radioactive releases or radioactive releases large enough to require long-term protective measures and actions.

(b) Comprehensive and systematic safety assessments are to be carried out periodically and regularly for existing installations throughout their lifetime in order to identify practicable or achievable safety improvements are to be implemented in a timely manner.

(c) National requirements and regulations for addressing this objective throughout the lifetime of nuclear power plants are to take into account the relevant IAEA Safety Standards and, as appropriate, other good practices as identified inter alia in the Review Meetings of the CNS.

A review of the CNSC regulatory requirements has shown that the latest revisions of the documents made as a result of the lessons learned from the Fukushima Daiichi accident address the principles of the VDNS as was highlighted in section 3. The CNSC requirements for Canadian NPP licensees that have been developed since the Fukushima Daiichi accident reflects the VDNS principles regarding preventing accidents and mitigating possible releases of radionuclides causing long-term offsite contamination and avoiding early radioactive releases.

The introduction of the Periodic Safety Review and the use of the IAEA guidance for its regulatory documents are some of the examples in which the Canadian regulatory framework addressed the Vienna Declaration of Nuclear Safety.

Other recent initiatives with respect to the management of the CNSC’s regulatory framework include the establishment of a five-year review cycle for all CNSC regulatory documents. This process ensures that the CNSC’s regulatory framework continues to be current and reflect the latest developments in domestic and international state of the art practices.

5. CONCLUSION

The Fukushima Daiichi accident triggered a host of lessons learned, including some important lessons regarding the regulatory framework approach, such as ensuring that prevention and mitigation of severe accident was strengthened. Notwithstanding all the changes made to specific regulatory documents, this article also conclude that an important aspect of the processes governing the regulatory framework is the capacity of the CNSC to adapt to new events and gain insights from it. The Fukushima omnibus amendments project is a good example of this adaptability.
The Canadian regulatory framework review following Fukushima has highlighted many insights and also supports the current practices of revisiting the regulatory framework instruments at regular intervals to improve them if required, consistent with continuous improvement principles.

The response of the CNSC to the events of Fukushima Daiichi illustrates that the organisation is committed to continuous improvement and that its structure has allowed enough flexibility to promptly address the main challenges from the Fukushima Daiichi event.

ACKNOWLEDGMENTS

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TOWARDS REGULATORY EFFECTIVENESS OF INSPECTION AND ENFORCEMENT ON SAFETY AND SECURITY OF RADIATION SOURCES IN BAPETEN INDONESIA

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Abstract

BAPETEN has been striving to achieve the above goals ever since its establishment. However, it should be kept in mind that regulatory effectiveness cannot be enhanced beyond a certain point without international cooperation. It was observed that the IRRS Mission, RASIMS, Open-Ended Experts Meeting on CoC 2004, development and use of procedures, standard review plans (i.e. checklists), also the important thing are policy and strategy of BAPETEN for inspection and enforcement as the basis for the review help in enhancing regulatory effectiveness. Regulatory effectiveness of inspection and enforcement on safety and security of radiation sources still strives for continuous improvements to its performance in BAPETEN, Indonesia.

1. INTRODUCTION

According to Law No 10 of 1997, nuclear regulatory is implemented through rulemaking, licensing and inspection [1]. Inspection is one of nuclear regulatory elements that has to be carried out by BAPETEN inspectors to ensure compliance of the nuclear regulation (GR No. 33 of 2007) [2]. While according to IAEA TECDOC 1526[3], enforcement is an action taken for ensuring compliance with regulatory requirements. So, inspection and enforcement have similar goals. They have to go hand in hand.

The achievement and maintenance of a high level of safety and security in the use of radiation sources depends on there being a sound legal and governmental infrastructure, including a national regulatory body such as BAPETEN with well-defined responsibilities and functions. These responsibilities and functions include establishing and implementing a system for carrying out regulatory inspections, and taking necessary enforcement actions in an effective manner.

2. SCOPE

This paper will address the effectiveness of inspection, regulatory enforcement and any activity related to it.

3. OBJECTIVE
To overview regulatory effectiveness of inspection and enforcement on safety and security of radiation sources in BAPETEN Indonesia.

4. RESULT AND ANALYSIS

Regulatory effectiveness itself means “to do the right work” whereas regulatory efficiency means “to do the work right”. This has been stated in NEA-OECD Improving Nuclear Regulatory Effectiveness [4]. In PDRP-4, Assessment of Regulatory Effectiveness [5] also elaborates that given the necessary authority and resources as prerequisites, the regulatory body is effective when it:

— Ensures that an acceptable level of safety is being maintained by the regulated operating organizations.
— Takes appropriate actions to prevent degradation of safety and to promote safety improvements.
— Performs its regulatory functions in a timely and cost effective manner as well as in a manner that ensures the confidence of the operating organizations, the general public and the government;
— Strives for continuous improvements to its performance [5].

BAPETEN ensures the compliance of the Act, GRs (Government Regulations), BCRs (BAPETEN Chairman Regulations), procedures and guides in term of inspection and enforcement in radiation sources facilities and activities. BAPETEN Inspection program is settled based on risk categories, financial and resources availability, such as funding, availability of inspectors and geographical distribution of licensees. The monitoring and evaluation system (Monev) within the BAPETEN is based on strategic performance indicators similar to the one described in PDRP-4.

4.1. IRRS (Integrated Regulatory Review Service) Mission

IRRS Mission to Indonesia has been done in August 2015. It addressed also how to do an effective inspection and enforcement based on regulatory infrastructure. These review teams and/or missions comprise of experts drawn from various countries and reflect international experience and practices. The IRRS Team observed inspections at the different radiation facilities and activities, and concluded that the inspections were carried out in a professional manner using procedures. However, the inspector level of competency could be improved. According to the Team, BAPETEN inspectors need further training on safety culture and patient protection. BAPETEN regulation has provision, inspectors to take immediate actions on the spot in case of acute health and safety issue with consultation of BAPETEN chairman. The BAPETEN has used this experience and the IAEA standards to increase its regulatory performance.
FIG. 1. Pre-inspection meeting in a medical facility during IAEA-IRRS Mission to Indonesia

FIG. 2. Inspection meeting (Document Audit) in a medical facility during IAEA-IRRS Mission to Indonesia
FIG. 3. Inspection (site visit) to a medical facility during IAEA-IRRS Mission to Indonesia

FIG. 4. Post-inspection meeting in a medical facility during IAEA-IRRS Mission to Indonesia

4.2. RASIMS (Radiation Safety Information Management System)

BAPETEN actively involved in RASIMS to evaluate its regulatory performance especially in inspection and enforcement, in the point of view of IAEA standards and guides. The information in RASIMS is used for a range of other purposes including the design of new technical cooperation (TC) projects and during the radiation safety clearance process prior to the provision of radiation sources to Member States. Member States can also use RASIMS to provide the Secretariat with feedback on IAEA Safety Standards[6].

BAPETEN also actively involved in Experts meeting for implementation of CoC 2004. It updates and continue to develop and implement the Code in the country [7,8,9].

4.4. Development and Use of Procedures and Standard Review plans (i.e. checklists) for Inspection and Enforcement

To be effective in conducting inspection and enforcement, in BAPETEN has been developed and implemented procedures, working instructions, and checklists. Examples procedures, working instructions and checklists for different uses of radiation practices and sources in medicine and industry, as the following:

— BAPETEN has 8 (eight) Procedures including Procedure of Inspection and Procedure of Regulatory Enforcement and 31 (thirty one) Working Instructions. Working Instruction including IK/PUK/DIFRZR/008.01 “Working Instruction of Pre-Reporting the Violation to Police Department”, IK/PUK/DIFRZR/008.02 “Working Instruction of Reporting Violation to Police Department” and IK/PUK/DIFRZR/008.03 “Working Instruction of monitoring follow-up of inspection findings.”

- Inspection Checklist for Diagnostic radiology
- Inspection Checklist for Nuclear medicine
- Inspection Checklist for Radiotherapy
- Inspection Checklist for Industrial radiography
- Inspection Checklist for Irradiators – research and industrial
- Inspection Checklist for Radioactive gauges
- Inspection Checklist for Well logging
- Inspection Checklist for Exporter and Importer

4.5. Policy and Strategy of BAPETEN in Inspection and Regulatory Enforcement

In order to achieve strategic objectives, vision and mission for DIFRZR-BAPETEN (Directorate of Inspection for Radiation Facilities and Radioactive Materials, BAPETEN) in the period of 2014-2019, it has been set strategic policy as reference measures for preparation of the target achievement indicators of inspection and enforcement for radiation sources and facilities[10]. In accordance with the structure of programming and activities based on the function unit DIFRZR, the measures taken are as follows:
(b) Carry out inspections to all users of radioactive substances and other radiation sources in medicine, industry, and research facilities and activities are based on risk-graded approach.

c) Improve planning, monitoring and evaluation of inspections effectively, including developing procedures and work instructions in complete manner.

d) Utilizing the human resources safety and security inspector in radiation facilities and activities optimally, coordinate with relevant internal stakeholders;

e) Applying Safety and Security Facility Reports to all users;

(f) Utilize a reliable data processing and communication device and information technology

g) Implement nuclear regulatory enforcement by coordinating with relevant stakeholders

Step strategy for achieving the predetermined event above is as following:

4.5.1. Risk based Inspection on Safety and Security of Ionizing Radiation Sources

To be effective, BAPETEN develops strategies as follows:

(a) Develop a risk-based inspection schedule to optimize the availability of inspector as valuable human resources. We appreciate them as an important regulatory task force.

(b) Conduct inspection safety and security of ionizing radiation sources according to workload and graded approach;

(c) To establish surveillance pilot areas in the province that has most number of users;

(d) To prioritize for carrying out inspections in radiation facilities and activities that have not been never inspected at all;

(e) To enhance radiation safety report forms and apply them to all users;

(f) To enhance quality of inspection checklists and inspection reports;

(g) To provide guidance for inspectors and internship inspector in conducting inspection.

4.5.2. Inspection and Monitoring follow-up of inspection findings

In order to get effectiveness of inspection and monitoring follow-up findings, BAPETEN develops strategies as follow:

(a) Develop standard operational procedures (SOPs) and work instructions in the entire activities process map of Inspection Directorate;

(b) To conduct medical examination or health monitoring to all inspectors;
(c) Provide adequate radiation measuring instruments/equipments for inspectors;
(d) To monitor the follow-up inspection findings;
(e) Build a network-based database in order to support the implementation of Inspection and enforcement;
(f) Perform data validation of radiation workers, radiation protection officers (RPOs), radiation facilities and activities;
(g) To evaluate the performance of inspectors in order to increase the competence and leveling of inspector;
(h) To facilitate the Inspector Assessment Team and its activities;
(i) To conduct valuation of safety and security index of radiation facilities and activities;
(j) To appreciate the users by facilitate them with BAPETEN Safety and Security awards (BSSA)

4.5.3. Regulatory enforcement in radiation facilities and activities that implementable

To execute regulatory enforcement in radiation facilities and activities effectively, BAPETEN applies strategies as follow:

(a) Socialization and coordination with relevant parties in regulatory enforcement.
(b) To follow-up on the results of monitoring follow-up of inspection findings in accordance with its category.
(c) To establish Assessment Team for Lawsuit and facilitate them in regulatory enforcement activities;
(d) To carry out follow-up inspections in the context of regulatory enforcement
(e) Facilitate the expert witnesses, reporting witnesses, and witnesses in the regulatory enforcement process for police and trial court.
(f) To conduct handling of evidence during the judicial process/regulatory enforcement process.

5. CONCLUSIONS

BAPETEN has been striving to achieve the above goals ever since its establishment. However, it should be kept in mind that regulatory effectiveness cannot be enhanced beyond a certain point without international cooperation. It was observed that the IRRS Mission, RASIMS, Open-Ended Experts Meeting on CoC 2004, development and use of procedures and standard review plans (i.e. checklists), also the important thing are policy and strategy of BAPETEN for inspection and enforcement as the basis for the review help in enhancing regulatory effectiveness.
Regulatory effectiveness of inspection and enforcement on safety and security of radiation sources still strives for continuous improvements to its performance in BAPETEN, Indonesia.

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STRENGTHENING REGULATORY EFFECTIVENESS IN INDIA – LESSONS LEARNT FROM FUKUSHIMA ACCIDENT

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Abstract

Following the Fukushima Daiichi accident in Japan, one of the most important lessons learnt, among other things, was the issue of strengthening the effectiveness of the regulatory bodies. Immediately after the Fukushima accident, national level safety audits were conducted to review safety of all operating NPPs in India. A national action plan has been prepared to implement the identified short term, midterm and long term measures. Atomic Energy Regulatory Board (AERB) has carried out self-assessment of the core regulatory processes. A pilot programme for developing a mechanism of assessing the safety performance of operating NPPs was initiated. A framework has been developed for assessment of safety culture within AERB. A limited set of indicators were established based on the early signs of declining performance and a methodology has been developed for quantitatively assessing the safety culture prevailing at operating NPPs through regulatory inspection findings. National Disaster Management Authority (NDMA) had taken up special exercises at each NPP site ensuring participation of all the stakeholders and governmental agencies including training of personnel involved at various levels. These exercises were in addition to the one conducted at plant, site and off-site domain in every three months, one year and two years, respectively. A gap analysis has been carried out and revision of the regulatory documents were taken up in a phased manner. The paper highlights the actions taken by India to strengthen regulatory effectiveness through improvements in the existing core processes, insights gained from the recent initiatives on safety performance indicators and assessment of safety culture and Indian perspectives on the further cooperation among the member states for enhancing the regulatory effectiveness for oversight of regulated nuclear organizations.
1. INTRODUCTION

The nuclear accident at Fukushima Daiichi nuclear power plants in Japan in March 2011 had brought the safety of NPPs under scanner. Immediately following the Fukushima accident, India undertook comprehensive technical review of all safety systems of the nuclear power plants.

NPCIL, the utility, conducted detailed review to assess available capabilities to deal with the extreme external events by considering extended station blackout and loss of ultimate heat sink provided in the existing design.

AERB constituted a high level committee (AERBSC-EE) with national level experts in the areas of (i) design, safety analysis and NPP operation, and (ii) external events in the field of seismology, hydrology and earthquake engineering, to carry out a comprehensive review of capability of NPPs to deal with external events within and beyond design basis.

The post Fukushima safety reviews carried out by both the utility and AERB, had shown that a number of strengths exist in the case of the Indian NPPs, for coping with the situation involving prolonged station blackout and non-availability of cooling water supplies through the normal design sources/routes. While recognizing the existing strengths, which are on account of the specific design features and the practices followed with respect to siting, design and regulation of NPPs, additional measures were identified to further enhance the robustness of the existing features. The safety aspects covered during these assessment and status of the implementation of the identified safety upgrades are provided in Section 2.

Apart from the safety enhancements at regulated organizations, AERB has carried out self-assessment of the core regulatory processes such as safety review and assessment, regulatory inspections and regulatory document development. The existing processes were found adequate for regulatory oversight, however, for continual improvement, two pilot programmes for developing a mechanism of assessing the safety as well as security performance of operating NPPs and enhancing the regulatory oversight of ‘Safety Culture’ were initiated. The development of the framework, methodology and insights received during this task has been brought out in Section 3 and Section 4 respectively.

Emergency preparedness and response got specific attention subsequent to Fukushima accident. AERB reviewed all the requirements which included onsite management capability during accidents at multi-unit site along with serious damage to the infrastructure and surroundings and installation of adequate monitoring system for deciding on intervention for early remedial actions in public domain. The details are covered in Section 5.

AERB constituted a Working Group (WG) for identifying the existing regulatory/safety documents of AERB that would require review/revision and also to identify the additional requirements / provisions that would require consideration during revision for addressing the lessons from Fukushima. The details are covered in Section 6.
Section 7 highlights the relevant observations of the Integrated Regulatory Review System (IRRS) mission of AERB on India’s response to Fukushima Accident.

2. POST-FUKUSHIMA SAFETY ENHANCEMENT MEASURES IN INDIA

The approach adopted for the safety reviews and enhancement measures following Fukushima accident involved includes the following:

— Re-confirmation of capability to withstand currently defined site specific design / review basis levels of external events for individual plants.
— Assessment of margins available for beyond the design / review bases levels of external events.
— Enhancing the capability of the plants to perform the safety functions under extended SBO/extended loss of heat sink through the design provisions. The measures being incorporated based on the above assessments include:
  — Alternate provisions for core cooling and cooling of reactor components including identification / creation of alternate water sources and providing hook-up points to transfer water for long-term core cooling,
  — Provision of portable DGs / power packs
  — Battery operated devices for plant status monitoring
  — Additional hook up points for making up water to spent fuel storage pools

Review and strengthening of severe accident management particularly with respect to:

— Hydrogen Management
— Reliable provision for containment venting
— Availability of key parameters for monitoring even under most extreme conditions
— Adequacy of SAM programme following an extreme external event, with the possibility of destruction of assisting facilities, both inside the plant and the surroundings; and affecting multiple units.
— Creation of an emergency facility at each NPP site which should remain functional under extreme events including radiological, with adequate provisions of communication and having capacity for housing essential personnel for a minimum period of one week.
The plant specific safety enhancements identified based on the above assessments are presently being implemented. The identified measures for enhancement of safety against external hazards were scheduled for implementation in short term (2013), medium term (2014) and long term (beyond 2015), taking into account feasibility, need for assessments/analysis/development, engineering & procurement and planned outages. Most of these measures have been implemented and the progress on the on-going measures is being monitored. All the identified safety measures are expected to be implemented by end of the 2016 [1].

3. DEVELOPMENT OF SAFETY PERFORMANCE INDICATORS

Many utilities around the world use the Safety Performance Indicators (SPIs) established by IAEA [2] in addition to other set of indicators specified by World Association of Nuclear Operators (WANO). These indicators are intended principally for use as a management tool by nuclear operating organisations to monitor their own performance and compare their performance relative to that of other plants of the world. Such indicators are good for global comparison but do not serve the purpose of identifying the regulatory practices and required regulatory strategies to deal with specific problems in NPPs. In order to assse such issues at micro level, in-house PI development at AERB was realized. A feasibility report was prepared and a pilot case was analysed using the data obtained during the year 2011-12 [3]. The framework was established for identification of defining safety performance indicators, data collection, assessment of the performance indicators, and preparation of annual report. Total six numbers of safety performance indicators were identified, namely: (i) Significant events, (ii) Technical Specifications (iii) Radiation Protection (iv) Nuclear Safety, (v) Regulatory Inspections and (vi) Safety Reviews. Based on the assessment, each NPP is ranked as per the ranking scale as indicated in Table 1.

<table>
<thead>
<tr>
<th>Colour Code</th>
<th>Performance Indicator Range</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>&lt; 51 % above the Industrial Average</td>
<td>Outstanding</td>
</tr>
<tr>
<td>Green-Blue</td>
<td>20 % to 50 % above the Industrial Average</td>
<td>Fully Satisfactory</td>
</tr>
<tr>
<td>Blue</td>
<td>Up to 20% above or below 20 % of the Industrial Average</td>
<td>Satisfactory</td>
</tr>
<tr>
<td>Orange-Red</td>
<td>21 % to 50 % below the Industrial Average</td>
<td>Needs attention</td>
</tr>
<tr>
<td>Red</td>
<td>51 % below the Industrial Average</td>
<td>Unsatisfactory</td>
</tr>
</tbody>
</table>

Subsequently, two more annual reports were issued covering the performance assessment of operating NPPs for the year 2012-13 and 2013-14 respectively [4, 5]. Based on the experience gained, a standard procedure is prepared for safety
assessment of performance of operating NPPs based on performance indicators [6]. In addition, AERB also developed safety performance indicators for physical security at NPPs for each of the security layers, namely; (i) Main Plant Boundary, (ii) Operating Island and (iii) Vital Areas to identify strength and shortcomings of NPPs on security aspects.

The insights gained from these indicators are used to support important safety related regulatory decision making process. It provides technical basis for a particular regulatory strategies adopted to deal with NPPs, which shows continuously weak performance/does not show improvement from existing low performance.

4. SAFETY CULTURE ASSESSMENT WITHIN AERB AND IN LICENSEES

It is recognised that the regulator has a dual role of promoting safety culture by way of setting example of having safety culture assessment system within regulatory body itself and establishing a mechanism of evaluating safety culture prevailing within regulated organizations. A framework has been developed for assessment of safety culture within AERB and a pilot study is done in one of the technical division to check its feasibility. A questionnaire survey was carried out and the outcome has been represented in terms of total nine numbers of safety culture indicators. The results of the assessment brought out the strength and weakness of the division and management actions required for continual improvement are also identified [7]. The major steps involved in the methodology is given in Fig. 1 (a).

- Identification of Symptoms /early signs of declining performance of NPP
- Develop Safety Culture Assessment scale
- Review of RI reports (2 Nos/ yr) for each NPP and map the findings against the symptoms
- Perform Trend Analysis
- Annual Safety Culture Assessment
- Annual Plan
- Management Review and Corrective Actions
- Procedure for Safety Culture Assessment within AERB
- Integrated Management System
- FIG. 1. (a) Safety Culture Assessment within AERB, (b) Safety Culture Assessment of Operating NPPs

The requirements for establishing safety culture within utility have been spelt out in the regulatory documents. AERB encourages utility to institute a good safety
culture during all the stages of NPPs. Utilities carries out Safety Culture Assessment of all Operating NPPs as per internal guideline document (Questionnaire Approach). In the recent initiative, safety culture of the operating NPPs is assessed based on regulatory inspection findings in the area of reactor physics, operation, technical audit & surveillance, maintenance, quality assurance, health physics, radioactive waste management and emergency preparedness & responses. Safety Culture attributes adopted from international guidelines [8] and modified to suit the AERB requirements. A total of 33 signs of declining performance or symptoms are used to represent 6 major areas indicative of prevailing safety culture at operating NPPs. Inspection findings are mapped on these attributes in order to evaluate the safety culture of NPPs. The indicators are trended over the years to derive useful insights in developing regulatory strategies for safety culture oversight of NPPs [9].

5. REVISION OF EMERGENCY PREPAREDNESS AND RESPONSE PLANS

AERB has published safety documents bringing out guidelines for preparation of emergency preparedness plan for nuclear facilities as well as non-nuclear facilities. Subsequent to the Fukushima accident at Fukushima NPPs, Japan, assessment of these guidelines was done within AERB and by National Disaster Management Authority (NDMA). AERB has developed new safety guide AERB/SG/EP-5 [10] by revising the existing safety guide taking into account of the guidelines given in IAEA Safety Standard Series No. GSG-2 [11]. This ‘safety guidelines’ provides criteria for establishing an emergency preparedness and response plan for nuclear and radiation facilities to deal with nuclear and radiological emergency. AERB has also undertaken revision of safety guide on “Preparation of Offsite Emergency Preparedness Plan”. Based on the reviews undertaken on safety assessments of Indian NPPs, in light of the accident at Fukushima NPPs, AERB had mandated the requirement for establishing the On-Site Emergency Support Centre (OESC) at all NPP sites.

6. REVISION OF REGULATORY REQUIREMENTS

The existing regulations were reviewed in the aftermath of Fukushima accident in order to identify enhancement of the existing regulations and the additional requirements / provisions that would require consideration during revision of the regulations for addressing the lessons from Fukushima. Fig. 2 provides details of number of recommendations considered for revision of the documents.
7. CONCLUSIONS

Following the Fukushima Daiichi accident in Japan, one of the most important lessons learnt, among other things, was the issue of strengthening the effectiveness of the regulatory bodies. Immediately after the Fukushima accident, a national action plan has been prepared to implement the identified short term, midterm and long term measures. The assessment indicates that national response to the Fukushima Accident for safety assessment of NPPs and subsequent actions and initiatives taken for safety enhancement of the NPPs in India are in-line with the objectives of the IAEA action plan. Sharing of regulatory knowledge and experience among themselves on the lesson learnt from Fukushima Accident would further help in enhancing the regulatory effectiveness in nuclear oversight of regulated organizations.

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REFERENCES


BOWTIE RISK MANAGEMENT METHODOLOGY AND MODERN NUCLEAR SAFETY REPORTS

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Abstract

The paper presents the results of a real-life application of the Bowtie risk management methodology to an existing Safety Report for an operating radioisotope production facility. Use of the Bowtie approach has the aim of improving the understanding, accessibility and usability of the existing Safety Report by its key end users. It is considered that one of the main purposes of the Safety Report should be to provide internal assurance within the licensee organization that risks to safe operation are being systematically and properly managed. Thus, it is crucial that the Safety Report is actively used by the operating and maintenance personnel as well as by senior management as an effective tool for the day-to-day management of operational risks. The experience gained by the authors in the application of the Bowtie methodology to other major hazard industry sectors (oil and gas, petrochemical, transport) allowed an in-depth implementation of the unique strengths of the Bowtie methodology. The result has been completed Bowtie diagrams depicting the interrelation between hazard, initiating events, consequences, engineering controls (both prevention and mitigation), procedural and administrative controls and their associated failure modes and links to the management system. The latter has been the basis for the implementation of a barrier management approach which is usually not shown in existing nuclear Safety Reports. The end result of the process is a more fit-for-purpose Safety Report, which: a) improves the understanding by the workforce of the barriers in place to control the hazards b) increases the awareness of the importance of safety critical tasks carried out by the responsible persons to support those barriers and c) allows the verification and audit of safety critical activities.

1. INTRODUCTION

The Safety Report plays a crucial role within the nuclear licensing regime as the principal means for demonstrating the safety of the facility and granting authorizations for the commencement of the main stages in the facility’s lifecycle. Historically, the majority of nuclear safety reports have been produced and applied under prescriptive legislative regimes, with emphasis placed on
demonstrations of the robustness of the facility’s design against technical standards and rules set by the Regulatory Body.

Safety Reports are often produced to ensure regulatory compliance and obtain regulatory approval. As a result, they are often “inaccessible” to key “users” – i.e. those who actually exercise direct control of the hazards and risks at the plant (e.g. operation and maintenance personnel) as well as the managers who hold specific accountabilities and responsibilities for ensuring safe facility’s operation [4,6]. This situation has a detrimental effect on the safety of the facility particularly during operations, when the Safety Report is intended to be actively used by those key users as an effective tool to support informed decision making in relation to the day-to-day management of operational risks. As a result, many nuclear safety reports are often left “on the shelf” and seldom used for their intended purposes.

In addition, and despite the fact that the safety management system constitutes the principal means for ensuring safe operation of the facilities, most nuclear safety reports lack explicit demonstration of the effectiveness of the management system, i.e. by showing the manner by which the system supports the ongoing integrity of engineering control measures put in place to ensure safe operation.

This paper explores the strengths of the Bowtie risk management methodology in producing fit-for-purpose, accessible and usable Safety Reports that will support current efforts by the nuclear industry to produce “Right First Time Safety Cases” [4].

2. “RIGHT FIRST TIME SAFETY CASES”

In March 2014, the UK Nuclear Safety Case Forum (SCF) released a guide entitled “Right First Time Safety Cases: How to Write a Usable Safety Case” [4] following the recommendations made in “The Nimrod Review” undertaken by Charles Haddon-Cave QC [10]. The Guide contains a set of best practices for the production of successful safety cases that are worth considering for the nuclear regulators. The following was stated in the Guide:

“Safety Cases should be ‘Right First Time’; the right case, produced at the right time and to the right quality. If a Safety Case is well written, proportionate, technically accurate and flexible, it will be easy to implement, easy to comply with and therefore more likely to be worked to. Improvements in the way in which Safety Cases are produced and presented should result in Safety Cases being simpler, clearer and more readily understood by all stakeholders. This should in turn enable improved configuration control and result in Safety Cases that are easier to keep up to date and ultimately, an overall improvement in safety”.

“Safety Cases are notoriously long, complicated, overly technical and difficult to follow. Some licensees feel that they are producing Safety Cases for the
regulator, not for themselves and yet they frequently fail to satisfy the regulator being accused of producing Safety Cases that do not “tell the story” and Safety Cases where the “claims, argument, evidence trail goes cold” [4].

The Nimrod Review highlighted many potential deficiencies associated with the process of preparation of Safety Cases in the military industry. The same deficiencies can severely undermine the process of preparation of nuclear safety reports and limit their subsequent use for the management of risks to safe operation. Some of the shortcomings pointed out by the Nimrod Review regarding the documented Safety Report and its production process are summarised in Table 1 along with the inherent strengths of the Bowtie methodology that could substantially improve the quality, understanding and usability of the Safety Report as an effective tool for the management of operational risks.

3. NUCLEAR SAFETY REPORTS AND EFFECTIVE SAFETY MANAGEMENT SYSTEMS

The importance of the safety management system (SMS) for ensuring safe operation of a facility has been long recognised by the IAEA in several documents [2, 12]. In order to discharge its prime responsibility for safety, the Licensee needs to establish an effective SMS. The importance of the SMS and its links with the Safety Report was highlighted by Lord Cullen in his famous report on the Piper Alpha disaster [13]. In this report Cullen stated the following:

“Safety is crucially dependent on management and management systems. One of the things that the Safety Case should demonstrate (amongst other things) is that the company has a suitable safety management system”

The above means that, apart from providing a design/engineering substantiation of control measures in place to manage hazards, the Safety Report must clearly establish and show strong links between engineering control measures and the management system through the safety critical actions needed to ensure the ongoing integrity of those engineering control measures. This will allow the following question to be answered: Once the ability of the engineering controls to fulfil their assigned safety functions has been determined, how can it be ensured and demonstrated that the engineering controls will work tomorrow/at all times?

Here, the Bowtie methodology offers a unique strength that is not always exploited to its full potential – the possibility of verifying the links between the engineering controls shown in the Bowtie diagram and the safety management system. By implementing the “Barrier Management” concept, the Safety Report will demonstrate that engineering controls are being properly maintained and safety critical tasks are undertaken by competent people, i.e. showing the manner in which
the management system ensures the ongoing suitability and effectiveness of the identified control measures.
### TABLE 1. SUMMARY OF SAFETY CASE SHORTCOMINGS AND BOWTIE STRENGTHS

<table>
<thead>
<tr>
<th>Shortcoming</th>
<th>Explanation</th>
<th>Bowtie strengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bureaucratic length</td>
<td>Too long and bureaucratic with unnecessary detail</td>
<td>Facilitates an easily accessible safety case</td>
</tr>
<tr>
<td>Inaccessible</td>
<td>Obscure, inaccessible and difficult to understand language (by the end-users)</td>
<td>Increases visibility and communication - “A picture paints a thousand words”</td>
</tr>
<tr>
<td>Lack of focus</td>
<td>Failing to highlight and concentrate on the principal hazards (Major Hazard Registers)</td>
<td>Ensures a comprehensive Bowtie Hazard Register focused on higher risks</td>
</tr>
<tr>
<td>Outsourcing</td>
<td>Routine outsourcing to organizations (external consultants)</td>
<td>Reinforces leadership and ownership of the Safety Case production process with an easy-to-use risk management methodology.</td>
</tr>
<tr>
<td>Lack of vital Operator support</td>
<td>From operators and maintainers who have the most knowledge and experience of the facility/activity</td>
<td>Ensures active workforce involvement through facilitated highly “Interactive Bowtie workshops”.</td>
</tr>
<tr>
<td>Compliance focus</td>
<td>Written to comply with the requirements of the regulation, rather than as an aid to thinking</td>
<td>Bowtie diagram building process forces “active thinking” to answer the following questions:</td>
</tr>
<tr>
<td>Compliance audits</td>
<td>Audits which focus on process rather than substance</td>
<td>Audits are barrier-based instead of activity based and focused on safety critical tasks and controls (Barrier Management)</td>
</tr>
<tr>
<td>On-the-shelf</td>
<td>Languish on the shelf rather than being “living documents”</td>
<td>Allows the materialization of true monitoring of barrier performance (integrating the results of incident investigation, audits, and reviews)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supports the Electronic Safety Case (ESC)</td>
</tr>
</tbody>
</table>
4. BOWTIE IMPLEMENTATION STEPS IN THE SAFETY REPORT PRODUCTION PROCESS

The Bowtie risk management methodology was applied to an existing Safety Report as per the steps summarised in Table 2, along with corresponding activities and tasks.

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Tasks</th>
</tr>
</thead>
</table>
| 1 Preparatory Activities (Not Bowtie Related) | Check of the existing list of identified facility hazards for completeness  
Compilation of a Risk Assessment Matrix (RAM) |
| 2 Bowtie Training Course | Delivery of a 1-day Bowtie training course for the conduct of Interactive Bowtie Workshops (IBTW) |
| 3 Bowtie Building Process | Preparation of “Draft” Bowties (with 1-2 specialists)  
Facilitation of IBTWs with facility personnel  
Assignment of responsibilities for barriers (System Custodians) |
| 4 ALARP Workshop | Definition of ALARP (Qualitative)  
Conduction of Bowtie/ALARP Workshop  
Compilation of Plan of Remedial Actions |
| 5 Bowtie Hazard Register | Compilation of Bowtie Hazard Register  
Identification of safety critical systems from the completed Bowties – Register of SCS  
Review of the adequacy of SCS  
Confirmation of Safety Critical Tasks (SCTs) |
| 6 Barrier Management | Development of Performance Standards (PS)/Functional and performance requirements  
Development of Summary of Operational Boundaries (SOOB) Matrices  
Development of Key Performance Indicators |
4.1. Bowtie methodology

The Bowtie method is a state-of-the-art risk management methodology that allows detailed analysis of prevention and mitigation control measures for specific hazards. The method helps to ensure that risks are managed rather than just analysed. A Bowtie diagram is constructed within an interactive framework for depicting the accident scenario that is being analysed by establishing the links between the hazard, top event, potential causes and ultimate consequences and all the associated prevention and mitigation measures.

With the Bowtie diagrams it is possible to visualize the link between the control measures and the Safety Management System (SMS). Each prevention control measure on the left side and each mitigation control measure on the right side can be linked to safety critical tasks (SCTs) carried out by competent persons to keep them working and effective at all times. The latter is crucially important for Safety Critical Systems (SCSs).

All SCTs can be linked to the competence assurance part of the licensee’s SMS while SCSs can be linked to the asset integrity part of the licensee’s SMS. The SCTs and asset integrity reports can then be used as checklists to verify that hazards are properly controlled. By checking the existing links between control measures and the SMS it is possible to discover any weaknesses in arrangements in place and to assess the actual effectiveness of the SMS in relation to those measures.

Licensees and regulators can use the Bowtie diagrams provided in the Safety Report to check for evidence that it is truly used by the workforce to systematically manage the risks to safe operation and reflects operational reality at the site.

Table 3 shows the main elements of a bowtie diagram along with their corresponding terms used in the nuclear industry [11].

4.2. Interactive Bowtie Workshops (IBTWs)

IBTWs are the principal means by which active and effective involvement of key users in the development and production of the Safety Report is assured. These Workshops were facilitated by external experienced Bowtie practitioners with the active involvement of operating, maintenance and management personnel whose input was critical for the construction of Bowtie diagrams. Previously, draft Bowtie diagrams were built to avoid “starting from scratch”. A scheme was also created to classify barriers both by type and effectiveness. A final bowtie workshop was devoted to risk reduction according to predefined qualitative ALARP criteria.
### TABLE 3. BOWTIE ELEMENTS

<table>
<thead>
<tr>
<th>Bowtie Element</th>
<th>Symbol</th>
<th>Corresponding Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard</td>
<td><img src="image" alt="Hazard Symbol" /></td>
<td>Radiation hazard</td>
</tr>
<tr>
<td>Top Event</td>
<td><img src="image" alt="Top Event Symbol" /></td>
<td>Hazardous event</td>
</tr>
<tr>
<td>Causes</td>
<td><img src="image" alt="Initiating Events Symbol" /></td>
<td>Initiating events</td>
</tr>
<tr>
<td>Consequences</td>
<td><img src="image" alt="Consequences Symbol" /></td>
<td>Consequences</td>
</tr>
<tr>
<td>Preventative Barriers</td>
<td><img src="image" alt="Prevention Barrier" /></td>
<td>Physical barriers, systems to protect the barriers and administrative procedures</td>
</tr>
<tr>
<td>Recovery Barriers</td>
<td><img src="image" alt="Mitigation Barrier" /></td>
<td>Physical barriers, systems to protect the barriers and administrative procedures</td>
</tr>
<tr>
<td>Escalation factors</td>
<td><img src="image" alt="Escalation Factor" /></td>
<td>System’s Failure Modes</td>
</tr>
<tr>
<td>Escalation factors controls</td>
<td><img src="image" alt="Escalation Factor Barrier" /></td>
<td>Management controls to prevent Failure Modes</td>
</tr>
<tr>
<td>Accountable persons</td>
<td><img src="image" alt="Accountable Person" /></td>
<td>Person accountable for the barrier</td>
</tr>
<tr>
<td>Safety Critical Tasks (SCTs)</td>
<td><img src="image" alt="Safety Critical Task" /></td>
<td>Activities carried out to ensure the integrity of the barrier</td>
</tr>
<tr>
<td>Actions</td>
<td><img src="image" alt="ACTION" /></td>
<td>Remedial actions</td>
</tr>
</tbody>
</table>
Table 4 provides information on the scheduled Workshops and their attendance. Table 5 summarises the main activities and tasks undertaken during IBTWs.

**TABLE 4. WORKSHOPS SCHEDULE AND ATTENDANCE**

<table>
<thead>
<tr>
<th>Workshop</th>
<th>Participants</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Estimation (Interactive Workshop)</td>
<td>Members of the Production Team, Maintenance personnel, Head of Radio pharmacy Department, Head of Radio diagnostic Department, Head of Radiation Safety Department, Radiation Safety Specialist</td>
<td>January, 22 2015</td>
</tr>
<tr>
<td>First Interactive Bowtie Workshop (IBTW)</td>
<td>Members of the Production Team, Members of the Radiation Safety Department, Mechanic</td>
<td>January, 29 2015</td>
</tr>
<tr>
<td>Second Interactive Bowtie Workshop (IBTW)</td>
<td>Members of the Production Team, Members of the Radiation Safety Department</td>
<td>February, 12 2015</td>
</tr>
<tr>
<td>Interactive Bowtie/ALARP Workshop</td>
<td>Members of the Radiation Safety Department, Members of the Production Team, Maintenance personnel, Head of Radiation Safety Department</td>
<td>March, 25 2015</td>
</tr>
</tbody>
</table>

**TABLE 5. ACTIVITIES AND TASKS UNDERTAKEN AS PART OF THE INTERACTIVE BOWTIE WORKSHOPS (IBTWs)**

<table>
<thead>
<tr>
<th>Bowtie elements reviewed</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazards and Top Events</td>
<td>Select a Hazard/Top Event pair to ensure they apply to the facility</td>
</tr>
<tr>
<td>Initiating events (causes)</td>
<td>Review each of the initiating events/causes in turn to confirm that it can lead to the Top Event</td>
</tr>
<tr>
<td>Consequences</td>
<td>Review each of the consequences in turn to confirm that it can result from the Top Event</td>
</tr>
<tr>
<td>Preventative/mitigating barriers</td>
<td>Select a Cause/Consequence and review the control barriers to ensure that they are applicable to the specific facility</td>
</tr>
</tbody>
</table>

- Assign responsibility to ensure the barrier is in place and effective
- Assess the effectiveness of the barrier
- Identify any relevant escalation factor (barrier failure mode) and the associated controls
- Review the Safety Critical Tasks (SCTs) to implement and maintain the control barrier
Select barriers with reduced effectiveness (yellow and red coloured)
ALARP Bowtie Workshop
Identify any remedial action required with appropriate timelines and responsibilities for completion (remedial action plan)

4.3. Barrier Management

The use of the Bowtie methodology allowed the implementation of the Barrier Management concept focused on safety critical systems (systems important to safety). This was supported by the incorporation of non-Bowtie tools that are commonly used in safety cases in other major hazard sectors that perfectly dovetail with the Bowtie method.

Among these non-Bowtie tools are:

- Hazard vs. SCS Matrix: Explains the function each SCS plays in the prevention and mitigation of accident scenarios;
- Performance Standards (PS) for each SCS: States the functional and performance requirements to be fulfilled by the system;
- System Custodian Methodology: Assigns responsibility to certain person for monitoring the status of the equipment, ensuring it is maintained and functioning to the required standard; and
- Key Performance Indicators (KPI): Provide information on the SCS’s health status.

4.3.1. SOOB matrices.

The SOOB is a record of operations that provides guidance for supervisors and managers allowing them to decide when to continue certain activities or stop operations depending on the actual effectiveness of some safety critical systems and when to apply compensatory barriers in case of reduced effectiveness of any SCS. It consists of both “permitted” and “prohibited” operations.

Table 6 details the activities and tasks conducted as part of Barrier Management, indicating whether these activities/tasks were part of the Bowtie methodology.
TABLE 6. ACTIVITIES AND TASKS UNDERTAKEN AS PART OF THE BARRIER MANAGEMENT APPROACH

<table>
<thead>
<tr>
<th>Activity</th>
<th>Tasks</th>
<th>Part of the Bowtie methodology?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of the Safety Critical Systems</td>
<td>Safety Critical Systems (SCS) were extracted from the completed Bowties and further categorised to facilitate their management</td>
<td>YES</td>
</tr>
<tr>
<td>SCS Register</td>
<td>A Hazard vs. SCS Matrix was developed to show how relevant the SCS was for the control of a specific hazard.</td>
<td>NO</td>
</tr>
<tr>
<td>Review of the adequacy of SCS</td>
<td>Each of the SCS was reviewed to check compliance with applicable standards (engineering control measure substantiation) against the following core attributes (Independence, Functionality Integrity, Reliability, Auditability Access Security and Management of Change)</td>
<td>NO (Not fully accomplished)</td>
</tr>
<tr>
<td>Audit of Safety Critical Tasks (SCTs)</td>
<td>Each SCT was reviewed to confirm that it was actually carried out by competent personnel</td>
<td>YES</td>
</tr>
<tr>
<td>Development of Performance Standards (PS) – Functional Requirements Specification (FRS)</td>
<td>A Performance Standard (PS) was developed for each of the identified SCS under the Farsi criteria (Functionality, Availability, Reliability, Survivability and Interactions)</td>
<td>NO</td>
</tr>
<tr>
<td>Development of SOOB Matrices</td>
<td>Operations vs. Operations and Operations vs. Operational Risk Factors/SCS</td>
<td>YES</td>
</tr>
<tr>
<td>Development of performance measures (KPI)</td>
<td>A simple KPI was developed for the maintenance activity</td>
<td>NO</td>
</tr>
</tbody>
</table>

5. RESULTS

The main results of the application of the Bowtie methodology to the existing Safety Report are:
— Bowtie diagrams; and
— SOOB matrices.

5.1. Sample Bowtie diagram

Figure 1 displays one out of 8 Bowtie diagrams that were developed for the facility. It corresponds to the accident scenario “Fire in the Radioactive Waste Storage”. Both prevention and mitigation barriers are identified for each cause (left hand side of the diagram) and consequence (right hand side of the diagram) respectively with the indication of barrier type (engineering/hardware, human/procedural or administrative). This classification facilitated the analysis of available risk reduction options.

For the most critical barriers (SCSs) escalation factors are identified along with their corresponding escalation factor controls (e.g. system disabled due to false alarms). Barriers are coloured depending on the effectiveness estimated by the workshops attendees. Actions were assigned to barriers with reduced effectiveness with the aim of strengthening their reliability along with a specific deadlines and responsibilities for their completion.

Each barrier is linked to the SMS by showing the information on accountable persons and safety critical tasks carried out by responsible persons to ensure the ongoing integrity of the barriers.

5.2. SOOB Matrices

An “Operations vs. Operations” SOOB matrix was built to determine whether certain facility operations could: a) be carried out simultaneously, b) be carried out with caution and c) not be carried out.

Figure 2 shows the “Operations vs. Operational Risk Factors (defeated SCSs)” SOOB matrix which determines whether a specific operation can be carried out (green colour), undertaken with caution (yellow colour) or stopped (red colour) when certain SCSs are defeated or with reduced effectiveness.
FIG. 1. Sample of a Bowtie Diagram for the Accident scenario “Fire in the radioactive waste storage” (Software BowtieXP)
FIG. 2. Sample of Operations vs. Operational risk factors SOOB matrix.
6. CONCLUSIONS AND RECOMMENDATIONS

Known shortcomings in nuclear safety reports limit their value as an effective tool for the day-to-day management of operational risks. The industry is actively working to overcome this, with the aim of producing fit-for-purpose Safety Reports which are easy to understand, readily accessible and usable by the key users. The bowtie methodology fits well into these efforts thanks to its unique strengths, not found in other methodologies commonly used in safety and risk assessments.

The IAEA Safety Case concept has successfully integrated the safety assessment with the Safety Report [1, 3]. The next logical step should be to integrate the safety assessment with the safety management system and make this integration visible within the Safety Report. This will significantly contribute to the demonstration that the existing safety management is indeed effective in supporting engineering controls upon which the safety of the facility is based. The Bowtie methodology will be the advisable option to show the manner in which safety critical tasks forming part of SMS ensure the ongoing integrity of those controls and monitoring of their performance.

Since the process of production of the Safety Report is as important as the final product, it is crucial that the process represents a true aid to thinking – a meaningful exercise reflecting the experience, knowledge and opinions of the “front line” people rather than a mere paper-based exercise to collect evidence to demonstrate that the system is safe.

The implementation steps described in the paper can serve as a practical “roadmap” for the production of safety reports that can be “actively embraced” by the non-nuclear sectors, particularly by the emerging technologies in the industrial and medical sectors. These modern technologies “deserve” modern safety reports incorporating state-of-the-art risk management methodologies that are fully compatible with other deterministic techniques commonly used in the nuclear industry, thus ensuring compliance with regulatory requirements.

Undoubtedly, the incorporation of the Bowtie methodology will improve the visibility, usability and accessibility of the Safety Report which will have a major effect in the reduction of risks from radiation sources used in those industries.

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NATURAL DISASTER AS A REASON TO ANNUL THE NUCLEAR LIABILITY
From National and International Law’s Perspective

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Abstract

One serious issue that deserves more attention from Indonesia before constructing its first NPP, regarding its "ring of fire" geological position, is the natural disaster as a reason to annul the nuclear liability. Article 32 of Act No 10 Year 1997 on Nuclear Energy stipulates that " nuclear installation operator shall not be responsible for the damage caused by a nuclear accident that occurred as a direct impact of a domestic or international armed conflict or natural disaster that exceeded the design limits and acceptance criteria set by the regulatory body. " In its explanation natural disaster includes earthquakes. This article adopts the provision of article IV paragraph 3b 1963 Vienna Convention on Civil Liability for Nuclear Damage. But, in 1997 Amendment Protocol, this provision has been deleted. Natural disasters often referred to as an "act of God" because it occurs outside the control of the human. Nevertheless, not all natural disasters could cause the operator to annul its civil liability. The most important question is: "has the operator taken all necessary preventive actions to prevent accidents, before and during the natural disaster?" In practice, an accident can occur due to a combination of natural disasters and negligence. For example is the 2011 Fukushima Daiichi disaster. The tsunami that occurred on the east coast of Japan was the direct cause of the accident. However, there was also the human error factor.

1. INTRODUCTION

Act No 10 Year 1997 on Nuclear Energy (Nuclear Energy Act) stipulates that nuclear installation operator shall not be responsible for the damage caused by a
nuclear accident that occurred as a direct impact of a domestic or international armed conflict or natural disaster that exceeded the design limits and acceptance criteria set by the regulatory body.\textsuperscript{4} In its explanation natural disaster includes earthquakes. This article adopts the provision of article IV paragraph 3b 1963 Vienna Convention on Civil Liability for Nuclear Damage. But, in 1997 Amendment Protocol, this provision has been deleted. Natural disasters often referred to as an "act of God" because it occurs outside the control of the human. Nevertheless, not all natural disasters could cause the operator to annul its civil liability. The most important question is: "has the operator taken all necessary preventive actions to prevent accidents, before and during the natural disaster?"

In practice, an accident can occur due to a combination of natural disasters and negligence. For example is the 2011 Fukushima Daaiichi disaster. The tsunami that occurred on the east coast of Japan was the direct cause of the accident. However, there was also the human error factor. For example, the decision to build a nuclear plant on the east coast of Japan that is highly vulnerable to tsunamis is questionable. In addition the design of a nuclear installation is not flood resistant, therefore all the batteries and emergency power facilities were directly flooded while the tsunami came. The big question comes from this accident is whether "natural disaster" can be a reason to annul the nuclear liability.

2. INTERNATIONAL CONVENTIONS ON NUCLEAR LIABILITY

There are some international conventions that can be used as the references. In the 1960s, there were three conventions referred to the nuclear compensation. First, the Organisation for Economic Co-operation and Development Nuclear Energy Agency Convention on Third Party Liability in the Field of Nuclear Energy of 29 July 1960 ("the Paris Convention"). Second, the Brussels Supplementary Convention to the Paris Convention on Third Party Liability in the Field of Nuclear Energy of 31 January 1963 ("the Brussels Convention").

Third, the IAEA Vienna Convention on Civil Liability for Nuclear Damage of 21 May 1963 ("the Vienna Convention"). The Paris Convention and the Brussels Convention are generally entered into force for Western Europe states, whilst the Vienna Convention is applied more globally.

Some common characteristics between the three conventions are: strict liability, exclusive channelling of liability to nuclear operators, limitation of the liability in amount and in time, and a compulsory financial security.

\textsuperscript{4} Article 32, Act No 10 Year 1997 on Nuclear Energy (Nuclear Energy Act)
The Paris Convention introduced the concept of "absolute liability". In this term, the operator is responsible for the material and immaterial loss due to the nuclear accident in a nuclear installation or as a result of nuclear material derived from the installation, which does not need to prove its fault before implementing its liability. This term is regarded as "absolute liability" because some of the things that generally exclude civil liability (including force majeure, natural disasters, or the result of a third party) can no longer be applied. The only exceptions are political matters, such as the armed conflict, war, or rebellion. In addition there are also exceptions for the grave natural disasters of exceptional character.

The Vienna Convention in principle provided similar regulation to the Paris Convention. However, in the Vienna Convention, it is possible for the operator to be free from its liability if the operator can prove that the accident occurred from gross negligence or act of omission of the victim. This convention got the urge to amend, especially when the 1986 Chernobyl incident occurred, which raised the latest generation of the liability conventions.

In the case to annul the nuclear liability, in recent conventions, natural disasters could no longer be used as the reason. The only exception is armed conflict, war, or rebellion. Since the 9/11 incident in 2001, there were discussions to include acts of terrorism as the reason to annul the liability, but up to now, such reason has not been stipulated in any conventions.

3. THE NUCLEAR LIABILITY SYSTEM IN JAPAN

Learning from the Fukushima Daiichi disaster, the nuclear liability system in Japan can be used as a comparison to Indonesia. Even though, its volcanic activities are higher than those in Indonesia, Japan is very brave for using about 20% of the overall domestic energy coming from nuclear energy.

In principle, based on Japan Law, not all natural disasters can be used as the reason to annul the nuclear liability, it is only for the grave natural disaster of exceptional character. Beside that, the operator is still responsible. For example through the indemnity agreement as stipulated in Japan Act on Indemnity Agreements for Compensation of Nuclear Damage, which the operator will pay indemnity to the Government.

The Act on Compensation for Nuclear Damage stipulates that the nuclear operator would be exempted from its liability if the accident were caused by a grave natural disaster of a exceptional character. Based on this Act, it became a big question wheter the combination of earthquake and tsunami was a grave natural disaster of an exceptional character.

The Japan Government at last decided that the combination of earthquake and tsunami happened in Fukushima was not a grave natural disaster of an exceptional character and concluded that the operator, in this case is Toyota Electric Power Company or better known by TEPCO, should not be exempted from its liability for nuclear damage.
4. UNITED STATES OF AMERICA JURISPRUDENCES

The “act of God” can be proven by measuring the level of the seriousness of the natural disaster. In this case, the natural disaster must be grave and exceptional in character.

In Sabine Towing Transportation Company v USA (1968), the Court rejected to categorize both spring runoff of melted snow and the unknown objects that ruptured the ship’s hull as a natural disaster. The Court stated that the reason to be accepted as the “act of God” is the occurrence must be of great magnitude.5

According to the jurisprudence of Joseph Resnick Co. v Nippon Yusen Kaisha (1963), one can no longer easily blame nature to escape liability. The damages might come from a combination between natural force and human activities or intervention. The Court stipulated that in this nuclear age, man's unlimited capabilities and scientific advancement have brought him to the very threshold of other planets. His newly-harnessed nuclear power causes atmospheric reactions as yet unresolved and unpredicted, next to which his ability to create rain by the use of dry ice seems almost primitive. Is it not time to relieve Nature of even the formal blame for many acts which now seem to be within the scope of man's prowess? Perhaps the term "act of God" should be replaced by a concept which reflects the possibility of human causality as well as that of the Divine.6

The Court in Donald McFeeters v M W Renollet (1972) formulated a natural disaster as an irresistible superhuman cause such as no reasonable human foresight, prudence, diligence and care can anticipate and prevent; and to be a defence must be an intervening cause which was not foreseeable and the consequences of which could not be prevented.7

From these three jurisprudences, it can be concluded that the damage caused by a natural disaster should meet the requirements of being grave, unforeseeable, unanticipated, unavoidable, and absent from human intervention, in order to be classified as an “act of God.”


5. PROVISIONS CONCERNING NATURAL DISASTER IN INDONESIA

The Nuclear Energy Act is not the main regulations on natural disaster regime. The natural disaster regime mainly refers to Act No 24 Year 2007 on Disaster Management (Disaster Management Act). The Disaster Management Act forms the foundation of the legal framework for disaster management in Indonesia. It contains a comprehensive set of provisions delegating national and regional government responsibilities, outlining community rights and obligations, the roles of businesses and international institutions, the different disaster management stages and their requirements, as well as disaster aid finance and management.

According to the Disaster Management Act, a disaster is defined quite widely to incorporate natural, ‘non-natural’ and ‘social’ disasters. This reflects Indonesia’s propensity to be subject to many types of natural disasters, as well as the potential for non-natural disasters and the possibility of social tensions. Furthermore, it defines disaster management broadly as a series of efforts encompassing policies on development with disaster risk, disaster prevention, emergency response, and rehabilitation.

Furthermore, the Act clearly stipulates that the Government and regional governments are responsible for disaster management. It requires the Government to establish a National Disaster Management Agency (BNPB) and the Regional Disaster Management Agencies (BPBD).

When it comes to the nuclear accident, there is a very confusing provision in the Disaster Management Act. The Act defines nuclear accident as a technological failure without any explanation. However, Head of BNPB Regulation No 4 Year 2008 on Guidelines for Disaster Management Plan defines technological failure as the incident caused by the errors on design, operation, negligence and human intention in using technology. The impact can be a fire, pollution chemical, radioactive / nuclear, industrial accidents, transportation accidents that cause loss of life and property.
6. CONCLUSIONS

Some common characteristics between the international conventions on nuclear liability are: strict liability, exclusive channelling of liability to nuclear operators, limitation of the liability in amount and in time, and a compulsory financial security. In recent conventions indicate that natural disasters could no longer be used as the reason to annul the nuclear liability.

Based on Japan Law, not all natural disasters can be used as the reason to annul the nuclear liability, it is only for the grave natural disaster of exceptional character.

From the USA jurisprudences, it can be concluded that the damage caused by a natural disaster should meet the requirements of being grave, unforeseeable, unanticipated, unavoidable, and absent from human intervention, in order to be classified as an “act of God.”

With respect to the Indonesia law, Indonesia current natural disaster legal frameworks seem deficient. Provisions in the Disaster Management Act are not in line with modern legal and scientific understandings.

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CHALLENGES IN REGULATING DISUSED RADIOACTIVE SOURCES AND RADIOACTIVE WASTE IN IRAQ

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Abstract

In this study, the national regulatory frameworks which influences radioactive waste management in Iraq was reviewed. Information on the management of radioactive waste was obtained largely through the face to face interviews with representatives of the organizations that are influential in the management stages, namely the regulators and waste management organizations. Other information regarding radioactive management facilities and activities in Iraq have been obtained through sites reconnaissance. The findings of this study indicate that national regulatory system in Iraq have many peculiarities and challenges. Urgent actions have been highlighted and recommended to strength and enhance the national regulatory framework in Iraq.

1. INTRODUCTION

The application of radioactive materials and radiation provides numerous benefits to people and society, and plays a significant role in everyday life. This includes scientific, medical, agricultural and industrial applications. It is a natural consequence of such applications that waste is generated. The radioactive waste needs to be managed in a safe and secure manner. Radioactive waste management involves treatment, conditioning, transportation, storage and disposal of all categories of radioactive wastes, including administrative, operational and safety-related activities. The primary objective is to isolate the radioactive waste from people and the environment for the period the waste remains hazardous [ANSTO, 2011].

Radioactive waste arising from decommissioning operations, Naturally Occurring Radioactive Material (NORM) waste from petroleum industries, along with legacy waste are packaged and relocated for interim on-site storage. Several radioactive waste storage facilities have been constructed in Al-Tuwaitha nuclear
site (20 km south of Baghdad). This paper describes the current national practice for radioactive waste management in Iraq and related regulatory challenges.

2. METHOD

The national regulatory frameworks which influences radioactive waste management in Iraq was reviewed. Information on the management of radioactive waste was obtained largely through the face to face interviews with representatives of the organizations that are influential in the management stages, namely the regulators and waste management organizations. Other information regarding radioactive management facilities and activities in Iraq have been obtained through sites reconnaissance.

3. REGULATORY AUTHORITIES IN IRAQ

Currently, Iraq has three entities which conduct regulatory functions for nuclear facilities and activities:

— Ministry of Health and Environment/Radiation Protection Center (MoHEN/RPC): The MoHEN/RPC is the primary governmental agency responsible for establishing regulatory programs that protect the public health and safety regarding nuclear energy, radiation, and radioactive materials. The MoHEN/RPC’s scope of responsibility also includes implementing and enforcing radiation protection laws, setting guidelines, monitoring radiological contamination, and promoting pollution prevention.

— Iraqi Radioactive Sources Regulatory Authority (IRSRA) is regulatory authority responsible for the management of sealed radiation sources;

— Ministry of Higher Education and Scientific Researches/Radiation and Nuclear Safety Directorate (MoHSR/RNSD) is an internal regulatory body responsible for performing regulatory oversight for all radiological and nuclear activities in Al-Tuwaitha site.

— Ministry of Higher Education and Scientific Researches/Iraqi National Monitoring Authority (MoHSR/INMA) has regulatory oversight for all nuclear materials, facilities and associated activities.

The MoHEN/RPC has been appointed as a regulatory body to govern nuclear decommissioning and radioactive waste management. The MoHEN/RPC rely on IAEA guidance to meet its internal regulatory requirements.
4. RELEVANT NATIONAL LEGISLATIONS AND STATUTES

Laws and regulations are a major tool in protecting the environment and human settlements. Parliament in Iraq passes several laws that govern environmental protection. To put these laws into effect, the Government of Iraq authorizes certain government agencies to create and enforce regulations. Workplace health and safety in Iraq is governed by a system of laws and regulations which set out the responsibilities of employers and workers to ensure that safety is maintained at work. In conjunction with the planning and implementation of the radioactive waste management activities, there has been an increased need for a proper legal basis for effective regulatory scrutiny as well as control over the radioactive waste management programme. The MoHEN/RPC and MoHSR/RNSD were tasked with providing the legal framework for radiation protection and environmental safety based on the relevant IAEA safety guides and the following national regulations:

— The specific national regulatory framework for the decommissioning of destroyed nuclear installations in Iraq is the Decommissioning Regulations No.1, entitled “Regulations for the Decommissioning of Iraqi Nuclear Facilities”, published in the official journal for the Republic of Iraq No. 4332, issued in 18 August 2014. These regulations provide the legal basis for the decommissioning, cleanup and waste management activities.

— The historical legislative basis for radiation protection and radiological safety in Iraq was provided according to the Law No. 99, issued in 1980. The law, entitled “Radiation Protection from Ionizing Radiation”, established the MoHEN/RPC as the primary regulatory body in Iraq and provide the legal basis for protecting the citizens and the workers from the hazardous effects of ionizing radiation. This law covers the essential aspects of the governmental and legal framework for establishing a regulatory body in Iraq and for taking actions necessary to ensure the effective regulatory control of exposure to ionizing radiation. This law set up the basic technical and organizational requirements to be complied with by radiation workers in order to ensure the protection of human health and the environment from the hazards associated with radiation practices. The majority of radiological activities in Iraq are regulated under this law. Other responsibilities and functions related to emergency preparedness and response, nuclear security and control of nuclear material are also covered within this law. The protection of the environment from ionizing radiation is not explicitly included at national level in this law.

— The safety regulations No. 1, entitled “Dose Limits for Exposure to Ionizing Radiation”, issued in 2010 by MoHEN/RPC provides the
regulatory limits for occupational (worker) doses and radiation dose limit for individual members of the off-site public. The scope of this regulation is limited to planned exposure situations. This regulation also provides dose limits for intervention in radiological emergencies.

— Draft regulations governing radioactive waste management have been prepared by Ministry of Higher Education and Scientific Researches/Radioactive Waste Management and Treatment Directorate (MoHSR/RWMTD) in 2014 (2nd Revision). These draft regulations contain description of the nature of all waste streams arising from the decommissioning operations and other radioactive waste producing activities in Iraq, and regulations for its disposition in terms of clearance, re-use, interim storage or disposal as radioactive waste. These draft regulations should be finalized and approved to provide an appropriate legal basis that would regulate the radioactive waste management process.

— Radioactive sources are regulated according to the internal system No.1, issued in 2006 by the Iraqi Radioactive Source Regulatory Authority (IRSRA). These regulations set specific rules about what is legal and what is not regarding safe management of radioactive sources.

— The basic law on environmental protection in the Republic of Iraq is the Protection and Improvement the Environment Law No.27, issued in 2009. This law is the guidance document in Iraq for the environmental protection and assessment of site contamination. It establishes a consistent approach to the assessment of site contamination to ensure sound environmental management practices by the community, including regulators, site assessors, environmental auditors, landowners, developers and industry. It provides adequate regulation of human health and the ecology where site contamination has occurred, through development of an efficient and effective national approach to the assessment of site contamination.

— The occupational safety regulations No. 3, issued in 1985 by the Iraqi Ministry of Work and Social Affairs, sets safety standards and regulations to improve occupational health and safety for all workplaces in Iraq.

Currently, MoHSR/RWMTD are moving forward with waste management activities based on the draft national regulations defined previously.
5. RADIOACTIVE WASTE MANAGEMENT IN IRAQ

Because of the wide variety of nuclear applications in Iraq, the amounts, types and even physical forms of radioactive wastes vary considerably. They include solid and liquid wastes. Due to absence of disposal facility, a huge number of unconditioned radioactive waste and disused radioactive sealed sources from all Iraqi territory are temporally placed and stored at centralized storage facilities in Al-Tuwaiitha nuclear site (20 km south of Baghdad) (Figures 1-3), pending final disposal when a disposal facility for radioactive waste established. At present, plans are being developed to construct a disposal facility at Al-Tuwaiitha site to dispose all types of radioactive waste. Some storage facilities in Al-Tuwaiitha nuclear site have never been licensed; those that have been licensed were often non-compliant with internationally accepted principles, and in most cases there were no environmental impact assessment for these facilities. Huge amounts of radioactive waste in storage facilities are not conditioned. Since the safety and security conditions of these waste is uncertain, needs to evaluate the regulatory infrastructure become priority in Iraq especially after 2003.

However, over the last decade, Iraq has successfully implemented measures and programs to enhance its regulatory oversight of radioactive waste and declared spent/disused radioactive sources to fully meet the provisions of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. Within MoHSR, the Radioactive Waste Treatment and Management Directorate (RWTMD) is responsible for waste management. In addition to being responsible for managing the decommissioning wastes, the RWTMD is responsible for more than 1000 disused sealed radioactive sources, depleted uranium (DU) contaminated debris from the Gulf Wars and (approximately 900 tons) of naturally-occurring radioactive materials (NORM) wastes from oil production in Iraq. The RWTMD has trained staff, rehabilitated the Building 39 (Radioactive Waste Storage Building), rehabilitated portions of the French-built Radioactive Waste Treatment Station, organized and secured thousands of drums of radioactive waste, organized and secured the store of disused sealed radioactive sources [Al-Musawi, 2013].
Figure 1. Legacy radioactive waste.

Figure 2. Legacy disposal areas in Al-Tuwaitha site.
6. RESULTS AND DISCUSSION

During the review of the regulatory work in Iraq, meetings have been conducted with senior managers, waste management operators, the regulator and other involved organizations. The review compared the Iraq’s regulatory framework for safety against IAEA safety standards as the international benchmark for safety. Site visits have been conducted to radioactive waste management facilities in Al-Tuwaitha site to observe inspections. The findings of this study indicate that national regulatory system peculiarities in Iraq can be summarized as below:-

— Iraq has a comprehensive nuclear regulatory programme that is undergoing change primarily due to realignment of responsibilities;
— National regulatory bodies in Iraq are totally independent;
— Staff with regulatory responsibilities in MoHEN/RPC and MoHSR/RNSD have received adequate practical training to develop and maintain skills that enable them to perform their regulatory duties effectively;
— There is an adequate system of authorization, licensing, or registration process for radioactive sources for government owned and non-government owned radioactive sources;
— There is an adequate system of inspection, monitoring, follow-up and record keeping for all declared disused/spent radioactive sources during the interim storage period.
However, the review shows that the management of radioactive waste in Iraq faces many challenges and deficiencies regarding the implementation of national regulatory oversight, include:-

— Lack of human and financial resources for the planned operations;
— Iraq has no long history of regulatory oversight, which means that radioactive waste management operators had no enough culture of responding to regulatory requirements;
— There was no single regulatory body;
— Most of the current radioactive waste management facilities in Al-Tuwaitha site had no existing licenses and no existing safety cases;
— Currently, there are draft laws and regulations governing radioactive waste management and control in Iraq. These draft regulations have not been approved or enacted yet by Iraqi parliament;
— Iraq do not give high enough priority to the radioactive waste problem because there are larger or more urgent issues demanding all of the available resources (such as security threats);
— Limitations on the storage capacity have not been prepared yet;
— Recent governmental mendings make radioactive waste management facilities more susceptible to being forgotten or ignored, which increases the risk of an accident;
— The current regulatory system and regulatory programs do not promote prompt reuse or recycle of disused radioactive sources. Rather, the regulatory environment promotes the acquisition of new sources and the storage of disused radioactive sources, thereby increasing the inventory and perpetuating the radioactive waste problem;
— The inventory of radioactive waste (including spent/disused radioactive sources) in storage facilities is infrequently accounted. The expected waste types consist mainly of very low level waste (VLLW), low level waste (LLW), and eventually minor quantities of intermediate level waste (ILW) and very limited amounts of high level waste (HLW);
— All radioactive waste (including disused radioactive sources) given the same amount of work regardless of their potential hazard;
— IRSRA and MoHEN/RPC share responsibilities for different activities or stages in the radioactive source life cycle;
— Accurate data on lost radioactive sources are not available (several orphan sources were found in the last years, which indicates that there are others).
7. RECOMMENDATIONS

The findings of this study highlighted the need for the following urgent actions:-

— A close co-operation with international agencies (such as the IAEA) to contribute to the improvement and strengthening the effectiveness of the Iraq’s regulatory framework for nuclear and radiation safety and bring it in compliance with modern safety standards. This is done through consideration of regulatory, technical and policy issues, with comparisons against IAEA safety standards, and, where appropriate, good practices observed in other regulatory authorities.

— MoHEN/RPC urgently needs to bring all unlicensed facilities using radiation under regulatory control.

— It was noted that MoHEN/RPC needs to update and revise the Iraq’s legislative and regulatory framework in line with modern international safety standards, develop and implement an integrated management system and use a graded approach that adapts the level of regulation to the level of associated risk.

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REGULATORY CAPACITY BUILDING IN ROMANIA
An International Nuclear Safety Cooperation between Norway, Romania and the IAEA 2013-2017

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Abstract
The Norwegian Radiation Protection Authority (NRPA), the Romanian National Commission for Nuclear Activities Control (CNCAN) and the International Atomic Energy Agency (IAEA) are enhancing the regulatory competence in Romania. The project started in the end of 2013 and will be completed in 2017. The goal of the project is to improve the competence of CNCAN in eight specific areas through the exchange of experience, best practices and capacity building with NRPA and the IAEA. The project is on-going and some of the results of the project are presented in the paper.

The project has a budget of 4.2 million euro, 85% covered by the Norway Grants and 15% covered by Romania. This is a continuation of a similar project implemented with the same partners in 2009-2011.

1. INTRODUCTION

The Romanian National Commission for Nuclear Activities Control (CNCAN), the Norwegian Radiation Protection Authority (NRPA), and the International Atomic Energy Agency (IAEA) are cooperating on a project named “Regional Excellence Project on Regulatory Capacity Building in Nuclear and Radiological Safety, Emergency Preparedness and Response in Romania”. The project started in the end of 2013 and will be completed in 2017.

The project has a budget of 4.2 million euro, where 85% is covered by Norway Grants and 15% covered by Romania. Norway Grants is the contribution of Norway to reducing economical and social disparities and strengthening bilateral relations with 16 EU countries in Central and Southern Europe. The entire project is organised through an IAEA extra-budgetary programme.
This project is a continuation of a similar project with the same partners that was successfully implemented in the period 2009-2011.

2. BACKGROUND

During the period 2009-2012 Romania experienced a substantial economic and political crisis which resulted into significant budget and salary cuts in the majority of governmental organizations. In that context, CNCAN employees have been unable to receive proper training or acquire/maintain proper software, hardware, and other tools needed to improve their working infrastructure to keep up to date with the challenges of increasing international and European expectations and standards for nuclear regulatory authorities. These challenges include the implementation of the recommendations and suggestions from the IRRS (International Regulatory Review Service) mission received by Romania in 2011 and of the lessons learned from the Fukushima accident.

3. GOALS AND OBJECTIVES OF THE PROJECT

The project was designed to address the above challenges. The goal of the project is to improve the regulatory competence of the Romanian regulatory authority CNCAN in the eight areas: nuclear safety, integrated management systems and knowledge management, oversight and inspections, safety of the transport of radioactive materials, emergency preparedness, control of radiation sources, radioactive waste, spent nuclear fuel and decommissioning, and safeguards. Other target groups in Romania includes the operators of nuclear power plant, research reactor facilities, radioactive waste facilities, users of radiation sources, and organizations that transport radioactive sources and radioactive waste.

Another important objective of the project is to share experience and best practices developed in the project to the international nuclear community through the active involvement of the IAEA.

4. RESULTS

The project is now more than halfway, and substantial results have already been achieved. Around 250 different activities have been planned. The project activities are carried out through the exchange of experience, best practices and capacity building.

The regulations, methodologies, procedures and guidelines that have been developed or revised during the project are in accordance with international standards and developed with the help of participation of international experts with special expertise in relevant areas.
Below is an overview of some of the results that have been achieved throughout the project:

— 15 of 30 planned new regulations, methodologies, procedures and guidelines have been developed in Romania.
— 5 of 16 planned regulations, methodologies, procedures and guidelines have been updated in Romania.
— 8 of 18 planned workshops have been conducted to explain and to receive feedback from stakeholders. One example is the national workshop on the predisposal of radioactive waste, which was held in Romania in June 2015, with 18 participants from 7 Romanian organizations and authorities. Another workshop was held on decommissioning in Bucharest, Romania in 2015, with 18 participants from Romania.
— A total of 350 staff member have been trained on 15 training events. One example is the National Training Course on Transport, which was held in Bucharest, Romania in June 2015, with 32 participants from Romania, and 3 international experts. Another example is the National Training Course on Expanded response in nuclear accidents that was held in Romania in July 2015, with 38 participants from Romania.
— 37 pieces of equipment have been purchased or upgraded, e.g. mobile communication devices for emergency response, software and hardware systems. For example, CNCAN has received two updated licenses for mechanical code for nuclear pipe systems calculation (BENTLEY AUTOPIPE) and five mobile multifunctional communication devices for emergency response.
— 1 of 5 planned field tests /pilot exercises have been conducted to examine improved arrangements.
— A number of recommendations from the IRRS mission (Integrated Regulatory Review Service) to Romania in 2011 have been integrated into this project. So far, 22 of 26 IRRS recommendations have been implemented.
— 43 IAEA review missions and 21 IAEA expert missions have been conducted in Romania.
— 10 of 13 planned documents have been developed and published by IAEA, and made available to all IAEA member states. One example is a generic Management System Manual for Regulatory Bodies that has been delivered to CNCAN. Another example is a training package on the inspection and enforcement processes including all documentation that has been delivered to CNCAN.
— Planning is on-going for a major emergency response exercise called Valahia 2016, which will be held in Romania in October 2016.
Apart from the tangible results consisting of new or revised regulations, procedures, training materials and equipment, the project offers the following benefits:

— CNCAN specialists interact with senior experts from the IAEA, from NRPA and from nuclear regulatory authorities and industry organizations from other countries and learn from each other by exchanging practical experience on various topics;

— The experience sharing leads not only to improved technical knowledge but also to a better understanding of the cultural diversity and of the way in which national and organizational cultures influence the regulatory approaches and practices; this is important for understanding the background for the good practices identified as applicable for use in our national regulatory framework;

— The project will also help CNCAN implement lessons learned from the post-Fukushima safety reviews. In addition, this project contributes to the implementation of several activities that are part of the action plan associated with the National Nuclear Safety and Security Strategy of Romania.

5. PROJECT PARTNERS AND THEIR ROLE IN THE PROJECT

CNCAN is the Romanian competent authority responsible for the regulation, licensing and control of nuclear activities, ensuring the peaceful use of nuclear energy and the protection of public and workers from the harmful effects of ionizing radiation. Within the project, CNCAN is responsible for achieving the objectives of the project. In addition, CNCAN coordinates activities with project partners, communication with project stakeholders, and is responsible for the project reporting, financial resources and publication of results.

NRPA is the Norwegian competent authority in areas of nuclear safety, all uses of radiation, natural radiation and radioactive contamination of the environment. In the project, NRPA is especially involved in the areas of nuclear safety, inspections, radioactive waste, spent nuclear fuel and decommissioning activities.

IAEA is an international UN organization with 168 Member States focusing on the safe use of nuclear energy. IAEA assists CNCAN in updating regulations, standards, methods and procedures, and development of new documents. IAEA’s involvement guarantees the implementation of project activities in accordance with international standards and with the participation of international experts with special expertise in these areas.
CHALLENGES IN REGULATING RADIATION SOURCES AND RADIOACTIVE WASTE IN NIGERIA

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Abstract

Identifying challenges that hamper the efficiency and efficacy of Regulatory Infrastructure (People and Processes) as regards ensuring safety & security of radiation sources and radioactive waste is a major step towards planning for improvement. In a world constantly motivated by technological advancements, there has been considerable increase in the use of new technologies incorporating radioactive sources in both medical and industrial applications due to its perceived benefits, hence changing the dynamics of regulation. The paper brings to the fore, contemporary challenges experienced by regulators in the course of regulating radiation sources and radioactive waste in Nigeria. These challenges encountered in the business of regulating radiation sources and radioactive waste in Nigeria amongst others include; knowledge gap in the use of novel technologies for industrial applications (e.g. radiotracers in oil & gas and wastewater management), inadequate collaboration with operators to ensure transparency in their operations, inadequate cooperation from other government agencies using ionizing radiation sources, lack of synergy between relevant government agencies, difficulty in establishing standard radioactive waste management facility for orphan & disused sources, and inadequate control of NORMS encountered in industrial activities (e.g. well logging, mining). Nigerian Nuclear Regulatory Authority (NNRA), the body saddled with the responsibility of regulating the use of ionizing radiation sources in Nigeria is empowered by the Nuclear Safety and Radiation Protection Act to ensure the protection of life, property, and the environment from the harmful effects of ionizing radiation, hence are not immune to the aforementioned challenges.

1. INTRODUCTION

— The Nigerian Nuclear Regulatory Authority was established by Act 19 of the Nuclear Safety and Radiation Protection, 1995 as well as a system of licensing
— The Nigerian Basic Ionizing Radiation Regulations (NiBIRR) establishes the framework for implementing Basic Safety Standards as is given in the IAEA – BSS
— NNRA has twelve (12) practice specific regulations, some have been reviewed while others are under review to conform with the latest IAEA Standards
— NNRA is administered by a Governing Board comprising of all stakeholder ministries: Environment, Petroleum, Science and Technology etc. and a National Security Committee

2. SOME REGULATIONS ARE AS FOLLOWS

— Nigerian Safety and Security of Radioactive Sources Regulations, 2006 (consistent with the IAEA Code of Conduct for the Safety and Security of Radioactive Sources)
— Nigerian Transportation of Radioactive Source Regulations, 2006 gives directive for Transport of radioactive wastes within the country consistent with the TS-R-1 of IAEA
— Guidance document for radioactive waste management

3. STATUS OF RADIOACTIVE WASTE MANAGEMENT

— The nature of radioactive waste in a country depends on the type of practice in the country. The use of radioactive material in Nigeria can be divided broadly into three and these are research, medical and industrial applications. The sources applied can be divided into three broad groups, which are:
— Unsealed source used in medicine, research establishment and process control in industry
— Sealed Source used in industry, medicine and research establishments.
— Research reactor fuel and activated products.
— Nigeria presently has one operational Waste Storage Facility at the Centre for Energy Research and Training Zaria

4. BILATERAL MECHANISM: THE NNRA IN CONJUNCTION WITH THE US DOE

Is carrying out security upgrade at the following facilities:

— NIRR-1 Research Reactor at CERT, Zaria
— Radioactive Waste Management Facility at CERT, Zaria
— Teletherapy unit at Eko Hospital, Lagos
— NNRA and IAEA Carried out National Search and Secure for orphan Radioactive Sources on Dec 2015
— The NNRA through international collaboration with the US DOE and the IAEA has established a complete inventory of the Legacy Sources at Ajaokuta Steel Company Limited in July 2008. The sources have been labelled and are presently stored in two ISO containers at the ASCL Complex. The final disposal of these sources is still a challenge

5. MAJOR NUCLEAR INSTALLATION AND USES OF RADIOACTIVE SOURCES IN NIGERIA INCLUDE:

— Information available on radioactive sources as compiled by the RAIS Team shows that the followings are the Major nuclear installations in the country generating or likely to generate radioactive waste:
— One 30 kW Miniature Neutron Source Reactor (MNSR) at the Centre of Energy Research and Training, Ahmadu Bello University, Zaria
— One 8MeV Van De Graff accelerator under installation at the Centre for Energy Research and Development, Obafemi Awolowo University, Ile-Ife
— Eleven 14 MeV Neutron Generators in research institutions and the oil industry
— A mega-Curie Cobalt-60 radioactive source due for commissioning at the Sheda Science and Technology Complex, Abuja
— A number of sealed radiation sources, Cobalt-60 and Cesium-137, are being used at the radiotherapy departments of the University Teaching Hospital, Zaria, Eko Hospital, Lagos and Grace Hospital Ibadan
— Couple of thousands of radioactive sources used as nuclear gauges in the manufacturing industry
— Several kilocurie Cobalt-60 radioactive sources used for biological research and due for decommissioning
— A considerable amount of radioisotopes including labeled compounds are used in various research laboratories, nuclear medicine centers, research institutes, universities, hospitals, etc for R&D and other routine activities
— A considerable amount of radioactive waste in the tin-mine tailings around Jos in Plateau State and in the petroleum industry in the form of TE-NORM
— Nigerian Nuclear Regulatory Authority has a regulation on NORM’S, which Authority is guarded with.
— NNRA with the assistance of IAEA has installed portal monitors at the export terminal of materials leaving the country as well as at various inland borders in the country. This is managed by the Custom authority.
— NNRA has over six (6) portal monitors installed at the import terminals for such materials. Recycling plants are by law expected to show evidence of monitoring of their inputs and NNRA organizes regular inspection of such facilities.

6. NATIONAL WASTE MANAGEMENT POLICY AND STRATEGY

— NNRA prepared a national policy on waste management as far back as 2005. This was actually drawn using the IAEA standards available at that time.
— With the establishment of NAEC, this document was transferred to them as the national promoter organization.
— In the policy, a Waste Management Organization will be created under NAEC, but NNRA is to license and have regulatory oversight on the project.
6.1. RAW and Decommissioning Provisions

— The Waste Management Regulation prescribes “return to manufacturer” principle. Before import license is granted, prospective buyers are required to obtain a written commitment from manufacturer to accept a source after use.

— No report of failure to accept has been reported since this agreement was entered into.
Acceptance of wastes for storage is on the ground that it has been packaged and meets transport condition.
Handling of wastes must be in designated facilities only.
The regulation has the classification in line with the IAEA standards.
All storage facilities are under surveillance and are regularly monitored.

6.2. Predisposal Management of Radioactive Wastes

The characterisation is prescribed in the regulations and the segregation processes are part of what the waste owner must do before presenting it to the central storage facility or it may be done at the temporal storage facilities.
Meanwhile RAW are not being processed during interim storage, processing will be done by WMO.

6.3. Storage of RAW

All storage facilities are to be licensed. No wastes are undergoing conditioning yet, so they are stored in packaged but retrievable way.
All storage facilities are supposed to have three licenses.
Site license – satisfactory design, and construction and security arrangement.
Operation license – satisfactory training of personnel in radiation protection and monitoring procedure, presentation of monitoring and radiation protection programme.
Decommissioning programme is part of site licensing.
The presently operating storage facility in CERT, Zaria has been reviewed, expanded and the security upgraded with assistance of IAEA and USDO.
A new Radioactive Waste Facility is being built. IAEA expert have visited at least thrice.

6.4. Disposal of RAW

Disposal of RAW is included in the national waste management policy.
The strategy is to gradually explore the disposal options and the repository sites.
Regulatory requirements will also be drawn up and the WMO will submit both the safety case and safety analysis report SAR depending on the technology chosen.
6.5. Decommissioning of Nuclear and RAM Containing Facilities

— Fund for decommissioning will be derived from charges derived during operation. However, government will be responsible for running the repository
— The WMO will draw up the plan for shut down of existing research reactor, but there is a standby tripartite agreement between the supplier, IAEA and Nigeria that the core of the reactor will be repatriated
— Nigeria has no plans to reprocess wastes

FIG. 2. Radioactive Waste in Storage Containers
FIG. 3. Orphan Sources
FIG. 4. Radioactive Source Container
FIG. 5. Radioactive Source Transport Container
FIG. 6. Cement, Concrete Mixer for 200 liters Storage Container (For Shielding)
QUALITY MANAGEMENT SYSTEM IMPROVES EFFECTIVENESS AND QUALITY OF ACTIVITIES OF RADIATION PROTECTION REGULATORY BODY IN LITHUANIA

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Abstract

Processes of creation of quality management system (QMS) in regulatory body in radiation protection field – Radiation Protection Centre (RPC) and the benefit of this system to ensure the quality of the performance of functions are described. RPC QMS compliant with ISO 9001:2008 standard and in line with the requirements of the IAEA GS-R-3 document. It allowed achieving a new quality of works carried out by RPC. Because creation and introduction of the QMS is a continuous process, the QMS of RPC is continually renewed and new procedures are developed.

1. INTRODUCTION

The Lithuania governmental and regulatory frameworks for safety and legal framework are in line with international standards. Lithuania has developed good radiation protection infrastructure as well. During the preparation of the quality manual (QM) and process description and working procedures the international ISO standards (ISO 9000:2007; ISO 9001:2008; ISO/TR 10013:2003; ISO/IEC 17025:2006; ISO 19011:2003) [1-5], IAEA-standards [6-10] and best practices from other institutions were used.

Ensuring radiation protection of Lithuanian population is a continuous process requiring routine and high-qualified work of specialists of the RPC. RPC prioritizes performance effectiveness and openness to the public at large. Since its establishment, RPC focuses on coordination of its activities, performance quality and productivity when discharging its functions: state supervision and control of radiation protection, assessment and expertise of public exposure.

2. ESTABLISHMENT OF QUALITY MANAGEMENT SYSTEM

For assuring consistent and focused quality of the exercised functions, particular attention appointed to the improvement of the quality of activities. For
that, RPC has established QMS. QMS of RPC is compliant with the ISO 9001 standard [2] and covers all regulatory body activity areas. Senior management of RPC has appointed members of the staff for all the processes and functions (managing, executive and supportive). They made an analysis of the IAEA-standards, EU directives and regulations and national legislative acts concerning their process or functions and described their function in policy documents, processes descriptions and working instructions. The senior management reviewed and authorized all the QMS documents before approving.

The scope of QMS is maintenance of the State Register of Sources of Ionizing Radiation and Occupational Exposure, authorization of the activities with sources, state radiation protection supervision and control, emergency preparedness and response to radiological accidents, expertise and assessment of public and occupation exposure, environmental monitoring and training on radiation protection.

QMS documents consist of different level documents: QM, procedures, which regulate the activity of RPC, and working instructions, where whole information how consistently to perform activities and processes are described. The quality policy includes the aim of RPC, the main tasks, which should help to implement the aim, leadership obligations. QM describes QMS processes sequences and interactions, the responsibility of the leadership obligations and the control management of resources. Criteria of monitoring analysis and the abilities of improvement are provided as well.

All the staff have recognized the benefits of the QMS. Constant improvement of QMS ensure implementation of the new quality objectives raised every year. Internal and external audits are among the key tools to improve it, as they allow disclosure of strengths and weaknesses in work organization and performance, and planning for improvement directions, based on the QMS. External and internal auditors monitor how RPC ensures incoming, in-house developed and electronically stored document handling and security, in which way the staff in the routine work process follow documents approved by QMS. Every year documents of QMS are reviewed and in case of necessity updated by responsible staff with help of quality manager. This all improves performance effectiveness, the quality of activities and contributes to developing a positive public attitude to regulatory body activities.

Success factors of QMS – the positive approach of the management and all employees to the QMS and its constant updating. Nevertheless day by day monitoring of the activities based on knowledge and transparent responsibilities allows RPC to be pellucid and fluent institution.

3. DOCUMENTS OF QUALITY MANAGEMENT SYSTEM

QMS documents cover all the main processes of RPC and help to achieve quality objectives. Majority of procedures and working instructions are meant to describe main RPC functions, which help to meet the needs of society. Procedures and working instructions about management of resources are equally important,
since they describe personal management, training and safety, financial planning, procurement and other processes, which enable RPC specialists to perform the main functions. Monitoring and analysis of RPC functions and results are also described in QMS documents. The sequence and interaction of QMS processes are specified in Fig. 1.

Since the creation of QMS, 29 procedures and 67 working instructions were prepared. The majority of procedures describe general activities of RPC, such as management of documentation, drafting of legal acts, management of human resources, financial planning and others.

The most working instructions, where detailed information how to perform activities are described, were created for those areas which have the widest range of functions, such as environmental monitoring, state radiation protection supervision and control, assessment of exposure.

The number of procedures and working instructions according to the areas of activities are shown in Table 1.
TABLE 1. THE NUMBER OF PROCEDURES AND WORKING INSTRUCTIONS ACCORDING TO THE AREAS OF ACTIVITIES

<table>
<thead>
<tr>
<th>Areas of activities</th>
<th>Number of procedures</th>
<th>Number of working instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>General activities</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>State radiation protection supervision and control</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Authorization</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Maintenance of State Register</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Emergency preparedness and response</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Expertise</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Assessment of exposure</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Environmental monitoring</td>
<td>1</td>
<td>24</td>
</tr>
<tr>
<td>Training on radiation protection</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

4. RESULTS

Within creation of QMS following documents were prepared: the QM describing sequences and interoperability of QMS processes, management responsibilities and resource management, including monitoring analysis criteria and improvement opportunities, quality policy and its goals, 29 procedures describing activities of RSC structural units and main processes and 67 working instructions to do specific works.

Safety culture of QMS at RPC is realized due to clearly described processes and formats of products, due to continuous training of staff for common understanding, due to supporting the individuals and groups of the staff for safety and qualified performance of duties. Described QMS improve effectiveness and quality of activities, the quality of provision of public services, and contributes to the development a positive public attitude to the Government authorities.

5. CONCLUSIONS

Described QMS obliges RPC to improve continuously the quality of discharging functions delegated to it and meet the ever increasing society needs. Management system maintains the efficiency and effectiveness of the RPC performing its functions and corresponds to responsibilities. This includes the promotion of enhancements in safety, and the fulfilment of its obligations in an appropriate, timely and cost effective manner to build confidence. Quality performance of RPC is crucial to ensure public and environment radiation protection in Lithuania.
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EXPERIENCE TRANSFORMED INTO NUCLEAR REGULATORY IMPROVEMENTS IN RUSSIA

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Abstract

The third International Conference on Effective Nuclear Regulatory Systems (Canada, 2013) identified the main action items that should be addressed, implemented and followed up. Over time many activities based on results of the IAEA IRRS mission in the Russian Federation, 2009, and post-mission, 2013, have been implemented. Progress have been achieved in many areas: implementation of national action plan on nuclear safety, complementary reviews of nuclear facilities other than Nuclear Power Plants, emergency exercises with the regulatory body participation, improving communication, development of national regulations and improvement of regulatory system in whole. The regulatory body ensures assistance in development of national regulatory infrastructure, safety culture to the countries planning to construct Russian design facilities (NPPs, RRs). The report outlines the transformed experience and future actions to improve nuclear regulatory system.

1. INTRODUCTION

The International Conference on Effective Nuclear Regulatory Systems, held 8–12 April 2013 in Ottawa, Canada, identified major issues to be addressed by regulators in strengthening global and national nuclear regulatory effectiveness with due account to lessons learned from the Fukushima Daiichi Nuclear Power Plant accident (F-D accident) and regulatory aspects of the IAEA Action Plan on Nuclear Safety and enhancement of regulatory measures aimed at management of nuclear or radiological emergency. Further, the International Conference on Global Emergency Preparedness and Response, held 19–23 October 2015 in Vienna, Austria, provides recommendations on actions to be implemented by regulators, operators, and national organizations for continuing improvements to Emergency Preparedness and Response (EPR).

In the Russian Federation (RF) the key areas important for the use of international approaches for strengthening national and international nuclear regulatory framework are addressed through implementation of Action Programme of Russian Authorities and Organizations Concerned in Implementation of the IAEA Action Plan on Nuclear Safety [1] and the Rostechnadzor’s Action Plan [2] that has been developed and implemented following the IAEA IRRS follow-up mission to the RF organized by the IAEA during 11-19 November 2013 (IAEA Mision-2013). The Action Plan contains arrangements and actions to be accomplished by the Rostechnadzor in order to meet the IAEA Mission-2013
recommendations with regard to improvement of the Russian regulatory system and strengthening regulatory EPR capabilities. In planning and doing improvement actions, the Rostechnadzor makes account of the commitments made from the mentioned international meetings and tries to transform international experience into the regulatory improvements. The report outlines the achievements and further activities scheduled in implementation of the Rostechnadzor’s Action Plan resulting from the IAEA Mision-2013 with focus on the EPR arrangements.

2. RECENT IMPROVEMENTS OF THE REGULATORY SYSTEM

2.1. Actions following the IAEA Mision-2013

The IAEA Mision-2013 was taken to review the national regulatory framework for nuclear and radiation safety, in particular measures undertaken to meet the recommendations and suggestions of the IRRS Mission-2009. The mission put special attention to regulatory implications of lessons learned from the F-D accident and EPR regulatory arrangements. The mission team made conclusion that 10 out of 25 recommendations and 17 of 34 suggestions issued by the IRRS Mission-2009 had been effectively realized and could be closed; 8 recommendations and 6 suggestions were considered as closed on the basis of progress made and confidence in their effective completion; 7 recommendations and 11 suggestions remained open. The IAEA Mision-2013 findings consisted of 3 recommendations, 1 suggestion and 3 good practices in respect of the regulatory system, and included 2 recommendations, 7 suggestions, and 2 good practices related to EPR module.

2.1.1. Good practices

The IAEA Mision -2013 team identified the following good practices in the Rostechnadzor regulatory activity:

- The RF, through its leadership and collaboration with various international stakeholders, has contributed effectively to the development of measures and programs that may strengthen the global safety regime in the wake of the F-D accident;
- The introduction of a systematic emergency exercise evaluation methodology and the adoption of extensive and detailed regulations on the contents of licensee emergency plans;
- The requirements for the emergency plans contents for all types of activities and practices are clearly and extensively defined in regulations;
- The Rostechnadzor has initiated joint inspection activities with foreign regulatory bodies to share best practices and experience in nuclear facilities supervision;
2.1.2. Action plan

The Rostechnadzor’s Action Plan for improvement of the regulatory system and addressing the IAEA Mission-2013 findings, was approved in December 2014. The plan covers 24 actions to be implemented over period till the end of 2018. The major actions concerning the lessons learned from the F-D accident and EPR arrangements are as following:

— Review of “Procedure for Announcement of Emergency, Prompt Information Communication and Emergency Assistance to Nuclear Power Plants in Case of Radiation-Hazardous Situations” (NP-005-98) to ensure the consistency of the criteria for announcement of emergency situation with the IAEA Safety Standard № GSR Part 7 (Deadline: 2016).
— Development of proposals on harmonizing the existing hazard categorization of radiation facilities, established by the Russian safety regulation “Main Sanitary Regulations of Radiation Safety” (OSPORB -99/2010) with the emergency preparedness categorization recommended by the IAEA Safety Standard № GSR Part 7. Submission of such proposals to the FMBA of Russia 2 (Deadline: 2016).
— Analysis and examination of the necessity to harmonize the established response criteria, in particular for immediate medical intervention, urgent decision-making at the initial stage of radiological accident, radioactive contamination levels, etc., defined in the Russian standard “Norms of Radiation Safety” (NRB-99/2009) with the criteria for use in preparedness and response for a nuclear or radiological emergency, defined by the IAEA Safety Standard № GSR Part 7 and General Safety Guide № GSG-2 [4].
— Development and submission of the corresponding proposals to Rospotrebnadzor3 leadership (Deadline: 2016). Analysis and examination of reasonability to harmonize emergency notification...

— Development of the safety guide “Mitigating Radiologic Consequences for the Population and the Staff in the Course of Accident Remediation at Power Units of Different Types. Optimization of Methods for Measures to Protect the Population and Site” (RB-094-14), providing guidelines for hazard assessment and determination of planning zones in line with the international guidance (Approved 19.03.2014)

— Development of annual action plans aimed at identification of gaps and enhancing abilities of the Information and Analysis Centre (IAC) of the Rostechnadzor. The plans envisage evaluation by the Rostechnadzor of emergency exercises and drills at radiation facilities. Currently the exercises involving facilities other than Nuclear Power Plants (NPPs) have been evaluated. The exercises on emergency response actions at Nuclear Research Facilities (NRFs) are planned. The last exercise with participation of the Rostechnadzor was conducted on 22 May 2015 at the research reactor BOR-60, JSC “SSC RIAR” (Dimitrovgrad).

— Assistance to regulatory bodies of foreign countries, which decided to embark a research reactor project and/or set up a nuclear programme for peaceful purposes. There is a special decree of the Government of the RF from 15.04.2014 that authorizes the Rostechnadzor to share experience accumulated in the Russia with the relevant national authorities of foreign countries, constructing or planning to construct nuclear facilities of Russian designs. This provides such countries with the unique opportunity and resources for training personal and development of qualified workers for creation of effective nuclear regulatory framework.
2.2. Strengthening of the Rostechnadzor EPR

Within the mandate, the Rostechnadzor plays a key role in development of the regulatory framework and overseeing to ensure the adequate emergency management at licensed nuclear facilities. The Rostechnadzor:

— Makes arrangements to ensure that the system of control over nuclear facilities is organized and maintained adequately in case of an accident;
— Creates, modifies and maintains an automated system of information analysis service, including its use for the needs of the Unified State Automated Environment Radiation Monitoring System (in Russian abbreviation – EGASMRO);
— Directs the activity of the sub-system for control over nuclear hazardous facilities within the Unified State System for Prevention and Management of Emergencies (in Russian abbreviation – RSChS).

For the needs of the EGASMRO the Rostechnadzor operates its own sub-system for control over nuclear hazardous facilities and maintaining an automated system of information analysis service. This sub-system is expected to be integrated with EGASMRO and RSChS at the federal level (Headquarter of Rostechnadzor) and at the regional level (Regional Offices of Rostechnadzor) that will provide wide possibilities of data exchange during normal operation and in emergency situation.

2.3. Rostechnadzor’ sub-system for control over nuclear hazardous facilities

According to Decree of the Government of the RF from 23.11.2009 the Situation and Crisis Center of State Corporation “Rosatom” (SCC of Rosatom) performs functions of a national warning point for information exchange and early notification in case of a nuclear accident, as it is specified by international treaties (agreements).

The Rostechnadzor has its own Information and Analysis Centre (IAC) that is equipped with workstations, telecommunication system for automat data exchange and may operate in two modes: a daily routine mode and an emergency response mode. Recently the enhancement measures for increasing efficiency of the IAC have been identified based on the detailed analysis of the Rostechnadzor operations in conditions of a facility accident. The IAC modernization will include renovation of the IAC premises, renewal of equipment and communication channels; installation of new software (domestic and foreign); development of fast running computer codes for express analysis of accidents at NPPs and assessment of emergency releases.
To improve data exchange the agreement between the Rostechnadzor and the State Corporation “Rosatom” on information exchange in the course of emergencies at nuclear facilities was signed on 01 September 2014. To increase protection of information exchange fast speed fiber-optic channel has been set between the IAC of Rostechnadzor and the SCC of Rosatom. The guidance documents for the IAC operation have been developed and approved, including IAC Statute (2013), IAC Operating Regulations (2014), and Regulation on Sub-System Operation within Framework of the RSChS (2015). The draft of “Administrative Regulations for Information Exchange between the SCC of Rosatom and the IAC of the Rostechnadzor” is in the process of developing. Regular exercises to test emergency response actions under the conditions of a NPP accident are conducted on the basis of the IAC of the Rostechnadzor with the participation of operating organization and scientific and technical support organizations. Video conferencing on plant safety with participation of all plants, the concern “Rosenergoatom” (Operating Organization for all NPPs) and technical support organizations are carried out systematically.

3. FURTHER IMPROVEMENT OF NUCLEAR REGULATORY SYSTEM

3.1. Rostechnadzor EPR arrangements

Further actions on improvements to the Rostechnadzor EPR measures are based to a great degree on recommendations of mentioned above the International Conference on Global Emergency Preparedness and Response (2015). These include taking actions on addressing observations and lessons from the IAEA Report on the F-D accident, need for steps in respect of effective integration of nuclear safety and nuclear security in EPR, measures on establishment of a unified command system, conduct of joint exercises and other issues. The Rostechnadzor also carried out analysis of approaches and good practices that were pointed in National Reports of Contracting Parties to the Convention on Nuclear Safety (CNS) at the 6th Review Meeting. The resulting proposals for enhancement nuclear regulatory system and EPR have been developed in the process of drafting “Seventh National Report of the Russian Federation on the Fulfillment of Commitments Resulting from the CNS”.

The Rostechnadzor has prepared draft of “Concept for Improvement of Normative Legal Regulations of Safety and Standardization in the Field of Nuclear Energy Use”, which should provide for consistency and stability of the safety requirements, technical and economic feasibility of safety requirements, harmonization of safety and security requirements with recommendations of international organizations in the field of nuclear energy use [6]. When developing new requirements and regulatory documents, the relevant IAEA requirements and standards are required to be examined and taken into account.
3.2. Expansion of EPR arrangements

At present an automated data transmission is available only for NPPs from the Crisis Center of the concern “Rosenergoatom” and is not provided in full scale from the SCC of Rosatom. In case of operational events at a nuclear facility the Rostechnadzor, acting as an independent body, informs, if required, the federal and local authorities on what has happened at the facility, and on the measures that have been or are being taken, and organizes interaction with mass media. Therefore the Rostechnadzor should get reliable and urgent information about state of facility, its major parameters and radiation monitoring results while normal operation and in case of emergency.

The Rostechnadzor’s sub-system for control over nuclear hazardous facilities that is a constituent part of the RSChS and maintains an automated system of information analysis service for the needs of the EGASMRO, should be expanded on nuclear facilities other than NPPs. Drafting of the IAC Work Plan is carried out now with consideration of emergency preparedness assessments of NRFs. Data automatic transfer systems, video-conferencing systems, models and computer codes for express-assessments should be developed and applied, if required, on the basis of graded approach with due account to potential hazard associated with a specific NRFs.

3.3. Challenges in implementation of the Rostechnadzor EPR

At present the Rostechnadzor conducts state safety regulation and supervision at 65 NRFs that are operated by 17 different organizations. At the federal level the Government of the RF established three authorities empowered to govern the use of atomic energy and coordinate activities at NRFs: State Corporation “Rosatom”, Ministry for Education and Science, Ministry of Industry and Trade. Taking into account that NRFs are very different in design, characteristic and power, and are governed by different authorities, they are not integrated in automated monitoring sub-system at local and federal levels. Nowadays the information exchange at the federal level is reduced to traditional communication means (phone, fax, e-mail).

On 22.11.2012 the Rostechnadzor issued Safety Regulation “Preparation and Transmission of Data of the Automated Information Support System for Control of Nuclear Research Facilities while Normal Operation and Emergency” (RB-077-12), that should be implemented at the Informational Support Centers (ISC) of operating organizations to facilitate their integration with automated information system within the RSChS and the EGASMRO. The operating organizations need to have adequate human and financial resources for this purpose, and this may require that corresponding amendments should be done in the national safety standards.
4. CONCLUSION

The Rostechnadzor carries out a well-planned activity on enhancement of effectiveness of the regulatory system accounting to lessons learned from the F-D accident including:

— Implementing the IAEA IRRS missions recommendations and suggestions;
— Improving regulatory body EPR to functioning in conditions of accidents;
— Drafting “Seventh National Report of the Russian Federation on the Fulfillment of Commitments Resulting from the CNS”;
— Drafting “Concept for Improvement of Normative Legal Regulations of Safety and Standardization in the Field of Nuclear Energy Use”.

One of the recent improvements of national safety standards addresses enhancement of unified command system and implementation of automated information exchange between operating organizations, nuclear authorities and regulatory authorities, while normal operation and in case of emergency.

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SUSTAINING NUCLEAR SAFETY: UPHOLDING THE CORE REGULATORY VALUES

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Abstract

The fundamental principles adopted by regulators across the globe have many similarities such as, creation of an organization which has a conflict-free primary responsibility of safety regulation, laying down the safety criteria and requirements for the respective industry and developing and using various tools and methodologies to ensure adherence to the laid down regulatory requirements etc. Yet the regulatory regimes in different States have evolved differently and therefore, have certain attributes which are unique to these and confer on them their identity. The paper introduces the principal tenets of regulatory philosophy of Indian regulatory regime which have assisted it in realizing its full potential and form the basis for continual improvement. The paper further corroborates the premise that a systematic adherence to core regulatory values together with the conscious efforts to do away with any form of complacency can significantly benefit any nuclear safety regulator. Pursuant to objective of strengthening the nuclear safety globally in the aftermath of Fukushima accident, international community unanimously adopted ‘Vienna Declaration on Nuclear Safety’ in 2015. It has been further highlighted that owing to its core regulatory values, implementation of actions identified to achieve the objectives of the Declaration can easily be effected through the existing regulatory systems itself, as is the case in India. The paper examines the various facets of a self-adoption approach vis-à-vis a legally binding approach in updating the global safety regime.

1. INTRODUCTION

‘Acceptable level of safety’ is a dynamic phenomenon and regulatory authorities have to keep on gauging the newer aspirations in the light of new state of art scientific and technical information. All major accidents were followed by review of regulatory processes and safety requirements by the global nuclear community to reconsider its various positions, assumptions and the very definition of ‘acceptable level of safety’. Pursuant to these accidents and the lessons learned, there has been
continual focus on strengthening the various aspects of safety including human factor, design of the NPP and consideration of external events of extreme origin, amongst others. There have been elaborate discussions on the suitability of one approach to regulation over other and desirability of one methodology of safety assessment over others and so on. These efforts are vital towards augmenting the existing strengths of our regulatory regimes. However, we run a risk of getting carried away from the core organizational values of our respective safety regulatory regimes, amid such gripping developments. Such core regulatory values have to be quite similar across the globe, however, may differ on account of some characteristics unique to that country or society. These values should be carefully identified and nurtured and that strengthening these values will significantly add to the regulatory effectiveness.

2. EVOLUTION OF SAFETY REGULATION IN INDIA

In India, the legal structure providing for activities pertaining use of nuclear energy and radiation energy itself, evolved in conjunction with scientists and engineers involved in the development of activities of use of nuclear energy and methodologies developed in this regard were inherited into the present-day system and continue to form the basis of safety regulation.

In initial years the safety regulation of various facilities including the research reactors was carried out basically through self-regulation i.e. the organizations evolved a dedicated committee structure especially looking after safety aspects. As the expansion of Indian nuclear energy programme took place, it was realized that a dedicated regulator is essential for ensuring safety of various nuclear and radiation facilities and associated activities. Towards this end, Atomic Energy Regulatory Board (AERB) was constituted in 1983 under the provisions of the Atomic Energy Act, 1962.

3. CORE VALUES OF SAFETY REGULATION IN INDIA

India is probably the first country to institute a system of renewal of licenses wherein operating license of an NPP is granted only for a limited period of five years. Subsequently, the issued licenses have to be renewed on the basis of comprehensive review of ‘Application of Renewal of License’ after a period of 5 years and an even more elaborate safety review as ‘Periodic Safety Review’ after 10 years. This is one of the examples of AERB’s modest attempts to devise means pursuant to what AERB held as its core values.

While there is not a universally accepted definition as to what organizational values can be termed as the ‘core values’ of the organization as these are influenced by, amongst others, the dynamics of the individual’s behaviour, organizational priorities and the inheritance of the organization; any attempt to do so will justifiably
deal with the introspection like ‘why are we here?’, ‘what is it that drives us? And ‘what is it that confers on the organization its uniqueness?’ etc.

According to aforementioned working-definition the core values of India’s regulatory regime have to include; reliance on state-of-art scientific knowledge in establishing the regulatory requirements and decision making, competent human resource, learning from the experience to improve upon existing regulatory system, regular safety assessment and enhancement as required, keeping regulation commensurate with the prime responsibility for safety of operator and consideration of stakeholders’ views in drafting regulations and regulatory decisions. The elements of few of these values e.g. competence build up and knowledge driven approach, were inherited from the regulatory systems existing prior to establishment of AERB. As can be observed, these attributes are not singular to AERB and any regulatory regime will subscribe to few or all of these; however, these are the very elements which form basis of AERB’s regulation and in turn have shaped AERB’s current regulatory processes.

3.1. Knowledge driven approach

Since its inception, AERB has adopted an approach of rooting the bases of its safety regulation from the state of art scientific knowledge and induction and cultivation of highly competent human resource to effect this regulation. It wouldn’t be much farther from truth to say that Indian regulatory regime for safety is performance based. Reliance on scientific principles and latest technical information plays significant role in all the regulatory processes including the processes for drafting and establishment of the regulatory requirements and carrying out safety review pursuant to grant of regulatory consents. There have been instances wherein the international experience was not much to gain from and only recourse was to rely upon the objective assessment of the safety case based on the best information available e.g. review of First of a kind (FOAK) systems while reviewing the design of various NPPs.

3.2. Competence build-up

No amount of legal empowerment or funds availability will be able to turn out the desired level of efficacy in the safety regulation, if the regulatory regime doesn’t have adequate level of competency in core areas of safety regulation and the various technologies being used in the facilities/ activities under the jurisdiction of the regulatory authority. India, in all facets of its nuclear power programme, has immensely benefitted from the vast pool of competent human resource being made available by various institutes/ universities. The establishment of various training schools under the Bhabha Atomic Research Centre (BARC) umbrella exclusively dedicated to nuclear sciences and enabling technologies, long back in 1950s; has manifested into a very elaborate training framework and is the corner stone of recruitment for India’s nuclear power programme. The criteria for induction in the
various facilities of DAE as well as regulatory body are very stringent and an elaborate programme has evolved over time to groom the freshly inducted young scientists/ engineers. These include the training of the newly recruited individuals in the various facilities being regulated and the extent of such on-job training include completing the requisite training for receiving the license for operating the reactor, as necessary.

AERB had expanded its independent R&D activities and for that purpose has also established its own Safety Research Institute, which carries out focused R&D on the areas of interest to AERB. It provides the much needed leverage to AERB, while reviewing the new reactor technology; of course AERB’s regulatory activities are facilitated by its Technical Support Organization (TSO) e.g. BARC.

A quick look on various reports of peer review missions carried out by IAEA for various member states indicate a somewhat disquieting situation in areas of availability of adequately competent and experienced human resource in the regulatory bodies as the Governments are finding is increasingly challenging to provide a highly qualified nation-wide pool of competent engineers.

3.3. Learning from experience

Improving the existing organizational systems/ functionalities based on the evaluated feedback is universally accepted as the best approach to elevate the efficacy across the organizational mandates and is not unique to any particular industry. The kind of organic growth Indian regulatory regime has undergone, has been very much guided by this approach; in fact the Indian nuclear power programme itself evolved in this manner. The AERB’s management processes catering for various aspects of regulation are periodically evaluated for their effectiveness and efficiency and are updated based on the experience available domestically as well as globally. While revising the regulatory requirements and carrying out various safety reviews, such available experience/ feedback is essentially accounted.

3.4. Regular safety assessment

Almost all the regulatory authorities decide the ‘acceptable level of safety’ by gauging the response of the public to the question ‘how much safe is safe enough?’.

As one can observe that response to this question may differ for different countries, societies and cultures and accordingly the regulatory authorities of respective countries have defined their ‘acceptable level of safety’ and means to achieve it. In India, the adoption of regular safety assessment as the core value of safety regulation by requiring Periodic Safety Review, has provided a regulatory tool to periodically evaluate the safety margins and require licensee to take measures whenever required. It also enables AERB to ‘maintain’ the already identified level of safety (as in accepted design of the plant) as well as having an enabling mechanism to ‘improve’ the safety. This later part related to ‘improving’ the safety confers on the regulatory
body, a much needed flexibility to update the definition of ‘acceptable level of safety’ by reflecting in its regulation state of art scientific findings and technical advancements as well as considering an objective evaluation of public perception of ‘acceptable level of safety’.

The regulatory oversight of AERB, inter-alia, is also significantly facilitated by the periodic reports and submissions from the licensee on virtually every operational aspect regarding safety and the review carried out for these at AERB.

As mentioned earlier, India adopted the system of renewal of operating licenses of NPPs for a maximum of five years and renewal of the same based on the outcome of Periodic Safety Review (PSR). This confers the inherent benefit of reviewing the performance and safety case of an NPP with respect to the whole range of technical dimensions including providing for the degradations and replacement, if any; ageing management amongst various others. Additionally, the existing safety margins are evaluated and the outcome is compared with expectations of the current safety requirements for acceptability and identification of corrective measures. As the approach to regulation in India is more oriented towards being safety-performance based, the transition to the implementation of any newly stipulated requirement is rather straightforward.

3.5. Prime responsibility for safety

The prime responsibility for safety lies with the operator of the facility and provisions in this regards have been made at the highest level of regulatory documents in accordance with the legal framework. The regulatory framework while ensuring adherence with the laid down safety requirements highlights the operator’s prime responsibility for safety and regulatory oversight of AERB is commensurate to this approach. The regulatory activities/ supervision for all the stages of the plant’s lifetime and associated activities have been structured in line with the prime responsibility for safety. This aspect is also highlighted in interactions with the licensees in various forums including meetings, symposiums etc. where it’s explicitly communicated that the licensees have responsibility to take their own initiatives to improve safety whenever reasonably practicable.

AERB has established various measures for encouraging the licensee to make continual efforts for strengthening the safety culture across all activities in their plant and to carry out periodic evaluation of safety culture for improving the same. These measures initiated by the regulatory body hinge upon the fundamental principle that the prime responsibility for safety always lies with the operator and conscious efforts are made that the extent of regulation should not undermine the operator’s prime responsibility for safety.
3.6. **Consideration of stakeholders’ views**

While laying down the various safety requirements the views of various stakeholders, including the domain experts from various academic institutes/industries/academia and representatives of the designer & the operators are sought. These views are objectively evaluated for their merit and value addition and accordingly disposition. This mechanism, while facilitating the consideration of stakeholders’ views for their suitability has manifested in to a level of licensee’s trust on regulators objectivity and consistency; which in turn has generated an environment of proactive sharing of any safety concern. The acceptance or inclusion of these views is based on the objective analysis of their value vis-à-vis safety and is solely decided by AERB.

The various regulatory aspects of Indian regulatory framework have been peer reviewed as a part of IAEA’s IRRS mission team. The IRRS Mission in its report has identified a few areas which need to be further augmented as well as few good practices of Indian regulatory system. In particular, the report acknowledges the unique educational and training system established at the national level supporting competence building for India’s nuclear programme and AERB; scope and depth of AERB’s recruitment and training programme; R&D infrastructure for supporting regulatory activities and extent of implementation and utilization of processes regarding regulatory and operational experience among others. Many of these positive aspects identified by the IRRS team as good practices can be mapped with the core regulatory values discussed above.

4. **FUKUSHIMA SPECIFIC MEASURES AND VARIOUS APPROACHES TO REGULATION**

In the aftermath of Fukushima accident, global regulatory regime revisited many of its assumptions and approaches to safety regulation. The suitability of various approaches e.g. prescriptive vs. performance based approach were examined for their effectiveness and efficiency. As mentioned earlier, Indian approach to safety regulation is rather tilted towards performance based approach and the experience during safety reviews for identifying the available safety margins as well as in implementation of identified corrective measures has been reassuring.

While keeping a close watch as the accident unfolded, AERB took proactive steps to engage with the licensee for carrying out re-evaluation of available safety margins with respect to external events which have not been considered in the design basis. Towards this, AERB constituted a higher level committee to review the safety of nuclear power plants in India against external events of natural origin and to recommend measures to protect the plants against such events, both within and beyond the design basis. The high level Committee included experts from the AERB, from the operating utility (NPCIL) and from other R&D organizations, national agencies, institutions having expertise in the natural phenomena to be taken
into account. AERB also simultaneously encouraged the utility to carry out its own independent evaluation. The approach to performance based evaluation facilitated the acceptance/implementation of newly laid down safety requirements in various high level safety documents. The implementation of various regulatory measures including laying down of new safety requirements, safety analyses & upgrades has worked out without any hindrance in case of Indian regulatory structure and convergence has been smoother and efficient. This was greatly facilitated by the performance based approach to regulation and closer engagement with the licensee in reviewing the safety case. The example of implementation of various measures in order to augment existing level of safety in the aftermath of Fukushima (newly laid down safety requirements in AERB Safety Codes and management of severe accidents and associated guidelines are the few examples) has further supported this position.

5. EFFORTS UNDER THE FRAMEWORK OF CNS IN THE AFTERMATH OF FUKUSHIMA

AERB had already initiated revision of its higher level safety requirements with respect to siting of nuclear facilities in 2010. The 2nd Extraordinary Meeting of the Contracting Parties of the Convention on Nuclear Safety (CNS) was held in 2012 to review and discuss lessons learned from the accident at TEPCO’s Fukushima Daiichi nuclear power plant, and to review the effectiveness of the provisions of the Convention. In the final summary report of the meeting, amongst other things, it was observed that Nuclear power plants should be designed, constructed and operated with the objectives of preventing accidents and, should an accident occur, mitigating its effects and avoiding off-site consequences. In line with this, AERB expedited the work being carried out at the regulatory body for updating safety requirements regarding siting of nuclear facilities while duly accounting the outcomes of the several reviews carried out at various international forums after the Fukushima accident. Building on this momentum, AERB had already started developing a dedicated safety code stipulating the design requirements for light water based reactor technology.

These documents prescribing the safety requirements with respect to siting of nuclear facilities and design of an NPP (i.e. AERB Safety Code on Site Evaluation of Nuclear Facilities and AERB Safety Code on Design of Light Water Reactor Based Nuclear Power Plants) were published in 2014 itself. The establishment of these higher level safety requirements in prompt manner was facilitated by the performance based approach of regulation which roots its basis on latest scientific/technical information and a conducive environment of mutual trust between the regulatory body and the licensee.

India’s position to support the Vienna Declaration inter-alia also took in to account this experience when it declared that though it was very pertinent to highlight the needs for additional measures with respect to strengthening NPP’s
design to achieve the objectives of no large radioactivity release and no long term off-site contamination; CNS processes have enough in-built mechanisms to keep the Convention up to date and contemporary without necessarily going in to any new legally binding instruments. The global convergence and unanimous adoption of Vienna Declaration vindicated India’s position.

Based on the outcome of the IRRS Mission, the team concluded that in response to the TEPCO Fukushima Daiichi accident, AERB acted responsibly and expeditiously and AERB initiated a thorough reassessment of the safety of the Indian nuclear power plants both operating and under construction, and requested in a timely manner the implementation of the measures deemed necessary to avoid the possibility of consequences similar to those in the Fukushima event.

6. SELF-ADOPTION VS LEGALLY BINDING APPROACH

After major nuclear accidents, the regulators across the globe have carried out critical introspection of the processes and bases of the safety regulation as established by them and have taken corrective measures wherever applicable. This has also resulted in the amendments of the various aspects of global legal regime for nuclear/ radiological safety, including institution of new conventions and codes of conduct. This later part, however, owing to its legally binding character has faced some difficulties in recent years and the approach of self-commitment of globally agreed new requirements for strengthening safety seems to gain distinct advantage over it in terms of efficient reconciliation among various parties. While legally binding instruments have their own merits with regard to strengthening the global safety regime, an approach of self-commitment for gradual implementation of internationally agreed new safety requirements/ aspirations seems to be more conducive as it offers leverage in management of resources and priorities. The experience of implementation of various regulatory measures and safety upgrades at NPPs also corroborate this observation

7. CONCLUSION

The organizational values identified as core regulatory values have proven to be vital for safety regulation of nuclear as well radiation facilities/ activities in India. The elaborate reviews carried out by AERB for verifying the effectiveness of the erstwhile regulatory regime and towards strengthening the same have generally resulted, inter-alia, in augmentation of the regulatory processes catering for the aforementioned core regulatory values. As can be observed, these regulatory values are not singular to India and have been adopted in most of the regulatory regimes globally in some or other form. A nuclear regulator, trying to improve its effectiveness can greatly benefit by tightening the screws of safety regulation in form of strengthening the regulatory processes providing for these core values.
ACKNOWLEDGEMENTS

The authors would like to extend their sincere thanks to Mr. Dinesh Kumar Shukla, Executive Director, AERB for his valuable insights in highlighting the various aspects of the evolution of Indian regulatory regime.

REFERENCES

The paper illustrates the actions required in order to follow up some recommendations relating the IAEA-IRRS Mission to Indonesia, to develop the nuclear regulatory system through mapping the potential activities that would be conducted by the relevant units of Indonesian nuclear energy regulatory agency (BAPETEN) with basis on the strategic short-term and long-term plan.

1. INTRODUCTION

At the request of the Government of Indonesia, an international team of senior safety experts met with representatives of the regulatory body of Indonesia (the Nuclear Energy Regulatory Agency of Indonesia - BAPETEN) from 2 to 14 August 2015 to conduct an Integrated Regulatory Review Service (IRRS) mission. The mission took place mainly at the BAPETEN Headquarters in Jakarta.

The purpose of the peer review was to review the Indonesian regulatory framework for nuclear and radiation safety. The review compared the Indonesian regulatory framework for nuclear and radiation safety and its effectiveness against the IAEA safety standards as the international benchmark for safety. The mission was also used to exchange information and experience between the IRRS Team members and the Indonesian counterparts in the areas covered by the IRRS.1

The IRRS Team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body including the authorization, review and assessment, inspection and enforcement processes; development and content of regulations and guides; emergency preparedness and response; decommissioning; transport of radioactive materials; control of medical exposure; occupational radiation protection; public and environmental exposure control; waste management; and selected policy issues.
The IRRS review addressed all facilities and activities regulated by BAPETEN, including research reactors, nuclear fuel cycle facilities, radioactive waste management facilities, and radiation sources facilities and relevant activities.

In addition, the IRRS review addressed preparations for the development of the nuclear power program from regulatory framework point of view.2,3

Based on the IRRS evaluation against the IAEA safety standards, the IRRS Team concluded that Indonesia, through the BAPETEN, is implementing a framework that provides for protection of public health and safety. The IRRS Team also identified areas where further improvement can be achieved by implementing an appropriate action plan.

Two month prior to the mission, BAPETEN provided the IRRS Team with advanced reference material (ARM) and documentation including the results of the self-assessment in all areas within the scope of the mission. Besides the ARM, BAPETEN also provided an ARM Summary Report in order to facilitate the IRRS team members in forming an initial opinion of the subject area to which they had been assigned, and identifying priority technical areas for review during the IRRS mission.2,4

Review of advance reference material and a series of interviews and discussions with BAPETEN were mainly used to evaluate the Indonesian regulatory framework as well as to assess the effectiveness of the regulatory infrastructure. The IRRS Team’s activities included visits to a research reactor, a fuel cycle facility, a waste facility, a hospital, an irradiator and industrial radiography facility. During these visits, the IRRS Team members observed BAPETEN’s working practices during inspections and held discussions with licensee personnel and management. Throughout the mission, the IRRS Team was extended full cooperation in regulatory, technical, and policy issues by all parties; in particular, the staff of BAPETEN provided the fullest practicable assistance and demonstrated extensive openness and transparency.

The IRRS review team made the following general observations:

— BAPETEN is expanding its program to address the regulation of nuclear power plant safety, while maintaining its focus on the safety of current facilities and activities in the country.
— BAPETEN is considered to have a clear and unambiguous focus on its safety mission; and a good recognition of the challenges ahead.
— BAPETEN participates in many regional and international activities concerning nuclear and radiation safety and has established effective cooperation with a number of countries through bi-lateral agreements.
— BAPETEN is implementing various programs for human resources development and to enhance the capabilities of its staff to meet challenges related to prospective nuclear power plants.
The IRRS Team observed the following good practices:

— The Government and BAPETEN make extensive use of bilateral and multilateral international cooperation for training and competence building.

— BAPETEN has developed a comprehensive database management for authorization, reviewing and assessment, inspection, transport approval and occupational dose register. The system is fully implemented for the review and assessment process.

Public information on environmental monitoring data supports the collaboration with interested parties.

The IRRS Team identified certain issues warranting attention and believes that consideration of these would enhance the overall performance of the regulatory system:

— The Government should develop and document a national policy and strategy for safety, supported by a national coordinated plan, to ensure the appropriate national infrastructure for safety is implemented.

— The Government should ensure that all essential elements, particularly the fundamental safety principles of the IAEA, are fully incorporated into the legal and regulatory framework for safety.

— The Government and BAPETEN should ensure that national legislation for safety, including relevant regulations and guides, are kept up to date with the current IAEA Safety Standards.

— The Government should provide BAPETEN with human and financial resources to ensure adequate discharge of its statutory regulatory obligation.

— The Government should ensure an appropriate coordination and liaison between BAPETEN and other relevant authorities in medical application of radiation and in transport of radioactive material.

— BAPETEN should strengthen its communication and consultation system regarding its authorization activities with interested parties.

— The Government and BAPETEN should conduct all necessary preparatory activities to establish the necessary infrastructure in a timely manner for potential future nuclear power plants.

The recommendations should be followed-up with arrangement the action plan that is required to close the finding.
2. METHOD

To obtain the comprehensive and appropriate ways for fulfilling some requirements in order to follow up the IAEA-IRRS Mission recommendations, the government of Republic of Indonesia through BAPETEN had conducted meetings that were involving the relevant units.

During the meetings, all the recommendation and suggestion were discussed and all possible and alternative ideas for solutions were issued, and the prospective activities in the future were identified.

Each of unit of the BAPETEN has responsibility on the relevant topics. The organizational structure of BAPETEN is established and based on the article 4 of the Act No. 10 Year 1997 on Nuclear Energy that states that Government establishes a regulatory body under and directly responsible to the President. This regulatory body has the task of controlling all activities using nuclear energy, by establishing regulations, processing licenses and conducting inspections.

![FIG. 1. Organizational Structure of BAPETEN](image)

3. RESULT

The recommendations were developed to be some action required. The action plan that contains detail activities is given in Table 1.
TABLE 1. RECOMMENDATIONS AND ACTION REQUIRED

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Action Required (Year)</th>
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<tbody>
<tr>
<td>The Government should develop and document a national policy and strategy for</td>
<td>Establish presidential regulation on national policy and strategy for nuclear and</td>
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<tr>
<td>safety, supported by a national coordinated plan, to ensure the appropriate</td>
<td>radiation safety (2018)</td>
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<td>national infrastructure is implemented.</td>
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<tr>
<td>The Government should ensure that the fundamental safety principles of the</td>
<td>Amend the Act No 10 of 1997 to incorporate safety principles of the IAEA SF-1 (2019)</td>
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<td>IAEA SF-1 are fully incorporated into the legal and regulatory framework for</td>
<td>Revise GR No 33 of 2007 (2019)</td>
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<td>safety.</td>
<td>Revise GR No 54 of 2012 (2023)</td>
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<td>Revise GR No 29 of 2008 (2019)</td>
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<tr>
<td>The Government and BAPETEN should ensure that the legal and regulatory framework</td>
<td>Amend the Act No 10 of 1997 to keep up to date and correspond to current IAEA standards (2019)</td>
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<td>is kept up to date and corresponds to the current IAEA standards.</td>
<td>Amend GR No 2 of 2014 (2021)</td>
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<td>Amend GR No 54 of 2012 (2023)</td>
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<td>Amend GR No 33 of 2007 (2019)</td>
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<td>Amend GR No 29 of 2008 (2019)</td>
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<tr>
<td>The Government should provide BAPETEN with human and financial resources.</td>
<td>Develop road map for new employees recruitment, both for new positions/formation and</td>
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<td>Responsibility of safety is assigned to the person or organization responsible for a facility or an activity.</td>
<td>Prime responsibility of safety on the person or organization responsible for a facility or an activity (2019)</td>
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<tr>
<td><strong>Recommendations</strong> resources to ensure adequate discharge of its statutory regulatory obligations.</td>
<td>Action Required (Year) replacing retired employees (2015)</td>
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<td></td>
<td>Recruit new employees (2016-2019)</td>
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<td>Dispatch staff to undertake higher education through related government budget (2015-2019)</td>
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<td></td>
<td>Allocate adequate budget for essential processes such as long term competence building, basic and refreshment training and performance of regulatory functions (2016-unspecified)</td>
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<td>Amend the Act No 10 of 1997 to assign the...</td>
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<td>The Government, through the legal framework, should ensure that there is appropriate coordination and liaison between BAPETEN and other relevant authorities in the areas of medical application of radiation and transport of radioactive material.</td>
<td>Sign MoU with Ministry of Health (2016)</td>
</tr>
<tr>
<td>The Government should ensure that there is appropriate coordination and liaison between BAPETEN and other relevant authorities in the areas of medical application of radiation and transport of radioactive material.</td>
<td>Implement MoU through establishing cooperation agreement with Ministry of Health for regulatory control of medical application of radiation (2016-2020)</td>
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<td>Sign MoU with Ministry of Transport (2017)</td>
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<td></td>
<td>Implement MoU through establishing cooperation agreement with Ministry of Transport for regulatory control of transport of radioactive material (2017-2021)</td>
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<td>The Government should establish and promulgate a national policy and strategy for radioactive waste management and decommissioning.</td>
<td>Develop national policy and strategy for radioactive waste management and decommissioning (2016)</td>
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<tr>
<td>The Government should establish provisions, in the legal framework, governing long-term radioactive waste management, spent fuel management and decommissioning, including funding of such activities.</td>
<td>Amend the Act No 10 of 1997 to establish provisions governing long-term radioactive waste management, spent fuel management and decommissioning, including funding of such activities (2019)</td>
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<tr>
<td>The Government should authorize BAPETEN to develop and implement the organisational structure that would be best suited to allow it to carry out its obligatory functions effectively.</td>
<td>Perform assessment on organisational structure that would be best suited to carry out regulatory functions effectively (2016)</td>
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<td>Implement the newly agreed organisational structure (2017)</td>
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<td>BAPETEN should review its management system to ensure that the vision, mission, safety culture and the application of a graded approach reflect the Governmental assignment of tasks and that those are communicated to and understood by all layers of the organization.</td>
<td>Revise BMS (2016-2017)</td>
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<td>Disseminate BMS to all staff members of BAPETEN (Start from 2015)</td>
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<td>BAPETEN should include appropriate values, policies and decision-making procedure.</td>
<td>Develop decision-making procedure (Refer to Act No 30 of 2014) (2016)</td>
</tr>
<tr>
<td>Recommendations</td>
<td>Action Required (Year)</td>
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<td>making procedure in its management system and ensure they are communicated to all staff.</td>
<td>Disseminate BMS to all staff members of BAPETEN. Disseminate values, policies and decision-making procedure to all staff members of BAPETEN (2016-2017)</td>
</tr>
<tr>
<td>BAPETEN should develop and include procedures for analyzing the need for organizational changes taking into consideration safety aspects, and ensure that the procedures are implemented and communicated to all concerned.</td>
<td>Develop procedures for analyzing the need for organizational changes (2016)</td>
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<td>Disseminate procedures for analyzing the need for organizational changes (2017)</td>
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<td>BAPETEN should implement the management system review stated in the BMS manual.</td>
<td>Perform management system review regularly (Start 2015)</td>
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<td>Revise licensing procedures to include provision for consultation with interested parties before issuing licenses for facilities with significant potential of radiological impact (2017)</td>
<td>Perform consultation with interested parties before issuing licenses for facilities with significant potential of radiological impact (Start 2015)</td>
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<tr>
<td>Revise the Act No 10 of 1997 to include requirement to obtain an authorization for a research reactor entering into an extended shutdown condition.</td>
<td>Amend GR No 2 of 2014 (2021)</td>
</tr>
<tr>
<td>BAPETEN should promote establishing criteria to review and assess the design of spent fuel storage facility.</td>
<td>Revise BCR No 11 of 2007 to include criteria for the design of spent fuel storage facility (2016)</td>
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<td>Develop procedures for the assessment of the management system arrangements of the manufacturers of the packages.</td>
<td>Develop procedures for the assessment of the management system arrangements of the suppliers.</td>
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<td>Revise the inspection procedure to apply different programme and frequency of inspections at different nuclear installations and materials based on the radiation risks (2016)</td>
<td>Develop the annual schedule of inspections of different nuclear installations and materials at different frequency based on the radiation risks (2017)</td>
</tr>
<tr>
<td>Amend the Act No 10 of 1997 to keep up to date and correspond to current IAEA standards (2019)</td>
<td>Amend GR No 2 of 2014 (2021)</td>
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<tr>
<td>BAPETEN should collect, analyze and disseminate information on non</td>
<td>Revise the enforcement procedure to include provision for collecting, analyzing and disseminating information on non-</td>
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### Recommendations

<table>
<thead>
<tr>
<th>Compliance and Enforcement Actions to Provide Feedback to Enhance the Performance of Regulatory Functions</th>
<th>Action Required (Year)</th>
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<tr>
<td>Enhance the coordination at the highest executive level with the relevant organizations within the national nuclear emergency preparedness and response system.</td>
<td>Develop regulations and criteria regarding countermeasures for early protective actions and restriction of food, drink and commodities, to ensure the safety to people. (2020)</td>
</tr>
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<td>Develop a procedure to collect, analyse and disseminate information on non-compliances and enforcement actions to provide feedback to enhance the performance of regulatory functions. (2016)</td>
<td>Revise regulation (BCR No 1 of 2010) to include provision for analysing the nuclear or radiological emergency and the emergency response in order to identify actions to be taken in an emergency situation (2020).</td>
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**BAPETEN** should revise its regulatory system in order to comply with the current relevant IAEA Safety Standards, namely:

1. Develop regulations and criteria regarding countermeasures for early protective actions and restriction of food, drink and commodities, to ensure the safety to people.
2. Ensure that the waste generated in an emergency situation will be managed safely.
3. Develop regulations addressing the roles and responsibilities of the licensees and stakeholders as well as the criteria for the termination of the radiological and nuclear emergency situation.
4. Ensure that the nuclear or radiological emergency and the emergency response are adequately managed in order to identify actions to be taken to prevent other emergencies and to improve emergency arrangements.

**BAPETEN** should develop regulations that oblige the licensees to place their EPR system under consistent and comprehensive quality management.

**BAPETEN** should refrain from providing verification of compliance testing.
4. CONCLUSION

To improve the nuclear regulatory system, the result of IAEA-IRRS Mission to Indonesia, which includes some recommendations, has been followed up. The prospective actions required have been established, some starting from post-mission, and others will be conducted in short-term period, meanwhile there are targeted after year 2020 would be fulfilled.

ACKNOWLEDGEMENTS

The present paper is a part of numerous assignment series relating to achieve an established nuclear regulatory system. We would like to express sincere gratitude to BAPETEN management especially Dr. YR. Akhmad for his kind-hearted direction and Ms. Dahlia C. Sinaga for her cooperation for completion this duty. We give our thanks to staff of Directorate for Regulation Development of Nuclear Installations and Materials, and also staff of International Cooperation Division in BAPETEN for helping us.

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Abstract

The paper intends to assess the effectiveness of an international response to a major nuclear power plant accident (NPP accident). There is no question that the main responsibility to control, limit, fight against any nuclear and radiological accident and adopt subsequent mitigation and recovery measures lies in the State where the accident occurs. However, a major NPP accident is an overwhelming event and stretches the State resources to its limit. In this sense, it is a sort of event where international solidarity and technical support is needed. Besides that, it is also of the best interest of the international community to contain as much as possible the radioactive cloud with its potential hazardous effect to its own population and territory.

1. INTRODUCTION

As it has been accepted by the international nuclear community, “A nuclear accident anywhere is a nuclear accident everywhere.” There is no question that the main responsibility to control, limit, fight against any nuclear and radiological accident and adopt subsequent mitigation and recovery measures lies in the State where the accident occurs. However, a major NPP accident is an overwhelming event and stretches the State resources to its limit. In this sense, it is a sort of event where international solidarity and technical support is needed. Besides that, it is also of the best interest of the international community to contain as much as possible the radioactive cloud with its potential hazardous effect to its own population and territory. The paper intends to assess the effectiveness of an international response to a major NPP accident.
2. DEVELOPMENT

Taking into consideration what was said above, one question may be raised: Did the lessons on the need of international coordination to face a nuclear emergency learned after the Chernobyl accident and international instruments developed accordingly made a real difference to tackle the aftermath of the Fukushima accident? To answer this question the authors will both identify the international response to each of those events and also assess potential shortcomings in the implementation of the provisions of the international cooperation instruments developed after Chernobyl in the area of emergency preparedness and response.

It has to be pointed out that the focus of this work is on the effectiveness of the international response to both accidents since the moment of the official recognition of an emergency situation. In this sense, any consideration on the differences about political regime between the concerned countries will be disregarded.

The sequence of events (see Box 1 and 2) in the case of both accidents led us to note that the accidents evolved very fast. In the case of the Chernobyl, human factors caused the accident in 24 hours. In the case of the Fukushima Daiichi, natural disaster overcame the safety design features in less than one hour and off-site emergency declared by the Government in less than four and half hours after the earthquake. In such circumstances, we may consider that the proper conditions to gather any international assistance at the first moments of the events may be absent or fragile. In this context, it is reasonable to speculate that more advanced reactors with additional safety features would allow more time for the onsite emergency team to react and international experts to assist on decision making, if so required.
Box 1 - The Chernobyl Accident

The unit 4 was to be shutdown for routine maintenance on 25th April 1986. It was decided to take advantage of this shutdown to determine whether, in the event of a loss of station power, the slowing turbine could provide enough electrical power to operate the main core cooling water circulating pumps, until the diesel emergency power supply became operative. The aim of this test was to determine whether cooling of the core could continue to be ensured in the event of a loss of power. This test was considered essential to the non-nuclear part of the power plant, was carried out without a proper exchange of information and coordination between the team in charge of the test and the personnel in charge of the safety of the nuclear reactor. Therefore, inadequate safety precautions were included in the test programme and the operating personnel were not alerted to the nuclear safety implications of the electrical test and its potential danger. The test was also delayed 24 hours after controller of the electricity grid in Kiev requested the reactor operator to keep supplying electricity to enable demand to be met. Consequently, the reactor power level was maintained at 1600 MWt until 23:00. At 26th April a note in the operating log of the Chief Reactor Control Engineer reads: "01:24: Severe shocks; the RCPS rods stopped moving before they reached the lower limit stop switches; power switch of clutch mechanisms is off.”


Box 2 - The Fukushima Daiichi Accident

At 11th March 2011 an earthquake of magnitude 9 occurred at 14:46 local time (05:46 UTC), as consequence the three operating units (1 to 3) were automatically shutdown (units 4 to 6 were under planned shutdown) and external power lines went down. With the loss of off-site power, the diesel generators of all six units were put online. There were no indications that the main safety features were affected by the vibratory ground motion generated by the earthquake. Conditions for offsite emergency started when the second tsunami with the high of 14-15m hit the site 50 minutes after the earthquake and overcome the seawall with the loose of AC/DC power at units 1, 2 and 4. Nuclear emergency was declared by the Government of Japan at 19:03 on 11 March.

Source: The Fukushima Daiichi Accident. Report by the Director General. IAEA GC(49)/14

Regardless the technical differences and similarities between both accidents, for the purpose of the paper the main questions would be:
— What was the international response to each of them?
— In which extension the role of the IAEA instruments and coordination was helpful to facilitate the international response to both accidents?

Based on some factors described above – namely, the speed of the sequence of events and available international framework for response - one way to approach the analysis of the effectiveness of the international response to both accidents would be to focus on the effectiveness of two elements: communications and coordination of international and interagency response. Therefore, a question can be raised: based on the instruments available, how communication and coordination tasks were implemented in each context?

Although the issue of a radiological emergency had been among the subjects covered by the IAEA since its beginning, the instruments available for implementing an international coordination role were very different at each context.

In 1986, the role to be performed by the IAEA in such area was based in the following documents [1]:

— Action Plan developed to provide assistance to Member States upon request following an accident involving radioactive materials (1959).
— Publication WP.35 that indicated the type of radiological assistance Member States could make available in the event of a radiation emergency in another country at the request of that State (1963).
— Guidelines for Mutual Emergency Assistance Arrangements in connection with a nuclear accident or radiological emergency (INFCIRC/310, 1984).

In 2011, the IAEA framework for emergency preparedness and response was constituted of the following instruments [2]:

— The primary international legal instruments: Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.
— The international safety standards in the area of emergency preparedness and response: IAEA Safety Standards Series No. GS-R-2 and No. GS-G-2.1. Safety Series No. 115 also included elements related to emergency preparedness and response.

2.1. The case of Chernobyl accident

Information and Communication

Despite the fact that the accident had occurred on 26 April 1986, it was only on the evening of 28 April that the ex-USSR authorities confirmed that a severe accident had occurred at the Chernobyl nuclear power plant. According to an article published at the IAEA Bulletin [3], before the announcement made by the ex-USSR authorities, “initial questions directed to the IAEA were whether the occurrence of a reactor accident had been reported to it, and if so, where. After the accident had been announced by the [ex-] USSR, IAEA Member States in Europe were concerned about the magnitude of the release, its distribution, and the extent of contamination measured.”

It is worth to note that the IAEA had no mandate for requesting European States about their measurements. Only informal contacts were established with radiation protection authorities as soon as the accident was announced. Nevertheless, countries started to provide the IAEA information on their radiological measures on a voluntary basis. In the case of the ex-USSR, only following the visit of the IAEA Director General, Hans Blix, to the country, the authorities started, on 9 May 1986, to provide readings on dose rates to the IAEA.

The IAEA also pointed out that the lack of information affected both decision making process and public perception. On that, the article says “the lessons learned from Chernobyl for responding to any possible future accident indicate that it is of vital importance to get information on the accident at as early a stage as possible. Early predictions of areas likely to be affected and the potential level of associated contamination, based on expected release and meteorological information, would help authorities to decide the course of actions needed in a timely manner. It is clear from the Chernobyl accident that national authorities will wish to receive radiological measurement data from their neighbouring countries for comparison and information purposes. These data should, however, be comparable in terms of parameters measured and units in which the measurements are expressed, in order to be of real assistance.”
In the wave of the Chernobyl accident, the IAEA Secretariat clearly made a reflection on the vulnerabilities in the fields of prompt provision of information and emergency assistance. Another IAEA Bulletin article [4] poses the following question: “why countries which could benefit from a structured arrangement for speedy notification and information exchange in the event of a nuclear accident, or for mutual emergency assistance, have been reluctant to enter into formal arrangements for this purpose, either on a bilateral or multilateral basis?”

One of the important results of that reflection was the request of the IAEA Director General at that time, Hans Blix, to the Board of Governors, to convene open-ended governmental expert groups to draft one international convention to deal with early notification and provision of comprehensive information about nuclear accidents with potential transboundary effects and other with the coordination of emergency response and assistance.

2.2. International and inter-agency response

The existence of some IAEA guidance for implementing an international response in the case of a nuclear accident made no difference for dealing with the Chernobyl accident.

One decade after the accident, an international conference informed that “The response to the accident was carried out by a large number of ad hoc workers, including operators of the plant, emergency volunteers such as fire-fighters and military personnel, as well as many non-professional personnel. All these people became known by the Russian term likvidator. About 200,000 ‘liquidators’ worked in the Chernobyl region between 1986-87 when radiation exposures were the highest. They were among some 600,000 to 800,000 persons who were registered as involved in activities relating to alleviating the consequences of the accident. This includes persons who participated in the clean-up after the accident (including cleaning up around the reactor, construction of the sarcophagus, decontamination, road building, and destruction and burial of contaminated buildings, forests and equipment), as well as many other general personnel who worked in the territories designated as ‘contaminated’ and who generally received low doses [5].”

2.3. The case of Fukushima Daiichi accident

At the time of that accident, the IAEA had four roles in the response to a nuclear or radiological emergency [6]:

(a) Notification and exchange of official information through officially designated contact points.
(b) Provision of timely, clear and understandable information.
(c) Provision and facilitation of international assistance on request.
(d) Coordination of the interagency response.
The roles (i) and (ii) can be grouped under the “Information and Communication element” and the roles (iii) and (iv) can be grouped under the “International and inter-agency response element”.

Consonant with these roles, in the immediate aftermath of the accident, IAEA activated the Incident and Emergency System, coordinated the inter-agency response and initiated briefings with Member States and media.

3. INFORMATION AND COMMUNICATION

The first and utmost important aspect to deal with any accident is information, which is the primary goal of the Early Notification Convention. Any approach or decision to be made regarding the response to the accident (at the national or international level) has to be based on “timely, clear and understandable information”. That information will be delivered to the emergency teams (onsite, offsite and international) and to the public (at the national or international level).

The IAEA Director General’s report on the Fukushima Daiichi Accident reveals some important findings on these matters:

— Communication with the official contact point (METI-NISA) in Japan in the early phase of the emergency response was difficult.

— The need of translation to the English language of the reports elaborated with Japanese language. At the initial stage of the emergency, IAEA made the option to release reports based on informal translations. This reflects the dilemma of having timely information vis a vis its accuracy and comprehensiveness.

— Communication between the IAEA and the contact point was improved after the visit to Japan from 17 to 19 March 2011 by the IAEA Director General, and the subsequent deployment of liaison officers to Tokyo.

— Some States advised their nationals in Japan to follow the orders and recommendations issued by the Japanese authorities in response to the emergency, while some States issued advice that differed from that provided by the Japanese authorities and other States. Differences in the recommendations among States were due to various factors, including a lack of information on the evolving situation. This happened in spite of the impressive volume of summary reports (more than 200), oral briefings (19 for the Permanent Missions in Vienna) and written briefings posted in IAEA web site (27 updated briefs and 129 individual posts). Not considering the phone calls and individual e-mails.
4. INTERNATIONAL AND INTER-AGENCY RESPONSE

The first offer of assistance made by the IAEA to Japan took place just 2 hours after the earthquake. The IAEA sent expert missions to Japan and coordinated the provision of Member States offers of assistance to Japan. The Japanese Government received offers of assistance directly via Ministry of Foreign Affairs as well.

Throughout the emergency event, the IAEA Incident Emergency Centre (IEC) received offers of assistance to Japan from IAEA Member States, the European Commission, international organizations and individuals.

IAEA operational instruments were not utilized to support States to provide assistance to Japan. The Assistance Convention was not invoked and RANET was not utilized. Based on that, some lessons to be taken into account for the further enhancement of RANET were identified and discussed at the meeting on the extension of RANET capabilities held in the early beginning of 2012. The absence of national arrangements for receiving international assistance in the early stages of the national response was identified as one of the main difficulties for a State in accepting such assistance.

5. CONCLUSIONS

Some findings can be pointed out on the effectiveness of the international response to a major nuclear power plant accident based on the comparison of the international action and support in the case of Chernobyl accident and the Fukushima Daiichi accident.

Although the Fukushima Daiichi accident has happened 25 years later the Chernobyl accident and many developments have been established by the IAEA in the field of international response so far, some important shortcomings still need to be addressed such as:

(a) There is still room for clearly describing in the emergency management system for response to a nuclear emergency the roles and responsibilities for the operating organization and for local and national authorities.
(b) Need for enhancement of arrangements to address public concerns locally, nationally and internationally.
(c) Insufficient awareness of international arrangements for notification and assistance in a nuclear or radiological emergency, as well as existing operational mechanisms.
(d) The fact that participation in existing mechanisms for the provision of international assistance under the Assistance Convention is not an integral part of national emergency preparedness efforts.
Absence of proper consultation and sharing of information mechanisms on protective actions and other response actions among States in an emergency in order to ensure that actions are taken consistently.

Absence of proper mechanisms for the IAEA Secretariat to provide the public with timely, correct, objective and easily understandable information during the nuclear emergency. The case of Japan shows us that IAEA could have a team of ad hoc translators in order to be ready to face urgent needs during a nuclear emergency, if necessary.

In sum, the speed and scope of international response to a nuclear accident highly depends on the adherence of the IAEA Member States to the full implementation of their obligations under both binding and non binding agreements and on the availability of “timely, clear and understandable information”. Both conditions are still requiring improvements in order to the international community to be better prepared to face another NPP accident, should it occur.

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Abstract

The report is in line with the report of the Director General on “Measures to Strengthen International Cooperation in Nuclear, Radiation, Transport and Waste Safety” during the 2014 IAEA General Conference. It aims to share the accomplishments and achievements of the above-mentioned project brought to the Nuclear Regulatory Division (NRD) – Philippine Nuclear Research Institute (PNRI) in delivering their regulatory functions. Also, it aims to project the perceived challenges of a regulator with the emerging state of the art industrial and medical nuclear technologies in the country. The introduction of the report, illustrated the 10-year period (2005-2015) and the current number of licensees and their radiation facilities and activities. The body described the existing legal and regulatory infrastructures for safety at the national context based on the IAEA Safety Standard Series
1. INTRODUCTION

According to Principle 1 of the Safety Fundamentals (SF-1), the licensee or a person or organization for facilities and activities which give rise to radiation risks must bear the primary responsibility for safety [1]. The government shall establish a legal and regulatory framework that provides for the creation of a regulatory body that is effectively independent of the licensee and of any other body, so that it is free from undue pressure from interested parties. The regulatory body must have the sole responsibility as mandated by law to independently regulate the licensees’ facilities and activities with adequate legal authority, technical and managerial competence, and human and financial resources to fulfill its responsibilities. It is also imperative for the regulatory body to have a management system which shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety [2].

“Ensuring safety in the use of radiation sources and operation of related facilities is of paramount importance for the protection of people and the environment from any associated radiation risks. In order to ensure radiation safety, a cradle-to-grave system for the control of radiation sources should be established.” [3]

The IAEA RAS Project which was made available to 28 countries of the Asia and Pacific Region with the objective, “To upgrade regulators infrastructure in the Asia and Pacific region for the safe control of radiation sources” and with outcomes: all participating countries can effectively implement regulatory control for radiation sources in accordance with IAEA safety standards and participating countries have the capability to establish arrangements for sustainable regulatory control. The project duration was initially 2012-2013 but was extended to 2014-2015.

The introduction of the report gives a picture of the 10-year period (2002-2015) and the current status on the number of licensees and its facilities and activities to create an idea on how the Nuclear Regulatory Division (NRD) - the regulatory arm of Philippine Nuclear Research Institute (PNRI) will be able to perform its mandated functions as described in Section 2, refer to Figures 1, 2 and 3 [4]. It will also give an idea on how big will be the tasks of NRD with its current staff. Section 2 provides a comprehensive description of the regulatory bodies and its mandated functions, based on IAEA Safety Standard Series No. GS-G-1.5 while
Section 3 shows the project matrix framework. Lastly, Sections 4 and 5 describes the achievements and challenges and conclusion and recommendations, respectively.

The above figure shows that there was no much increase in the number of license from 2005-2011 while the last four years from 2012-2015 showed a steady increase. The current total number of licensees is 369.

The above figure shows that the most number of the licensees are under the category of industry, medical is next with a sign of steady increase in numbers from 2012 to present. Commercial category that is almost half the number of the medical
licensees is at third position. The industrial radiography and research with almost the same numbers have the least number of licensees not considering the particle accelerator. The increase in medical applications was notable especially with the introduction of new technology which bring challenges to NRD on how they can effectively regulate to ensure the safety of the patients, the radiation workers and the public as well.

The above figure shows that from the current total number of 369 the industry has the most numbers of licensees at 43% followed by medical and commercial, respectively, and the last with the same percentage are industrial radiography and research at 8%. The medical cyclotron has two licensees.

2. THE REGULATORY BODIES

2.1. Legal Framework

Currently, there are two regulatory bodies in the Philippines responsible for the regulation and control of radiation sources to protect the public, workers and the environment from the harmful effects of ionizing radiation. Atomic energy facilities and materials regulated by the Philippine Nuclear Research Institute, Department of Science and Technology (DOST), whereas facilities and devices that electrically generate ionizing radiation are regulated by the Center for Device Regulations, Radiation Health and Research (CDRRHR) under the Food and Drugs Administration (FDA), Department of Health (DOH).
The Development and hierarchy of legislation that provides the of PNRI as the regulatory authority for atomic energy facilities and radioactive materials are as follows [5]:

(b) RA 5207, Atomic Energy Regulatory and Liability Act (1968), as amended by RA3589 and by Presidential Decree (PD) 1484, established the authority of the PAEC and in particular its regulatory and licensing authority for atomic energy facilities (in part III) and atomic energy materials (part IV), and provisions specifying licensing requirements (part V); administration and review (VI) and nuclear liability (VII).
(c) Presidential Decree (PD) 606 of August 17, 1982 created the PAEC as an independent and autonomous body and transferred it from the National Science Development Boards (NSDB) to the Office of the President (OP).
(d) Executive Order (EO) 128 of January 30, 1987, of the President, reorganized the Government and renamed the PAEC as the PNRI under the Department of Science and Technology (DOST). A Department of Justice advice of January 2, 1989 stated PNRI had the same responsibilities and authority as PAEC.
(e) PNRI was Rationalized in 2010, Nuclear Regulations, Licensing and Safeguards Division (NRLSD) is now Nuclear Regulatory Division (NRD).

Development and hierarchy for Department of Health radiation regulation are as follows [6]:

(a) Presidential Decree 480 (1974) entitled “Creating a Radiation Health Office in the Department of Health” determined the functions separate to those for the PNRI (given by RA5027) to regulate radiation emitting apparatus that does not contain atomic energy materials.
(b) PD 1372 amended PD 480 creating the Radiation Health Office (RHO) in the Ministry of Health (MOH).
(c) Executive Order 119 reorganized the Ministry of Health, its attached agencies and other purposes.
(d) Executive Order 102 redirected the functions and operations of the Department of Health.
(e) Republic Act No. 9711 “Food and Drug Administration (FDA) Act of 2009” Signed August 18, 2009. reorganized Bureau of Health Devices and Technology (BHDT) into CDRRHR under the Food and Drugs Administration (FDA) under the DOH.
In order to be consistent with the international standards to establish as independent regulatory body for nuclear and radiation safety and to harmonize the implementation of regulatory functions of PNRI and CDRRHR, draft House Bill No. 147 entitled “Comprehensive Nuclear Regulation Act of 2015”, was filed in the House of Representatives [7]. It has undergone several revisions since its inception in 2005. This latest version of the proposed House Bill was reviewed at the technical working group level of the House of Representatives. A parallel version of the Bill is also proposed at the Upper House (Senate).

2.2. **Principal Functions and Activities**

The principal functions and activities in PNRI are carried out following the requirements of a quality management system, PNRI being certified to ISO 9001:2008 in 2014. The NRD initiated the QMS system in PNRI having been certified to ISO 9001:2000 in 2008 and later to ISO 9001:2008 in 2012. The PNRI – wide QMS is an expansion of the NRD QMS. All NRD processes and activities are performed in accordance with formal written procedures and work instructions.

2.2.1. **Authorization**

Currently, PNRI issues licenses for the following: atomic energy facilities such as production accelerators and possession and storage of nuclear fuel; medical use of unsealed sources for diagnosis, therapy, and radioimmunoassay; sealed sources in teletherapy and brachytherapy; industrial uses of sealed sources in gauging devices; industrial radiography; commercial sale and distribution of radioactive materials and equipment; researches and for teaching purposes. Any person or organization with the intention to acquire, receive, possess, own and use a radioactive material should file an application for a license. The basic requirements that should be complied prior to the issuance of a license are documents describing adequate facility and equipment, trained and qualified personnel and adequate radiation safety programs and procedures, among others. Both PNRI and CDRRHR have developed procedures for review and assessment of licence applications, with description of process flow charts and evaluation checklists. The PNRI radioactive material license is valid for only 1 year while facility license is valid for 5 years, and shall be amended for changes in accordance with pertinent provisions of the Code of PNRI Regulations, i.e. in radioactive materials and activities to be carried out not covered by the current license. CDRRHR is examining the need to introduce a procedure for controlling sources in terms of potential magnitude and nature of the hazards. PNRI has adopted IAEA TECDOC 1344 on categorization of sources through PNRI Administrative Order No. 1, series of 2004 [9].

In 2004, NRD was tasked to implement the “PNRI Internal Regulatory Control Program (IRCP)” through PNRI Office Order No. 2, series of 2004 whose purpose is to set-up an internal authorization process for all PNRI nuclear and
radiation facilities and laboratories. The program covers the following: a) Philippine Nuclear Research Reactor (PRR-1) b) Co-60 Gamma Multipurpose Irradiation Facility c) Radioisotope Dispensing Laboratory d) Radioactive Waste Management and Storage Facility e) Secondary Standard Dosimetry Laboratory and other research laboratories handling radioactive materials. Thereby, all the said facilities are subjected to regulatory compliance monitoring applying the CPR relevant to the practices. Also, it covers the decommissioning process being undertaken by the PRR-1.

2.2.2. Radiological Assessment

The PNRI performs radiological impact assessment of the authorized activities involving the use of radioactive materials in licensed facilities. The potential impact during normal operations and abnormal scenarios where the use of radioactive materials may be involved are studied to determine whether these may affect the workers exposed to radiation, public and the environment. Long and medium terms researches in relevant areas to support requirements to be included in regulations developed form part of the main functions for radiological impact assessment.

2.2.3. Inspection

The PNRI, in fulfilling its mandated regulatory functions, carry out regulatory inspections and audit to verify that PNRI-licensed facilities and activities using radioactive materials are in compliance with the relevant Philippine law, applicable parts of the Code of PNRI Regulations, conditions set forth in the PNRI Radioactive Material License, commitments stated in the Radiation Safety Program and the best practices and standards set forth by PNRI. An Annual Regulatory Inspection and Audit Schedule is prepared at the beginning of each year based on the following parameters: graded approach with respect to potential risk associated with authorized practice; performance history of licensees for the last five (5) years; categorization based on IAEA Categorization of Sources. Given priority for inspection schedule are those of Category 1 and 2 sources, and medical facilities using unsealed sources, like nuclear medicine, PET centers; and industrial radiography facilities. Not all licensees are inspected yearly but facilities not scheduled for the year, based on their performance, are required to submit proofs of compliance.

Planned regulatory inspection and audit are conducted annually on licensed facilities using radioactive materials used in medicine, industrial radiography, nuclear gauges, research and education, including PNRI authorized facilities and laboratories. Inspections are based on the approved Annual Regulatory Inspection Schedule. Unannounced inspections of licensees are conducted when there is proof, suspicion or high probability that there is a breach of the regulations. Follow-up
inspection of licensees with findings of non-compliance for verification of the licensee response /corrective actions are also part of the inspection activities. Corrective actions submitted by licensees are evaluated for closing out non compliances and inspected for effectiveness in the implementation.

2.2.4. Enforcement

The PNRI, as part of the oversight process imposes enforcement actions to licensees who are found to have violated any licensing and regulatory requirements relative to acquisition, possession, use of radioactive materials. The basis for enforcement are the law, PNRI Administrative Order No. 3, series of 2004 “Procedure for the Imposition of Regulatory Sanctions for Violations of PNRI Licensing and Regulatory Requirements Relative to the Acquisition, Possession and Use of Radioactive Materials”, issued in 25 October 2004, and Administrative Order No. 2 Series of 2011 “Regulatory Criteria in Determining Severity of Violation(s)”. The provisions specified in the legislation are stipulated in Sections 26-28 of RA 2067 and Section 26 of RA 5207. Such enforcement actions may be a Notice of Violation, PNRI Order, or Administrative Sanctions and require specific actions to ensure safety and security. In assessing the significance of a noncompliance, PNRI considers the following specific issues: actual safety consequences; potential safety consequences; actual and potential security consequences, impact on the regulatory process; and wilfulness. To determine the appropriate enforcement action, violations are categorized into Severity Levels I, II, III, and IV; Level I is the most significant. Further, PNRI may withhold, recall or order the withholding or recalling of radioactive material from any licensee who is not equipped to observe or fail to observe such safety standards to protect health and safety as may be established by the Institute.

In the case of DOH the penalty clause in PD1372 Section 3 on violations partly address enforcement matters.

2.2.5. Development of Regulations and Guides

Practice specific regulations are called Code of PNRI Regulations (CPR) are developed by the NRD and approved by the Director. These are published in the Official Gazette and implemented 15 days after publication [10]. Regulatory guidance documents as Information Packages (INFOPACs) issued by Chief of NRD. NRD Regulatory Information Bulletins or Notices are also developed for licensees and issued by the Chief of NRD. CPR Part 27 “Security Requirements for the Transport of Radioactive Material” issued in November 2013, revised CPR Part 26 “Security of Radioactive Sources” issued in February 2014 and the Revised CPR Parts 11, 14 and 17 issued in 2010 are the latest regulations approved and published in the Official Gazette for compliance. In 2014, a revised CPR Part 13 “Licenses for Medical Use of Unsealed Radioactive Materials” was published including the
accompanying Regulatory Guide or INFOPAC. Regulations covering those practices under the DOH jurisdiction are issued as Administrative Orders authorised by Secretary of Health. DOH regulatory guidance material takes the form of Bureau Orders and Guidelines and issued by CDRRHR Director.

2.2.6. Safeguards and Security

The current safeguards and security functions of NRD are doing plans, programs, conducts and carries out projects and inspections in support of international nuclear safeguards commitment and the physical security of nuclear and radioactive materials and facilities. It perform the following: maintains the national system of accounting for and control of nuclear materials; conducts Physical Inventory Verification (PIV) inspection of nuclear materials and Design Information Verification (DIV) of nuclear facilities in conjunction with IAEA safeguards inspections; coordinates the formulation and implementation of the physical security regulations for nuclear and radioactive materials and facilities; carries out projects and inspection in support of the physical security of nuclear and radioactive materials and facilities; and provides report to the IAEA Illicit Trafficking Database (ITDB) of any loss, theft, missing and unauthorized disposal of nuclear and other radioactive materials; among others.

2.3. Functions Shared with Other Governmental Agencies

Co-ordination and co-operation between the two regulators and other national agencies occurs at the national level most often informally and to a lesser extent formally via Memoranda of Agreement (MoA). MoA covering radiological emergencies exists with the Department of Interior and Local Governments (DILG) and the Department of National Defense. The MoA between PNRI and the Bureau of Customs has expired and is currently being re-negotiated. There is a draft MoA with the Bureau of Food and Drugs (BFAD) and Department of Transportation and Communications (DOTC). PNRI has arrangements with the Department of Environment and Natural Resources (DENR) regarding radioactive contamination in scrap metals and discharges through various environmental media.

2.4. Organization and Staffing

The funding for both the PNRI and CDRRHR, including for their regulatory activities, comes from general appropriations of the Philippine Government. The regulatory functions of each are not dependent on the collection of regulatory fees and charges. There are indications that inspection activities are constrained by budget pressures which affect transportation, equipment and follow-up inspections and audits. Within PNRI it is noted that there is no separate budget allocation for regulatory activities.
2.4.1. Staffing and Training

The NRD-PNRI has 39 “plantilla” staff positions dedicated to radioactive materials regulation. There are currently 14 vacancies in the division mostly due to compulsory retirement. Also, most of the personnel involved in the safety assessment and inspection of the Philippine Nuclear Power Plant -1 (PNPP-1) in the late 70’s and early 80’s are no longer with PNRI. Access to dedicated regulatory legal expertise is not available to the NRD chief and staff. At PNRI, although there is an annual training program submitted to the Planning Unit, there is no structured training program designed to build the competency of the regulatory personnel. The process to avail of training and workshops relies on the invitation and grants from IAEA and other international organizations.

As part of the Quality Management System of PNRI, it has constituted a Competency Committee with the objective of assessing the training needs and design individual training roadmap for every PNRI personnel in coordination with the Human Resources Management, Records and Communication Section (HRMCRS).

The PNRI normally asks for assistance from the IAEA for consultation and advices thru technical projects and expert missions.
2.5. Support Services

2.5.1. Personal Dosimetry Service for External Exposure Control

The PNRI acts as the principal national service provider for individual external dose monitoring. Each organization, PNRI and CDRRHR maintains its own separate database on results of personal occupational dosimetry for external dose. Presently, both TLD and OSL based dosimetry systems are utilised. There is no regulation stipulating which organisations may provide dosimetry services and there is no accreditation process for the current and future service provider.

2.5.2. Secondary Standard Dosimetry Laboratory (SSDL)

The calibration of all measuring devices is required by regulations. The PNRI SSDL is part of the Radiation Protection Services. It provides a calibration service for all instruments used for radiation safety and clinical radiation measurements. The calibrations are traceable to primary standards through the IAEA SSDL. The PNRI SSDL is participating in the IAEA inter-comparison SSDL network and the Asia Pacific Metrology Program (APMP). The DOH also provides an SSDL services.

2.5.3. Infrastructure for Radiological Emergency Preparedness

Emergency planning and preparedness is part of the licensing process. All licensees including PNRI authorized facilities are required to prepare and submit a facility response plan for approval of PNRI. The level of preparedness is commensurate to the level of hazards expected in the facility.

PNRI is the lead agency in the development updates and maintenance of a National Radiological Emergency Preparedness Plan (RADPLAN). The RADPLAN aims to establish an organized emergency response capability for timely and coordinated actions of the country’s authorities in the event of a radiation related incident or radiological emergency. The RADPLAN was approved by the Secretary of National Defense in November 2000. It is currently being revised.

The management of the national response is determined by the National Disaster Risk Reduction Management Council (NDRRMC). The national response requires the coordinated action of several national agencies and the appropriate authorities in the local government organizations that need assistance. The Office of Civil Defense (OCD) and the PNRI are responsible for coordinating the national response to all radiological emergencies anywhere in the country. The responsibilities of the PNRI in coordinating all national response activities are defined in another emergency plan known as the PNRI Radiological Emergency Response Plan (RESPLAN).

The Nuclear Response Support Center (RSC) which is located in one of the rooms (ground floor) at PNRI NART Building was inaugurated last December
2008. This will serve as a central station and evaluation of appropriate emergency response and action in the assessment of doses and all analytical measurement necessary for the emergency. All nuclear response activities and technical assistance emanate from the RSC.

2.5.4. **Infrastructure for Radioactive Waste Management**

The Proposed House Bill No. 5429 is an Act providing for a Comprehensive Hazardous and Nuclear Waste Management that outlines the principal guidelines in the safe management of nuclear and radioactive waste in the country. This proposed Act shall cover the requirements for processing, handling, storage, transportation, collection, recovery, use and final disposal of hazardous and nuclear wastes in the country for whatever purposes.

CPR Part 23 “Licensing Requirements for Land Disposal of Radioactive Waste”, issued in May 2005, contains technical and procedural provisions applicable in all phases of the Lifecycle of a Low Level Waste (LLW) Facility. This includes specific technical requirements involving siting, design, operations and closure, monitoring, waste classification, and institutional requirements. The requirements were basically based on international best practices and accepted guidelines as those recommended by the IAEA.

The PNRI operates and maintains a centralized Radioactive Waste Management and Storage Facility (RWMSF) for collection, aggregation, and treatment of wastes generated primarily from medical, industrial, research and education application of radioactive materials. It adopts two basic waste treatment and conditioning options for radioactive waste: 1. waste collection and packaging for decay storage for final disposal as ordinary refuse and 2. waste collection, aggregation, treatment, conditioning and packaging followed by interim storage awaiting final disposal in a repository. The facility is located inside the compound of PNRI in the middle of Quezon City, Metro Manila. It has a total land area of almost 0.4 hectares and a building with floor area of about 600 square meters.

The country is in the process of selecting a site for national near surface repository for the disposal of low to short lived intermediate radioactive wastes being carried out by the Subcommittee on Radioactive Waste Management under the Nuclear Power Steering Committee constituted in 1995 thru Executive Order No. 243. A preferred site has been selected and the thrust of the project now is to develop safety assessment methods and capabilities to guide further investigation and research. In 2013, an expert mission from the IAEA assisted and guided the PNRI in drafting and establishment of the national policy on radioactive waste management.
2.5.5. Infrastructure for Safe Transport of Radioactive Materials

CPR Part 4 “Regulation for the Safe Transport of Radioactive Material in the Philippines”, was published in the Official Gazette on 25 October 2004. The regulations in this Part establish standards for safety to protect persons, property and the environment from the hazardous effects of radiation associated with the transport of radioactive material in the Philippines. It also establishes the:

(a) Requirements for packaging and packages, preparation for shipment and transport of radioactive materials; and

(b) Procedures and standards for the control of shipments and for the approval of packaging and packages.

An “Authority to Transport” is issued by PNRI for every shipment of radioactive materials (local and international) upon presentation of the licensee of a “Transport Certificate” signed by the Radiation Safety Officer (RSO), together with other pertinent shipping documents. Also, a “Release Certificate” addressed to the Bureau of Customs has to be secured from PNRI to facilitate the release of imported radioactive materials.

As part of transport safety and security, the Global Threat Reduction Initiatives Project by US-DOE facilitated for the installation of portal monitors at two major sea ports in the country to monitor for radioactive materials in all outgoing or for export cargos. PNRI is the lead implementing agency in cooperation with the Bureau of Customs.

Another US-DOE project facilitated for the installation of physical protection equipment and security management in all category 1 sources in the country, e.g. teletherapy and gamma irradiator facilities. PNRI has already provided all the necessary assistance and training in the development of security plan for facilities with category 1 source. Its recent activities were the conduct of workshop and writeshop in September and October 2010, respectively, on the development of security plan for facilities with category 1 radioactive sources.

2.6. Quality Management System (QMS)

In [11] and [12], the establishment and sustenance of NRD-QMS certified under ISO 9001:2000 and 2008 version was discussed and its impact to the NRD’s performance. NRD-PNRI was awarded by the Office of the President in Malacañang on December 2008 as one of the first 30 government agencies certified to ISO in compliance with the Executive Order.
3. IAEA PROJECT RAS/0 9/062: PROMOTING AND MAINTAINING REGULATORY INFRASTRUCTURE FOR THE CONTROL OF RADIATION SOURCES

Objective: To upgrade regulators infrastructure in the Asia and Pacific region for the safe control of radiation sources.

Outcomes:
For Outputs 1 and 2: All participating countries can effectively implement regulatory control for radiation sources in accordance with IAEA safety standards.
For Outputs 3 -7: Participating countries have the capability to establish arrangements for sustainable regulatory control.


The Table below shows the project matrix framework developed by the IAEA which was modified to also serve as monitoring tool. It shows the PNRI outputs and outcomes that were gained in participating with the project activities that, partially or totally, met the project objective. These outputs and outcomes were listed in the preceding section as achievements.

TABLE 1. IAEA Project RAS/09/062 Matrix Framework

<table>
<thead>
<tr>
<th>Outputs</th>
<th>Action Plans/Activities</th>
<th>Inputs</th>
<th>Indicators</th>
<th>PNRI Outputs / Outcomes (Achievements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The status of the national regulatory infrastructure in the Member State (MS) is determined in an objective and consistent manner against the IAEA safety standards</td>
<td>Participating countries make self-assessment of their regulatory infrastructure against IAEA safety standards</td>
<td>Training course on self-assessment and SAT</td>
<td>RTC implemented on time in 2012 “Regional Training Course (RTC) on self-assessment and SAT” Regional Workshop on Self-Assessment of National Regulatory Infrastructures for Safety (SARIS), 26-30 January 2015, Austria</td>
<td>Participated</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No participant. However, has participated in the “Technical Meeting on Implementation of IAEA’s Self-Assessment</td>
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<tr>
<td>Methodologies and Tools,” 17-20 December 2012, Austria (1 staff)</td>
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<tr>
<td>Installing and utilizing SAT in the participating countries to make self-assessment</td>
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<tr>
<td>Installed SAT</td>
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<tr>
<td>An echo seminar was conducted in 2014 among NRD staff. There was an attempt to constitute or form the SARIS Project Team but hindered by human and financial resources and other matters.</td>
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<tr>
<td>Independent assessment of the regulatory infrastructure in the participating states</td>
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<tr>
<td>Independent peer review mission in 2012 -2013 (if requested, 2 missions each year) budget estimation is based on the assumption of a 4-expert team conducting a 1-week review mission</td>
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<tr>
<td>Mission has taken on place time</td>
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<tr>
<td>Did not avail of the missions because NRD is not yet prepared to do the self-assessment (pre-requisites)</td>
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<tr>
<td>Preparation of realistic action plan to implement the outcome of the self- or independent assessment</td>
<td></td>
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<tr>
<td>Prepare and implement an action plan to fill in the gaps and shortcomings identified in the self- or independent assessment</td>
<td></td>
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<tr>
<td>Prepared action plan to implement the outcome of self-assessment and peer review</td>
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<tr>
<td>Not applicable because did not avail of the mission.</td>
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<tr>
<td>Updating of RASIMS profile – National Regulatory Infrastructure and Radiation Safety</td>
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<tr>
<td>Participating MS to update their RASIMS</td>
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<tr>
<td>Updated RASIMS</td>
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<tr>
<td>Updated RASIMS with the designation of a new coordinator on December 2014 and</td>
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<tr>
<td>Activity Description</td>
<td>Description</td>
<td>Result</td>
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<td>------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
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<tr>
<td>Radiation safety regulations are updated in accordance with IAEA safety standards</td>
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</tr>
<tr>
<td>Revising radiation protection regulations</td>
<td>Reviewing radiation protection regulations.</td>
<td>Did not avail of the expert mission or national workshop since it was already avail in the previous project.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>School of drafting regulations (3 weeks)</td>
<td>Workshops implemented on time with First School for Drafting Regulations on Radiation Safety for Asia and the Pacific, 14 January – 1 February 2013</td>
<td>Philippines was not included</td>
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<tr>
<td></td>
<td>2nd School on Drafting Regulations, 9-20 November 2015, Austria (1 staff)</td>
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<tr>
<td>Ensuring that the provisions of the CoC and Guidance on Import and Export of Radioactive Sources (GIERS) are adequately addressed in national regulations</td>
<td>Workshop on CoC and GIERS</td>
<td>Technical Reports were published in the Proceedings of the “International Conference on Safety and Security of Radiation Sources,” 27-31 October 2013 United Arab Emirates, i.e., “A National Report to Share the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measures are in place for effective and independent performance of regulatory functions.</td>
<td>RTC on national strategies for regaining control over orphan source</td>
<td>RTC on National Strategies for Regaining Control Over Orphan Source”</td>
<td>RTC implemented on time in 2012 “RTC on National Strategies for Regaining Control Over Orphan Source”</td>
<td></td>
</tr>
<tr>
<td>Implementing CoC and GIERS provisions in national regulations</td>
<td>CoC and GIERS covered in the regulations</td>
<td>PNRI Administrative order No. 2 Series of 2006, Adoption of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources and IAEA Guidance on Import and Export of Radioactive Sources. [14]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graded approach to the implementation of authorization, inspection and enforcement.</td>
<td>RTC on effective and sustainable regulatory control of radiation sources.</td>
<td>RTC implemented on time in 2012 “RTC on Effective and Sustainable Regulatory Control of Radiation Sources”, 15-19 October 2012, Indonesia (2staff)</td>
<td>Participated</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>Description</td>
<td>Result/Outcome</td>
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<tr>
<td>Participated</td>
<td>“Regional Training Course on Regulatory Enforcements,” 12-16 October 2014, Qatar (2 staff)</td>
<td>Participated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participated</td>
<td>Training Course for Radiation Safety Reviewers in IRRS Mission, 7-10 April 2015, Austria (1 staff)</td>
<td>Participated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revising the implementation of the regulatory program in the participating countries to ensure that the regulatory functions are conducted in accordance with graded approach and in an independent manner (4xEM)</td>
<td>Revise and improve the implementation of the regulatory program</td>
<td>The Inspector’s Manual was revised to incorporate the graded approach.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completing national registers of sources</td>
<td>Training course on the new version of RAIS and national register of radiation sources</td>
<td>RTC implemented on time in 2013 “RTC on the New Version of RAIS and National Register of Radiation Sources”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Installing RAIS and making efforts to</td>
<td>Installed and operational RAIS</td>
<td>PNRI RAIS 3.1 Web, upgraded to</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RTC = Regional Training Course
<table>
<thead>
<tr>
<th>Arrangements are in place for adequate information management</th>
<th>collect and complete the information and inventory of radiation sources in the country</th>
<th>3.2 Web maintains the current national inventory of Category 1 and 2 radioactive sources and partially updated inventory of Category 3-5 radioactive sources.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhancing national coordination of regulatory functions.</td>
<td>Ensuring that regulatory body functions are well coordinated with the relevant national authorities such as MoH, Customs and MoE/EPA</td>
<td>Established formal arrangements such as MoUs for national coordination</td>
</tr>
<tr>
<td>Enhancing international</td>
<td>Participating in regional and</td>
<td>High Level Regional Meeting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Arrangements</th>
<th>Enhancing national coordination of regulatory functions.</th>
<th>Establishing information management system that provides for collecting and analyzing regulatory data, lessons and regulatory experience.</th>
<th>RTC implemented on time in 2014 “Advanced Training Course on the Application of RAIS 3.3 Web for Management of Regulatory Programme,” 18-22 August 2014, Mongolia (1 staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishing arrangements for analyzing regulatory experience and deriving lessons learned</td>
<td>Advanced training on RAIS, covering maintaining and analyzing regulatory data, performance indicators, feedback of regulatory experience</td>
<td>Established arrangements for analyzing regulatory experience</td>
<td>No developed procedure yet.</td>
</tr>
</tbody>
</table>

- Participated
cooperation with regard to the exchange of regulatory information.

<table>
<thead>
<tr>
<th>Regulatory bodies of the participating countries have the capability to establish a management system</th>
<th>Support participating countries in establishing a management system in accordance with a graded approach.</th>
<th>Training course on development, implementation and assessment of regulatory body processes</th>
<th>RTC implemented on time in 2012 “RTC on Development, Implementation and Assessment of Regulatory Body Processes”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing expert advise on establishing management system (3xEM)</td>
<td>Expert mission or national workshop</td>
<td>Did not avail of the expert mission or national workshop since it was already availed in the previous project.</td>
<td></td>
</tr>
<tr>
<td>Establishing arrangements for continuous monitoring, assessment and improvement of the regulatory system</td>
<td>Establish monitoring, assessment and improvement of the regulatory system</td>
<td>The NRD-PNRI conducts an annual Internal Quality Audit (IQA) and Management Review Meeting (MRM) since 2008 based on...</td>
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<tr>
<td>Measures are to place for proper human resource management</td>
<td>Measures are in place for maintaining organizational knowledge within the regulatory body.</td>
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<td>----------------------------------------------------------</td>
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</tr>
<tr>
<td>Supporting regulatory bodies of the participating countries in establishing strategies.</td>
<td>Supporting participating countries in implementing knowledge management.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training on organization and competence of the regulatory body</td>
<td>Training course on knowledge management</td>
<td></td>
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</tr>
<tr>
<td>RTC implemented on time in 2014 “Regional Training Course on Organization, Staffing and Competence Management of Regulatory Body,” 27-31 January 2014, Philippines (4 staff)</td>
<td>Provide advise on knowledge management</td>
<td></td>
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</tr>
<tr>
<td>Successfully hosted the event with 25 participants from 15 member countries</td>
<td>Expert mission or national workshop</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of SARCoN tool is in big progress now headed by a Committee Chair</td>
<td>Establishing arrangements for maintaining organizational knowledge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Establish and maintain organizational knowledge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISO 9001 QMS – Certification. Drafting of IMS based on IAEA GSR Part 2 is targeted in 2016</td>
<td>Did not avail of the expert mission or national workshop since it was already availed in the previous project.</td>
<td></td>
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</tr>
<tr>
<td>Knowledge Management is already included in the PNRI QMS as a support process. The process owner is a Committee</td>
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</tbody>
</table>
4. THE ACHIEVEMENTS AND CHALLENGES

4.1. Achievements

The outputs and outcomes attained by the NRD-PNRI can be considered or perceived as their achievements or success stories which brought a very satisfactory and outstanding satisfaction ratings for NRD based on the customer’s satisfaction surveys [15].

— Integration of Knowledge Management (KM) in the PNRI QMS and Strategic Performance Management System (SPMS)
— Successful hosting of the “Regional Training Course on Organization, Staffing and Competence Management of Regulatory Body,” 27-31 January 2014, with 25 participants from 15 member countries
— Active participation in regional and international regulatory network, meetings and conferences, among others
— Installation of PNRI RAIS 3.1 Web later upgraded to 3.2 Web that maintains the current national inventory of Category 1 and 2 radioactive sources and partially updated inventory of Category 3-5 radioactive sources. Currently, the system is operational but needs further customization and utilization.
— PNRI staff served as IAEA expert-lecturer on the “Workshop on Establishing a Register of Radiation Sources Based on RAIS”, 23-27 June 2014, Myanmar
— Submitted to the IAEA, “A National Report to Share the Experiences and Lessons Learned in the Implementation of Code of Conduct on the Safety and Security of Radioactive Sources”: The Philippines. It was the first report and serves as the baseline information
— Recent and latest published Code of PNRI Regulations
— Updated RASIMS with the designation of a new coordinator on December 2014
— Maintained and sustained the certification of NRD QMS based on ISO 9001:2008 since 2008 and expanded it to the whole PNRI organization in 2014 for the 3rd cycle
— Sustenance of PNRI QMS as certified to ISO 9001:2008, soon to be revised based on 2015 version and migrate it to IMS based on IAEA GSR Part 2 (draft)
— Continual improvement on monitoring, assessment and improvement of the regulatory system with the conduct of annual Internal Quality Audit (IQA) and Management Review Meeting (MRM) since 2008 based on ISO 9001 QMS – Certification.
— Exchange experience, information and share the impact of this project with other member states in the region

4.2. Challenges

The remaining tasks or activities that have to be fulfilled through the project can be considered as challenges.

— Conduct of self-assessment using SARIS and/or IRIS in preparation for scheduled IAEA IRRS mission
— Frequent updating of RASIMS, i.e., annually, likewise addressing the gaps
— Validation of the effectiveness of the regulations thru interested parties' feedbacks
— Full implementation of RAIS, taking advantage of its many useful features
— MOA and close coordination with other relevant government agencies
— Full implementation of SARCoN coming up with structured training program for competency building and individual training roadmap.
— Development and establishment of IMS based on IAEA GSR Part 2 (draft)
— Establishment of arrangements for analysis of regulatory experience and derived lessons learned
— Development and promotion of Safety Culture and serve as the role model as regulator to the operating organizations

5. CONCLUSION AND RECOMMENDATIONS

Based on the NRD-PNRI outputs and outcomes which were perceived as achievements from the implementation of the above-mentioned RAS Project has strengthened the NRD regulatory infrastructure and brought a lot of improvement in the performance of its regulatory activities. Therefore, it can be concluded that the execution of the said project was very successful. The recommendations will be the effective application of knowledge, skills and ideas gained from the project, i.e., to develop a strategic plan on the following:

(a) The best strategy to expedite the enactment of the Philippine House of Representative House Bill 147 through a well developed communication
strategy and plan involving the relevant government agencies and rightful decision makers, e.g. ensure that creation of “An Effectively Independent Nuclear/Radiation Regulatory Authority” is embedded in ratified treaties and conventions, e.g. in Convention on Nuclear Safety (CNS).

(b) Prioritize the conduct of SARIS through IAEA TC Project and/or expert mission as pre-requisite for a future IRRS and/or IRIS Mission involving the government and using its results as basis for the national policy and strategy for safety, Make SARIS as part of IMS based IAEA GS-R-3 or GSR Part 2 (draft).

(c) Envision the “Journey to Excellence” by aiming to achieve the Philippine Quality Award (PQA) using the IMS and Safety Culture roadmap and an effective communication plan,

(d) Development and implementation of strong safety culture and act as role model in its promotion,

(e) Continual active participation in the global network, ANSN, Control of Sources Network (CSN) website on the RegNet/GNSSN platform, RCF and ASEANTOM, among others.

(f) Develop a structured training program to strengthening the competence building activities starting from TNA, SARCoN and Knowledge Management (KM),

(g) Full implementation of RAIS (identify weaknesses and needs), including regaining control of orphan sources and management of disused sources and radioactive wastes.

(h) Frequently updated RASIMS, and

(i) Strong and consistent leadership and management commitments, among others.

REFERENCES

MAINTAINING THE NATIONAL REGULATORY CONTROL OF SPENT RADIOACTIVE SOURCES

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Abstract

In order to fulfilling the obligations connected to the international conventions to which Republic of Moldova is a part, to implement the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources and after the focusing of the international community on the importance of maintaining strong control over radiation sources during the last years, our country continue to improve its regulatory system in the field. The regulatory control of spent radiation sources can be conducted only in comprehensive mode with their normal use. Also, the poor management of spent radiation sources could lead to their illicit trafficking, other criminal acts and radiological accidents. The main location in the country where the most of spent radioactive sources are located is radioactive waste storage - the State Enterprises of Special Purpose "Special Objects nr.5101, 5102". The inventory contains the spent sources used in medicine, industry, agriculture and science. The paper reflects: the Regulatory infrastructure of management of spent radioactive sources in the country; the Current status and storage of spent high activity sources, registration and accounting; Physical protection and monitoring at the disposal facilities in the country; the National and regional challenges associated with spent radioactive sources; and some achieved Good practices.

1. INTRODUCTION

In order to fulfilling the obligations connected to the international conventions to which Republic of Moldova is a part, to implement the provisions of the Code of Conduct on the Safety and Security of Radioactive Sources and after the focusing of the international community on the importance of maintaining strong control over radiation sources during the last years, our country continue to improve its regulatory system in the field.
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The main location in the country where the most of spent radioactive sources are located is radioactive waste storage - the State Enterprises of Special Purpose "Special Objects nr.5101, 5102". The inventory contains the spent sources used in medicine, industry, agriculture and science.

2. REGULATORY INFRASTRUCTURE OF MANAGEMENT OF SPENT RADIOACTIVE SOURCES

Normative regulation is achieved through regulations governing nuclear and radiological safety and security, physical protection of nuclear materials and radioactive sources, the regulations on radioactive waste management, transport of nuclear and radioactive materials, radiation protection requirements for the personnel, approved by the Government.

Other regulatory legal acts in the field, such as instructions, guidelines, technical standards, are developed and approved by the regulatory body.

The elements of infrastructure in the field of nuclear and radiological activities in the country are:

— National Agency for Regulation of Nuclear and Radiological Activity;
— Authorities with duties in nuclear and radiological activities;
— Physical and legal persons authorized on nuclear and radiological activities;
— Qualified cadres in the field of nuclear and radiological activities;
— Scientific-research organizations in the line.

Under the Law nr.132 from 8 June 2012, on safe deployment of nuclear and radiological activities, in the country was established a single regulatory body, named National Agency for Regulation of Nuclear and Radiological Activity (NARNRA).

According to its Statute, the National Agency is the public branch body, created by the Government and is affiliated to the Ministry of Environment, with the status of the legal person and the necessary level of independence for performance of the regulation functions. The structure of the NARNRA, its Regulation and Director are approved by the Government.

Among the main responsibilities of the NARNRA are the authorization, evidence of ionizing radiation sources, inspection and enforcement, development and review of regulations and normative acts, control of nuclear non-proliferation and respect the international treaties.
The main Regulations approved by Government Decrees, which are in force in Moldova:

— Government Decision no. 54 of 24 January 2014 on approving of the modifications in GD no. 1017 of 1 September 2008 on the National Register of ionizing radiation sources and authorized physical and legal persons;
— Government Decision no. 153 of 28.02.2014 on approval of the Regulation on state control and supervision of nuclear and radiological activities, and nuclear non-proliferation regime;
— Government Decision no. 727 of 09.08.2014 on approving the Regulation on the authorization of nuclear and radiological activities;

— The current legislation in the field places the prime responsibility for the safe management of, and the security of radioactive sources on the radiological license holders.

3. CURRENT STATUS AND STORAGE OF SPENT HIGH ACTIVITY SOURCES, REGISTRATION AND ACCOUNTING

In the country is managed the National Register, electronically and on paper, under Government Decision no. 1017 of 01.09.2008 on the National Register of ionizing radiation sources and authorized physical and legal persons.

The record keeping system of ionizing radiation sources consist of 4 sub-registries of evidence: ionizing radiation sources, including spent sources; nuclear materials; radiological facilities; the issued authorization.

Currently is included in the National Register information on: 5671 radioactive sources, including spent sources distributed by the categories (Fig. 1), 1137 generators, 1023 associated equipment, 401 authorized radiological facilities.

The manufactured IRS are taken under records at the entrance in warehouse of finished products. While radiopharmaceuticals, the sets for immunological tests, radioisotopes used in medicine, radionuclide markers, radioisotope preparations and solutions based on radionuclides with half-lives up to 60 days, including iodine-125, with a summary activity less than 10 GBq, are emphasize only by operating organizations.

Procedure of the authorization started from official notification and is made through on site safety assessment (evaluation) of condition on safe deployment of
nuclear and radiological activities. The authorization is performed by radiological issuing the authorization, which has a term of validity of 5 years.

According to the current legislation the authorized persons are obliged to provide the possibility for transfer of radioactive sources and radioactive waste to the supplier or user.

For searching of missing sources and securing found sources are available some appropriate facilities and services adequately equipped. The NARNRA have a sufficient number of devices for detection and identifying of radioactive and nuclear materials as all as some radioprotection equipment for its staff involved in the process of searching of lost sources.

In the implementation of TACIS project was received the equipment in form of mobile radiological laboratory with advanced gamma spectrometer. Received and installed the rationalistical equipment of gamma spectrometer with extra-pure Ge detector for radiological environmental monitoring (as an element of primary responce to radiological or nuclear accident) in the amount of 85 000 Euros, placed under contract at State Hidrometeorological Service.

This equipment is obtained from cooperation with the Sweden radiological regulatory authority.

The Order nr.37 from 18 June 2012 was approved by the Director of NARNRA about Mobile Expert Team (MEsT) for reacting to radiological incidents, with approved procedure for response. In this regard, was coordinated and signed by the NARNRA, Customs Service, Border Police and Service of Civil Protection and Emergency Situations the CONOPS (concept of operation). On improving the procedures for reacting in case of radiological emergency was conducted above 20 field exercises.

![Radioactive sources distribution by categories](image)

**FIG.1 Radioactive sources distribution by categories.**

4. PHYSICAL PROTECTION AND MONITORING AT THE DISPOSAL FACILITIES IN THE COUNTRY
In different locations within the country, strengthened arrangements of physical protection measures, combating illicit trafficking, communication and interaction between different State authorities involved in nuclear security issues were observed.

One example is the former laundry facility of Rad Waste Storage, which has been reconstructed, with the assistance of the IAEA and USA, into a radioactive waste conditioning facility.

Also, the construction of a new radioactive waste storage facility for high activity radioactive spent sources has been finalized, which is now equipped with a new physical protection system.

Several transportations had been conducted to remove unused radioactive sources from Transnistria, including those containing nuclear material.

Based on its yearly plans, NARNRA routinely conducts national inspections in order to ensure compliance with the country’s legislation and international obligations. These inspections typically address several different areas such as radiation safety, emergency preparedness and physical protection, including safeguards. The results of these inspections are recorded in protocols and archived at NARNRA.

**National and regional challenges associated with spent radioactive sources**

In addition to the new waste storage of State Enterprises of Special Purpose “Special Objects nr.5101, 5102”, the old Radon-type storage contains uncharacterized radioactive waste, which may contain radioactive sources. Moldova has agreed with the IAEA to commence in 2017 y. a Technical Cooperation Project for conditioning of this radioactive waste.

During last five years in Republic of Moldova have occurred three cases of illicit trafficking involving nuclear materials and 2 cases involving radioactive materials (one – to be confirmed).

Have been found 4705 undeclared radioactive sources, including 40 radioactive sources of Sr-Y (90) and 5 containers of protection containing depleted uranium (three containers of brachytherapy facility AGAT-VU and two K3-1 model for transportation of defectoscopy radioactive sources), with total weight of about 600 kg., at the State Enterprises of Special Purpose “Special Objects nr.5101, 5102”.

**Good practices:**

— Systematic capacity building of NARNRA staff involved in safety and security implementation;

— Systematic interaction with MFA, Ministry of Internal Affairs and authorization holders;
— Ongoing provision of necessary training to other organizations involved in safety and security implementation;
— Routine performance of national inspections to ensure compliance with legal requirements, conditions of authorizations;
— Completion of annual physical inventory taking requirement;
— Transportations of unused radioactive sources from Transnistria, including those containing nuclear material subject to safeguards;
— On-line provision of information from the radiation monitoring systems at Customs check Points;
— Development and promotion of the Government Decision draft on approval the Law on approval of the National Strategy on radioactive waste management for the 2016-2025 years – partially achieved sent to re-examination to the ministries.
SUPPORT OF INTERNATIONAL COOPERATION
AND NUCLEAR REGULATORY ASSISTANCE
THE US NUCLEAR REGULATORY
COMMISSION’S INTERNATIONAL PROGRAMS

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Abstract

Nuclear energy offers long-term economic and environmental benefits providing a reliable energy source with significant environmental. National governments in countries operating or planning to establish nuclear facilities have instituted regulatory regimes on the use of nuclear materials and facilities to insure a high level of operational safety. The national regulatory agencies fully recognize the potential risk involved in operating nuclear facilities and the additional risk that could extend beyond national boundaries. This unique feature of the risk in operating nuclear facilities require international cooperation among nation states regardless whether they actually operate any nuclear facility. International cooperation allows addressing safety problems going beyond national regulatory regimes and offers the potential for cooperation and promotion of common nuclear standards through international regulatory coordination.

The US Nuclear Regulatory Commission (NRC), Office of International Programs’ international assistance, training, and technical support include wide ranging regulatory and technical areas through cooperative training programs, workshops, and joint projects. The main benefit of the regulatory and technical cooperation is the improvement in regulatory and technical capabilities both at the nuclear regulatory agencies and the respective Technical Support Organizations (TSOs). The future challenge is to ensure that the cooperation between NRC and foreign regulatory agencies responds to the country specific regulatory needs and further increase the capabilities with an overall increase in the safety of the nuclear facilities. The cooperative regulatory and technical assistance program improves the capabilities of the regulatory agencies and TSOs in the licensing process allowing improved reviews and confirmation of technical approaches selected by the licensees and insuring that adequate
safety is maintained. The paper will further explore the history and various components, which are used to transfer technologies and establish cooperative projects.

1. INTRODUCTION

Nuclear energy offers long-term economic and environmental benefits providing a reliable energy source with significant environmental advantages in reducing the effect of human activities on global warming. National governments in countries operating or planning to establish nuclear facilities have instituted regulatory regimes on the use of nuclear materials and facilities to insure a high level of operational safety. The national regulatory environments fully recognize the potential risk involved in operating nuclear facilities and the additional risk that could extend beyond national boundaries. This unique feature of the risk in operating nuclear facilities require international cooperation among nation states regardless whether they actually operate any nuclear facility. International cooperation allows addressing safety problems in an international forum going beyond national regulatory regimes and offers the potential for cooperation and promotion of common nuclear standards through international regulatory coordination.

In the US the Atomic Energy Act of 1954 together with the Energy Reorganization Act of 1974 (establishing US Department of Energy (DOE) and Nuclear Regulatory Commission (NRC)) provide for the development and regulation of the uses of nuclear materials and facilities with the general goals of promoting “world peace, improve general welfare, increase the standard of living, and strengthen free competition in private enterprise.” The Acts empower the NRC to establish rules and orders governing the use of nuclear materials “to protect health and safety and minimize danger to life and property.” The NRC supports the international safe and secure use of nuclear materials and actively participates in various international organizations. It aims to provide advice and assistance to international organizations and foreign countries to develop effective regulatory organizations and safety standards. Many of these activities are carried out in direct cooperation with the International Atomic Energy Agency (IAEA), the Nuclear Energy Agency (NEA), or other international organizations. In addition, a number of programs in foreign countries are conducted directly with the counterpart agencies under bilateral regulatory and research cooperation agreements.

One of the key elements determining the operational safety of nuclear facilities is an appropriate regulatory regime establishing the regulatory requirements and the safety envelope for nuclear operations. The US NRC Office of International Programs provides overall coordination for NRC’s international activities, in concert with other NRC offices, carrying out policies in the international arena. The OIP establishes and maintains working relationships with individual countries and international nuclear organizations, as well as other involved U.S. Government agencies. The NRC actively participates in international
working groups and provides advice and assistance to international organizations and foreign countries to develop effective regulatory organizations and enforce rigorous safety standards.

Many activities are conducted directly with counterpart agencies in other countries pursuant to regulatory and research cooperation agreements. NRC has close working relations with nuclear agencies in more than 35 countries and exchange operational safety data and other regulatory information. The NRC provides safety and safeguards advice, training, and other assistance to countries that seek U.S. help to improve their regulatory programs. The NRC originally worked primarily with major nuclear power countries, but later expanded its cooperation to include countries with small nuclear power programs, as well as some of those about to enter the nuclear field.

NRC’s information exchange arrangements serve as communications channels with foreign regulatory authorities, establishing the framework for NRC to gain access to non-U.S. safety information. The international cooperative programs also serve as vehicles for the health and safety assistance NRC supplies to less-developed countries in their attempts to prevent accidents and to develop and improve their regulatory capabilities and nuclear safety infrastructure. The international cooperation arrangements facilitate NRC’s strategic goal to support the safe and secure use of nuclear materials and in nuclear non-proliferation both in the US and abroad.

In the early 1990s the NRC OIP established an international regulatory safety assistance program in countries with Soviet-designed nuclear reactors. In many of those countries the nuclear regulatory authorities were not well established, had no clear division of responsibility, and had difficulty in enforcing regulatory requirements due to lack of basic nuclear regulatory laws and legal requirements. The initial safety assistance programs provided critical training and technical knowledge of regulatory personnel using US technical experts based at NRC and DOE laboratories such as Brookhaven National Laboratory (BNL).

The international assistance, training, and technical support include wide ranging regulatory and technical areas containing a significant infrastructure component. The nuclear regulatory support program is part of a large US international nuclear technical and regulatory assistance that is authorized by the US Government. Figure 1 indicates the various institutional components and participants in this wide ranging cooperative program that involves governmental institutions with appropriate industrial partners.
The TSOs traditionally have been a significant factor in contributing to the regulatory process of the licensing, constructions, and operation of nuclear power plants. Historically, the TSOs helped establishing the licensing framework in conformance of the regulatory standards existing in each country including appropriate laws and regulations. In many countries, the TSOs have seen increased activities due to potential expansion of the nuclear industry including plans for constructing new reactors and becoming a critical resource in the licensing process. The regulatory bodies play a significant role in clarifying the role of TSOs, the expectation of their responsibilities, and support the TSOs efforts in improving their in-house technical capabilities and financial resources. The US NRC’s regulatory assistance program fully recognizes that while the TSOs are largely independent organizations, they still have a specific relationship and perform most technical work at the request of the nuclear regulator.

2. PROGRAM CHALLENGES

The US NRC fully recognizes that TSOs providing support in regulatory decisions, in general, do not carry out technical developments to improve technologies or operational methodologies, which are more appropriate for the nuclear industry. The technical developments performed by TSOs are primarily serving the needs of the licensing processes and regulatory decisions making sure that the methods used by industries provide adequate safety. The TSOs also need to expand their developmental horizons for potential future needs based on industry initiatives or general research directions. The technical assistance program must respond to not only the regulatory needs of each country, but also provide support in developing TSO’s capabilities in wide-ranging technical areas that may serve future research and/or regulatory methodologies. Regulatory reviews require certain capabilities that provide the basis for selecting the organizations serving as a TSO for the nuclear regulator, such as a) technical competency in reviewing licensee’s methodology and proposed actions, b) capability of carrying out plant specific
analysis, and c) have analytical capabilities, computer codes, and sufficient plant operating experience.

In the early 1990s, the US NRC regulatory assistance program was originated under the Lisbon Nuclear Safety Initiative recognizing the potential nuclear safety concerns in countries that had Soviet-designed nuclear reactors. The objective of the US NRC’s technical assistance program is the comprehensive improvement in the regulatory capability of not only the nuclear regulator, but also the TSOs technical ability to provide significant support in regulatory decisions and also developing a regulatory regime that insures adequate nuclear safety. One of the key elements that determine the nuclear safety is a robust nuclear regulatory regime with an independent nuclear regulator at its center. In many countries, there is an expectation of a large expansion of nuclear power in the coming decades raising the concern of the nuclear regulator’s status, the organization and relationship of the nuclear industry, regulator, and the TSOs, and the availability of critical manpower for all these institutions. The assistance program, besides providing specific technical assistance, all along emphasized the importance of an effective regulatory structure to help sustaining a viable nuclear industry and establishing and maintaining an independent and effective nuclear regulation. Figure 2 shows the most common organizational structures found in many countries either with an independent nuclear regulator or as part of a larger ministerial institution.

![Fig. 2. Nuclear Regulatory Organizations - Common Institutional Arrangements](image)

The international regulatory assistance program faced many challenges and successes in strengthening the regulatory and technical capabilities of the foreign nuclear regulatory organizations and the TSOs. Over the years the NRC’s international regulatory support program has expanded beyond its original scope encompassing many countries with operating or planned nuclear facilities. The international assistance, training, and technical support include wide ranging regulatory and technical areas through cooperative training programs, workshops, and joint projects, such as:
— Safety analysis methodologies and code applications, design basis analyses
— Life cycle management, maintenance optimization, support periodic safety reviews
— Licensing and inspection procedures,
— Risk informed and analytical methods design basis analysis,
— Severe accident methodologies and procedures,
— Emergency response and infrastructure development,
— Development of regulatory guidelines and bases for regulatory actions
— Significant infrastructure component providing improvement in analytical hardware, dosimeter equipment, networking capabilities, and communication infrastructure

The technical assistance program is tailored encouraging the TSOs to develop and maintain close contact with the nuclear installations through the regulatory agencies. In addition, the support programs have a significant component providing access and information exchange on international experience and regulatory standards [1]. Safety assessment methodologies are established insuring in-depth technical knowledge of the installation, supporting exchanges with the design and operating organizations, and providing the latest technical and scientific results from the international nuclear community.

Many of the program elements were developed supporting comprehensive data bases at the TSOs including operating events, installation specific design and operating information, technical data, technical and regulatory assessments utilizing knowledge management systems. Obtaining and transferring critical scientific tools, computer codes, and methodologies were and still are a significant component of the cooperative programs allowing the TSOs to perform analytical assessment as an independent agency, and providing sound scientific and technical bases for critical regulatory decisions. The international regulator assistance program consider and use the basic principles applied in US NRC and international regulatory experience such as, the defense-in-depth concept, risk-informed regulatory approaches, and sound radiation protection principles.

The NRC’s nuclear regulatory assistance program has changed over the years responding to new, international developments, specifically the planned expansion of nuclear installations in countries with relatively limited nuclear regulatory infrastructure. The program provides assistance to countries with new or expanding nuclear power programs helping to establish and maintain effective nuclear safety and security regulatory authorities. The cooperation program assists in the development of regulatory agency infrastructure, organization, staffing, training, and also providing significant technical support. It also supports the development of nuclear regulatory programs, overview of laws and regulations related to nuclear
industry and regulation as well as regulatory guidance, and the development and delivery of training for regulatory agency management and staff.

In recent years the cooperation has increased to technical areas beyond safety analysis, severe accident events, and initial licensing methodologies, issues related to new construction of nuclear facilities, and the application of a risk-informed regulatory regime [2]. A limited sample of recent cooperative programs indicates a wide-ranging interest among nuclear regulators in these specific technical areas reflecting the need to expand the scientific knowledge base at the TSOs enabling a better response to industry initiatives and future regulatory challenges:

- Assist in improving training guidance and instructions in, a) inspection procedures and b) targeted inspections plans
- Cooperate on construction inspection methods as applicable to certified designs
- Assist in implementing risk-informed inspection processes, developing risk-informed regulatory regime and severe accident managements, external hazard analyses
- Provide support in using PRA techniques for Technical Specification improvements
- Information exchange on NPP license extension, aging, reduction of uncertainties in safety analysis assumptions and methodologies
- Evaluate methodologies assessing operating margins
- Safety issues in application of digital instrumentation
- Support establishing a regulatory review framework for standardized/certified designs
- Treatment of human and organizational factors
- University based regulatory training – providing potential future regulatory personnel
- Modification of fuel cycle facilities, decommissioning approaches.

In contrast to US practices, most countries have limited sets of TSOs that the nuclear regulator may rely on to supplement and augment regulatory review capabilities. In addition, some of the countries have institutional arrangements assigning dedicated TSOs for regulatory review functions. Normally, a few dedicated TSOs are available as separate legal entities allowing direct contractual relationship between the TSOs and international organizations. The technical assistance for TSOs concentrate on two general areas, a) developing very specialized skills and experience applicable to nuclear regulatory reviews and b) improving or developing general engineering expertise. In awarding contracts, the NRC encourages and supports assistance that avoids conflict of interests that may arise due to the limited nuclear expertise available in many countries. In order to maintain public confidence in the regulatory reviews, the conflict of interest issues are extremely important and are fully recognized by nuclear regulators. Due to the
institutional arrangements, where dedicated TSOs are preselected for regulatory reviews, the contracting procedure is using mostly sole source processes, which pose difficult issues in the US involving sensitivities to legal requirements. A sound contracting process ensures that the regulatory agency has access to experienced and knowledgeable TSO staff that can provide technical expertise enhancing the capabilities and public confidence of the regulator.

3. CONCLUSION

One of the important objectives of the US NRC’s international regulatory assistance program is to strengthen the oversight capabilities and effectiveness of the foreign nuclear regulatory agencies and improve the TSO’s ability to carry out the required technical supports. In each respective country, the OIP’s regulatory assistance program further enhances the regulatory regimes; improve nuclear regulations and standards, which are more consistent with international and IAEA practices. The main benefit of the regulatory and technical cooperation is the improvement in regulatory and technical capabilities both at the nuclear regulatory agency and the TSOs. The future challenge is to ensure that the cooperation between NRC and foreign regulatory agencies responds to the country specific regulatory needs and further increase the capabilities with an overall increase in the safety of the nuclear facilities.

International cooperation among the nuclear regulatory agencies and TSOs significantly enhances nuclear safety in all the respective countries. The nuclear regulatory agencies have many important responsibilities, which are complimented by the TSOs technical expertise on specific technical and scientific areas. One of the important functions of the TSOs is to develop and maintain well trained experts in the respective technical and scientific fields. The international nature of the nuclear industry also requires the cooperation among the regulatory bodies including TSOs contributing to the development of global network of institutions, which may serve as the basis for a coordinated approach to improved nuclear regulatory methodology and increased nuclear safety.

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CHALLENGES IN REGULATING RADIATION SOURCES AND ASSOCIATED WASTE MANAGEMENT

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Abstract

Radiation sources are widely used in the fields of medical, industry, agriculture, research, etc. Owing to the inherent risk of exposure to ionizing radiation while using the radiation sources and management of associated waste, safety measures are of utmost importance including robust regulatory control. Pakistan Nuclear Regulatory Authority (PNRA) is responsible for supervising all matters pertaining to nuclear safety and radiation protection in the country. Since its inception, PNRA has made rigorous efforts to regulate the radiation facilities, for which regulatory framework was further strengthened by taking into account international norms/practices. However, due to vibrant use of these facilities, there are numerous challenges being faced while implementing the regulatory framework. These challenges pertain to shielding design of some facilities, control over service provider for QC/repair/maintenance of radiation equipment, assessment of patient doses and establishment of national diagnostic reference levels for radiological procedures. Further, the regulatory framework also delineates requirements to minimize the generation of associated radioactive waste. The requirements also necessitate that certain sealed radioactive sources (SRS) are returned to the supplier upon completion of their useful life, while other radioactive sources are stored at designated radioactive waste storage facilities in the country.

1. INTRODUCTION

Radiation sources have many beneficial applications in different fields such as medicine, industry, agriculture, research, etc. Radioactive waste is also generated by the use of radiation sources at different types of radiation facilities. Ionizing radiation emitted from the radiation sources and radioactive waste is a potential hazard to human health and the environment. Regulatory systems are established to control the use of radiation sources and to ensure the protection of people and environment from harmful effects of ionizing radiation. Like other countries, the use
of radiation sources is increasing in Pakistan with the passage of time. There are more than four thousand (4000) licensed radiation facilities in the country [1]. Different types of licensed radiation facilities are shown in Fig.1.

The Pakistan Nuclear Regulatory Authority (PNRA) is the independent regulatory body of the country established by Govt. of Pakistan under Pakistan Nuclear Regulatory Authority Ordinance 2001 [2], with the responsibility to ensure the safe operation of nuclear installations and radiation facilities and to protect radiation workers, general public and the environment from the harmful effects of ionizing radiation.

FIG. 1. Different types of licensed radiation facilities

2. CHALLENGES AND PNRA EFFORTS

Since its inception, PNRA has made various efforts to regulate the radiation facilities effectively. In regulating radiation facilities, the challenges being faced are relevant to shielding design of facilities, control over service provider for QC/repair maintenance of radiation equipment, assessment of patient doses and establishment of national diagnostic reference levels for radiological procedures and management of Disused Sealed Radioactive Sources (DSRS). PNRA has already taken steps and further planning to overcome the challenges in regulating radiation sources so that protection of workers, public and environment may be ensured. The identified challenges and PNRA efforts to overcome them are described as follows.
2.1. Shielding design of radiation facilities

The licensee has to submit details of shielding design of radiation facility along with other submissions under Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) - PAK/908 [3], at the time of registration/licensing of radiation facility. The submissions relevant to shielding are reviewed thoroughly in the light of IAEA/international standards/guidelines and licensee is informed if any discrepancy is observed or further information is required. PNRA has developed software for the shielding calculations of medical radiation facilities. The adequacy of provided shielding is also verified through radiation survey during pre-licensing inspection of radiation facilities.

On some occasions, leakage of radiation has been observed through the installed/constructed shielding usually at the joints of structures. The flaws in the shielding are due to lack of quality management during construction of buildings of radiation facilities. PNRA issues directive to the licensee for corrective action. The modifications to remove the flaws in the shielding are difficult and expensive for licensee. Furthermore, PNRA inspectors have to conduct follow-up inspections to verify the corrective actions taken by the licensee.

There is shortage of qualified experts in radiation protection and licensees face problems in shielding design/calculations for radiation facilities particularly Medical LINAC facilities or PET-Cyclotron facilities. PNRA has established National Institute of Safety and Security (NISAS) for the training of PNRA employees as well as licensee’s personnel in the fields of radiation protection, nuclear safety and security. PNRA organizes training courses at NISAS relevant to shielding design of radiation facilities from time to time for its licensees.

2.2. Service provider for QC/repair/maintenance

Generally, companies have business of import and sale of radiation generators/equipment are involved in the installation/testing/maintenance of radiation generators/equipment within the contract period agreed with licensees. There is lack of service providers for QC/repair/maintenance of radiation generators/equipment in the country; therefore, licensees face problems in the periodic QC/repair/maintenance of radiation generators/equipment. In addition, there is no check on quality of services they are providing to the licensees. PNRA organizes training courses to aware/train licensee’s personnel regarding QC of radiation generators/equipment. PNRA inspectors also perform some QC tests like collimation, beam alignment of diagnostic X-ray machines during periodic inspections of radiation facilities and provide guidance to licensees for QC/repair/maintenance of equipment.

PNRA is regulating import and sale of radiation generators/equipment; whereas, the service providers involved in QC/repair/maintenance are not being regulated. PNRA intends to regulate the service providers by including a provision
in the Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installations - PAK/908 [3]. These regulations are currently under revision and after gazette notification of the revised regulations, only authorized service providers will be allowed to perform QC/repair/maintenance of radiation generators/equipment.

2.3. Patient dose assessment and national diagnostic reference levels

Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that a cancer is not cured or the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome. In X-ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, a diagnostic reference level is used to indicate the need for an investigation [6]. PNRA has specified guidance levels for medical exposure in the Regulations on Radiation Protection - PAK/904 [4] for the use by medical professionals in the conduct of diagnostic and therapeutic radiological procedures. These guidance levels are adopted from International Basic Safety Standards (the BSS) [7].

Periodic studies are essential in order to assess patient exposures to radiation in the conduct of radiological procedures. PNRA has conducted few studies for assessment and comparison of patient doses with the guidance/reference levels in diagnostic radiology, interventional cardiology and nuclear medicine procedures. PNRA intends to enhance frequency of such studies to assess patient exposures in various types of radiological procedures. These studies will be useful to know the status of patient dose management at medical centres and in making strategy for the improvement of radiation protection of patients. PNRA also intends to establish national diagnostic reference levels for medical exposures. There is need of wide scale surveys at national level for this purpose.

PNRA is facing problems like shortage of trained personnel, unavailability of appropriate equipment/tools and financial resources to conduct studies and surveys for the patient dose assessment and establishment of national diagnostic reference levels. However, PNRA is planning to obtain data for different types of radiological procedures from medical centres through distribution of data collection forms to licensees. The collected data may be helpful to achieve the goal.

2.4. Management of disused sealed radioactive sources

PNRA has issued Regulations on Radioactive Waste Management - PAK/915 [5] for the safe management of radioactive waste including Disused Sealed Radioactive Sources (DSRS). The regulations describe the responsibilities of licensee for the safe and secure use and management of radiation sources. PNRA has established the requirement for the licensee to minimize the generation of radioactive waste as practicable. Certain sealed radioactive sources (SRS) after their useful life are returned to the supplier for their management however, other radioactive sources throughout the country are stored at designated radioactive waste
storage facilities. Fig. 2 illustrates the status of sealed radioactive sources in the country.

PNRA implements cradle-to-grave approach to keep the track of all radioactive sources. PNRA issues NOCs for import of new radioactive sources or radiation generators into the country and for export of disused radioactive sources and generators/empty containers. PNRA conducts inspections to check the compliance of regulatory requirements and for physical verification of inventory of SRS. Presence of Disused Sealed Radioactive Sources (DSRS) at radiation facilities is discouraged due to safety and security concerns.

![FIG. 2. Status of sealed radioactive sources](image)

Sometimes, PNRA face problem of delay from licensee side in returning the DSRS to supplier or transferring it to the designated storage facility due to some administrative or financial reasons. If any DSRS is found at a radiation facility for long time, PNRA inspectors conduct special inspection and discuss the problem with the licensee or directives are issued to the licensee to resolve the problem without further delay. PNRA is also considering to include a responsibility of licensee in the Regulations PAK/908 (currently under revision) to ensure the availability of funds for decommissioning of radiation facilities or disposal of radiation sources, at the time of licensing of radiation facilities.

3. CONCLUSION

PNRA is continuously striving for effective regulatory control over the safe and secure use of radiation sources in the country. PNRA pays special attention to capacity building of its employees as well as licensee’s personnel and believes that it
can play a vital role in overcoming the challenges. PNRA has made rigorous efforts to discharge its responsibilities and is committed to overcome all the challenges to accomplish its mission.

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Abstract

One of the elements essential for any organization to become a learning organization is to learn from its own and others experience. The importance of utilizing experience feedback for enhancing operational safety is highlighted in nuclear industry again and again and this has resulted in establishment of several national and international forums. In addition, IAEA action plan on nuclear safety issued after Fukushima accident further highlighted the importance of experience sharing among nuclear community to enhance global nuclear safety regime. PNRA utilizes operating experience feedback gathered through different sources in order to improve its regulatory processes. During the review of licensing submissions, special emphasis is given to utilize the lessons learnt from experience feedback relating to nuclear industry within and outside the country. This emphasis has gradually resulted in various safety improvements in the nuclear power plants being installed in Pakistan. Accordingly, PNRA has developed a systematic process of evaluation of international operating experience feedback with the aim to create safety conscious approach. This process includes collecting information from different international forums such as IAEA, regulatory bodies of other countries and useful feedback of past accidents followed by its screening, evaluation and suggesting recommendations both for PNRA and its licensees. As a result of this process, several improvements concerning regulatory inspection plans of PNRA as well as in regulatory decision making and operational practices of licensees have been highlighted. This paper will present PNRA approach for utilizing experience feedback in its regulatory processes for enhancing / improving nuclear safety.
1. INTRODUCTION

It is widely observed in everyday life that serious accidents are nearly always preceded by minor precursors. If lessons can be learned from the precursors and these are put into practice, the probability of occurrence of serious accident can be reduced significantly. In nuclear industry, including all stakeholders i.e. utility, regulatory authority etc. the recurrence of events can be prevented by effectively utilizing the operating experience feedback program. The importance of operating experience feedback program was prominently acknowledged all over the world since after TMI accident in 1979 and need for its systematic evaluation was highlighted by nuclear power plant operators and regulatory bodies.

Fukushima accident further highlighted the importance of sharing operating experience feedback and eventually this element was reflected as one of the major element in IAEA action plan on nuclear safety [1].

Regulatory framework requires from licensee to consider utilization of operating experience feedback for achieving the ultimate objective of safe operation of nuclear power plants. The role of regulator in this regard is defined in IAEA safety standard GS-R-1 which establishes requirement regarding verification of effective functioning of operating experience feedback process of licensee [2]. This verification ensures that operating organization is executing appropriate analysis, disseminating lesson learnt to the responsible units and monitoring the effective implementation of the process.

Regulatory core processes also ensure that the objective of safe operation of NPPs are being met, therefore, evaluation of experience feedback by regulatory body also provide insight for the enhancement in the existing core processes / regulatory oversight.

2. IMPORTANCE OF OPERATING EXPERIENCE FEEDBACK (OEF) IN PAKISTAN

The importance of utilization of experience feedback is widely acknowledged and reflected in processes both at operating organization and regulatory body in order to learn from experiences of others and to avoid similar problems at Pakistan.

The national experience feedback of nuclear industry comprises of several decades and is useful source of improvement for emerging nuclear power projects. Pakistan Atomic Energy Commission (PAEC) being the only operating organization in the country has established operating experience feedback process for utilizing national and international experience. The events occurred at one plant are shared with others to avoid recurrence of similar events.

Pakistan Nuclear Regulatory Authority (PNRA), being the nuclear regulator in Pakistan, has established requirements for licensees in its Regulations on the Safety of Nuclear Power Plant Operation PAK/913, to formulate formal process for utilizing operating experience feedback in operating organization [3]. Moreover,
PNRA management system manual requires reviewing its regulatory framework in the light of feedback from stakeholder, operating experience and current international standards and practices.

Therefore, PNRA is primarily responsible for ensuring, by regulatory oversight process, that OEF process of licensee is functional and effective as well as PNRA also evaluates international and national operating experience in a systematic way to:

- Improving regulatory processes e.g. inspections, review and assessment, licensing etc. at PNRA;
- Recommend actions to licensees in order to enhance nuclear safety in operating NPPs;
- Conveys feedback of regulatory concerns raised during operation of NPPs to the NPP projects (i.e. under construction, installation etc.) so that problems could be resolved by consideration in design improvements rather than retrofitting in design after bringing that plant into operation.

3. USE OF EXPERIENCE FEEDBACK IN IMPROVING REGULATORY PROCESSES

PNRA is striving to improve its regulatory processes learning from experience feedback and so far following core processes have been further refined;

3.1. Licensing Process

Utilization of OEF is specially focused during review of applications submitted by licensee for authorization at different stages of NPPs (e.g. construction licence, permission for introduction of nuclear material into the nuclear installation, etc.). Initially PNRA process for review and assessment of licensing submissions was composed of two phases i.e. review of format and contents and detailed review phase. The detailed review phase was augmented in 2005 with audit calculations (i.e. limited scope) of safety assessment presented by licensee in its submissions learning from experiences of other regulatory authorities in the world.

In order to further utilize experience feedback in review and assessment process, in addition to said phases, third phase was also introduced in 2005 i.e. review in the light of operating experience feedback. The purpose of addition of third phase was to review the licensing application to ensure that appropriate measures have been taken into account in the design of NPPs and in the practices that will be followed at NPPs to avoid reoccurrence of similar events in Pakistan.
3.2. Development / Revision of Regulatory Framework

In line with PNRA management system, process for revision and development of regulatory framework considers input of experience feedback received internationally on regulatory requirements e.g. revision of IAEA standards, practices of other regulatory authorities, major accidents in nuclear industry etc. for improving PNRA regulations.

As an example, PNRA reviewed regulatory framework for licensing of operating personnel in the light of experience feedback and practices followed at other regulatory authorities. Currently, annual renewal of operating personnel licence at NPPs is required as per regulatory framework. For this renewal, licensee has to submit the evidence of re-training, completion of minimum shift duties and medical fitness certificate. It has been learned through experience that knowledge level of operators degrade with the passage of time for those areas that are not regularly in use by the operators but are still essential for their activities as reactor operator/shift engineer/shift supervisor.

Learning from this experience, need for revalidation of operating personnel licence after certain period of time was felt which is currently not included in PNRA's regulatory framework. Moreover, such practices for revalidation of licence of operating personnel are also followed in other countries. PNRA is also considering to include the step of revalidation of operating personnel licence (i.e. after specific period of time) in the authorization process for ensuring that required level of knowledge is being maintained by the operating personnel in all areas required for carrying out safety related activities.

Particularly, PNRA also considered/reviewed its regulatory framework in the light of lessons learnt from Fukushima accident so that further improvements can be made in order to cater new areas highlighted from the accident. Accordingly, comprehensive review of PNRA regulations related to the safety of nuclear power plants was initiated. The review process comprised of three steps; identification of regulations that might need revision as a result of this accident, thorough review of these identified regulations and furnishing recommendations for the improvement in these regulations.

After completing this review process, PNRA issued a report on the ‘Review of PNRA Regulations on Nuclear Power Plants Safety based on Feedback of Fukushima Accident’ providing recommendations to modify PNRA regulations for incorporating lessons learnt from the accident [4]. The proposal for modification in the regulations was initiated for thorough review as per established procedure for revision of regulations at PNRA. A view of the report is shown in Figure-1.
3.3. Regulatory Inspection Process

A number of events reported in nuclear industry are also relevant to equipment manufacturing, therefore, PNRA focused inspection process during manufacturing of safety significant equipment. In this process, PNRA made improvements in the following two fronts;

a. Scope of Selection of Inspection Points and Preparations for Regulatory Inspections

Issues like flaw detection in the Reactor Pressure Vessel (RPV) of Belgium during In-Service Inspection require pro-active approach from the regulatory body. As RPV is the limiting equipment and determines the life of the nuclear power plant, scope of regulatory inspection during manufacturing needs to be enhanced so that such failures can be avoided. In order to utilize this feedback, PNRA revisited its selection process for inspection during equipment manufacturing. Accordingly, following steps have been taken;

— As a first step PNRA requires from the licensee to submit the quality plans of the forgings and test coupons of long lead equipment i.e. RPV, Steam Generator (SG) etc., Withstanding of regulatory overburden and graded approach, PNRA selected control points mostly as "record point" for regulatory inspection;

— As a second step, PNRA extended the reporting requirements by including the submission of lists of Non-Conformance Reports (NCRs) of all categories related to nuclear safety class equipment on quarterly basis. This list enabled PNRA to further probe into the disposition of significant NCR and also helped PNRA to further inquire/verify the record of relevant NCRs in subsequent manufacturing inspection.
— As a third step, basis for preparation of checklist for the manufacturing inspection has been broadened by including the feedback of previous regulatory inspections, briefing session among the pool of experts involved in the previous/similar inspections (i.e. for extraction of tacit knowledge), events reported at international level (i.e. IRS, INES, etc.) and list of non-conformances submitted in second step.

b. Chain Verification of Certificates

Learning from experiences of other countries like South Korea regarding submission of forged documents to regulatory body, PNRA is considering to include chain verification of certificates on sampling basis submitted by licensee/applicant. Accordingly, chain verification step will be added in regulatory processes e.g. regulatory inspections, etc. This will further augment the layers established by PNRA for ensuring safety. PNRA is thinking on following lines in order to include the chain verification of certificates;

— Chain verification can be performed by extending the scope of existing regulatory oversight or this can be required through the inclusion of respective requirements in the Management System of the licensee/applicant;
— In case of extension of regulatory oversight, PNRA may perform the audit inspection/verification of the internal process of the subcontractor involved in the issuance of that certificate;
— Where appropriate, PNRA can require the same examination by third party to get the similar certification e.g. material testing/qualification certificates.

It may be mentioned that the concept of chain verification can also be implemented during the licensing process of operating personnel e.g. medical examination report of operating personnel.

4. PNRA EXPERIENCE FEEDBACK UTILIZATION PROCESS FOR ENHANCING NUCLEAR SAFETY

PNRA has been receiving feedback on operating experience through different sources such as IRS, INES and from the channels of regulatory bodies of other countries. In recent years, PNRA has evolved a structured mechanism for collection and evaluation of international operating experience feedback for suggesting recommendation to licensees (i.e. operational NPPs, equipment manufacturers, NPPs under construction and installation phase, research reactors, etc.) and also for PNRA in order to ensure / enhance safety. The methodology for evaluation of
operating experience feedback was developed based on practices being carried out internationally and is shown in Figure 2.

One of the purposes of this process was to assure that safety relevant operating experience, especially accident precursors, are not overlooked. The outcome of evaluation of international operating experience feedback process is also very important to support the activities that PNRA has to perform in areas such as safety assessments, drafting regulations, etc. This is a cyclic process and a report is issued after completing each cycle in six months. The process for evaluation of operating experience feedback at PNRA is described in PNRA procedure [5]. Different steps of the methodology are described in following sections;

4.1. **Formation of Evaluation Team**

A dedicated team having experience of licensing and inspections of NPPs is formulated for evaluation of operating experience feedback being received at PNRA. In case of specialized areas, additional expertise opinion may also be obtained from within PNRA on case to case bases.
4.2. Collection of all Relevant Operating Experience Information through Identified Sources

For evaluating the international operating experience feedback, first step is to collect the relevant information from identified sources. These may include IRS reports, INES reports, useful information from the channels of regulatory bodies of other countries and information received from previous accidents at nuclear installations. This information is distributed among all the team members for further processing / evaluation.

4.3. Screening of Information

Screening of information is carried out on the basis of “safety significance”, “technical applicability” and “generic applicability”. Safety significance is determined by assessing the potential and real impact of event on safety of the plant and potential consequences. Technical applicability is determined from the type of plant on which event has occurred. If the plant is of similar type to that of Pakistan's NPPs (PWR and PHWR type) then the event is evaluated to extract any specific lessons to avoid occurrence of such event at Pakistan's NPPs of similar type. There may be few events occurring on plants of different types but provide generic safety oriented information which may be applicable at plants of other types. Such events are evaluated to extract lessons of generic nature.

4.4. Analysis of Information and Recommendations / Actions

The information screened out in the previous step is evaluated and analyzed thoroughly to extract lessons applicable to nuclear installations in Pakistan and also regulatory processes being carried out at PNRA. After evaluation, recommendations / actions are proposed with actions assigned for the relevant licensees and PNRA. This evaluation is in the form of traceable record, e.g. report, letter, directives, etc. PNRA has so far issued six reports on biannual basis as shown in Figure-3.

4.5. Communication of Recommendations/Actions to Licensee and within PNRA

The recommendations/actions set forth are communicated to licensee (if deemed necessary) with the view that these recommendations/actions will be considered to avoid occurrence of similar events at Pakistan's nuclear installations. Recommendations for improvement in PNRA processes are also circulated to directorates responsible for that specific activity (i.e. inspections, review and assessment, etc.) so that proposals for necessary improvements in regulatory processes may be developed in order to enhance regulatory effectiveness.
4.6. Follow-up

After communicating the recommendations / actions, follow-up of these actions is carried out to ensure that they have been implemented for improving / enhancing nuclear safety and also regulatory processes.

4.7. Outcome

Operating NPPs at Chashma and Karachi have initiated actions against recommendations being highlighted in reports issued by PNRA for NPPs. These actions / recommendations have been widely circulated by plant management to relevant work units for evaluation / relevance and identification of proposal for initiation of any actions e.g. administrative actions, changes / modifications etc. Plant management is also being contacting designer in few cases for gathering expert opinion related to implementation of certain modifications originating as result of these actions. Moreover, feedback of these operating experiences has also been included in training sessions of plant personnel (i.e. including operators).

In order to cater actions for improvement of regulatory processes at PNRA, proposals have been initiated at relevant forums for revising / improving regulatory processes for enhancing regulatory effectiveness.
5. SHARING OF IMPLEMENTATION STATUS OF OEF AS A RESULT OF FUKUSHIMA ACCIDENT

After the Fukushima accident, PNRA required operating and under-construction NPPs in Pakistan to revisit the areas like hazards, design, emergency arrangements, availability of power sources, etc., in line with IAEA action plan on nuclear safety to incorporate the feedback and lessons so far learnt from the accident. The progress of implementation of these actions is being reflected in the National report of Pakistan on Convention on Nuclear Safety i.e., 6th National Report (2014) [6] and National Report for the 2nd Extraordinary Meeting (2012) [7].
6. CONCLUSION

Effective use of experience feedback has pivotal role in improving nuclear safety. As per regulatory requirement, the responsibility lies with operator to develop effective process for learning from national and international operating experience feedback. Along with licensee, PNRA also performs independent evaluation of operating experience feedback received at PNRA from nuclear industry around the globe from regulatory perspective in order to support its functions, responsibilities and missions. The theme and intentions of learning and implementation of lessons learned from previous events are to adopt safety conscious approach so that recurrence of such events is avoided. This process has so far proved useful and acknowledged by the licensee by incorporating recommendations in its corrective action plan. Moreover, valuable improvement in regulatory process has also been carried out learning from experiences of other countries.

REFERENCES

BAPETEN GOES SOCIAL MEDIA INITIATIVE
An age-based segmentation service to communicate with public

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Abstract

The paper proposes a shifting method to communicate with public using age segmentation. It utilizes the power of social media as an additional way to disseminate information along with the existing classic website. Empowered by the legal basis to provide simple and effective mechanism to share public information and driven by social media popularity in Indonesia, BAPETEN finds a new direction to better understand its audience.

As a starting point, it uses third party RSS (Really Simple Syndication) feed mechanism that allows BAPETEN to syndicate material across the web (from one to many). As long as the system works, the information created in the web will be automatically posted to the social media platforms.

1. INTRODUCTION

Many terms used to explain social media. Buettner [1] expressed social media as computer-mediated tools that allow people or companies to create, share, or exchange information, career interests, ideas, and pictures/videos in virtual communities and networks. Kaplan and Michael [2] defined it as a group of internet-based applications that build on the ideological and technological foundations of Web 2.0, and that allow the creation and exchange of user-generated content.

According to Working Group on Public Communication of Nuclear Regulatory Organisations (WGPC) [5], social media is referring to various activities that integrate technology, social interaction and content creation. It is fast, cheap to the consumer, easily available and part of the fabric of people’s lives. Social media also brings attention as it enables conversation that everyone can participate in.

Public relations practitioners around the world have been paying attention to social media as an important communication tool. Research done in 2010 by the public relations firm Burston-arsteller found that eight of 10 Fortune Global 100 companies used at least one of the most popular social media platforms i.e. Twitter, Facebook, YouTube or corporate blogging. Furthermore, a post-Fukushima informal poll indicated many nations’ nuclear regulators are looking at broadening their social media use, although some may not know how to proceed, and everyone can benefit from the “lessons learned” by others.
2. REGULATORY REQUIREMENTS FOR PUBLIC COMMUNICATION

Relevant IAEA Safety Standards have stated the responsibility of government to set up appropriate means of informing and consulting interested parties and the public parties about the possible radiation risks associated with facilities and activities, as well as the processes and decisions of the regulatory body. In particular, such communication shall be conducted in an open and inclusive process.

At national level, Act Number 14/2008 regarding Public Information Disclosure is a key regulatory framework that mandated all government institutions to provide public information in plain language and easy to understand through any effective and efficient means. This Act divided the information into three categories:

- Periodic (should be updated every 6 months), e.g. institutional profile, current activities, regulations, financial report, procurement, etc.;
- Immediate (information that potential to threaten lives) e.g. emergency response and evacuation procedure; and
- Available (upon request) e.g. policies, project plans, Memorandum of Understanding, procedures, etc.

Classified information remains to protect law enforcement process, intellectual property rights, national economy security, state defense as well as international relationship.


So far, we disseminate public information by three different media: (1) printed, (2) electronic, and (3) public gathering. But the fast growing of internet technology in public sector has introduced a competitive advantage compared with the other two.

3. BAPETEN AND E-GOVERNMENT ESTABLISHMENT

E-government is argued as an essential component in overall reform agendas since it can be used as a tool to reform and renew interest in public management, and points out the commitment to good governance objectives (OECD 2003) [5]. It can improve efficiency; provide greater opportunities for citizens to participate in government activities and decisions democratically; and build trust between government and citizens. In view of this, it is well-acknowledged fact that many countries, including developing countries, have implemented e-government initiatives to replace the functions performed by traditional government.
Along with that fast emerging of internet technology and so e-government, the penetration of mobile technologies is also increasing even faster, especially in developing countries, which causes people to be more inclined to mobile usage than landline connections. International Telecommunication Union in 2014 predicts by the end of 2014 the mobile cellular subscriptions worldwide will reach about 7 billion, two times greater than internet users. In developing countries, these numbers have been massively increasing in five years, from 3.3 billion to 5.4 billion for mobile cellular subscriptions and from 974 million to 1.9 billion for internet users.

In Indonesia, the significant changes in political system has led to the implementation of e-government and m-government. A study by Sadat [6] shows that m-government in Indonesia’s LAPOR! has the potential to increase citizens’ participation in government activities. The available policies and regulations, mobile infrastructure and technologies, and applications and content development can support participation by using m-government. Its success rate and positive impacts/benefits also indicates its potential in encouraging more participation, particularly by addressing some identified challenges.

Accordingly, as stipulated in The ICT Master Plan 2015-2019, a number of IT projects within BAPETEN have been established to improve and simplify regulatory functions. A major project was initiated in 2012 as a part of the Indonesian National Single Window (INSW) Project. Being the first government agency to be fully integrated with the INSW, BAPETEN has offered substantial changes in licensing process to its customers. Within this scheme, the approval process that took several days can now be reduced to a single day. Once approved, customers can go directly to the clearance process in the airports and seaports customs.

4. NEXT: GO SOCIAL MEDIA, CREATE LARGER AUDIENCE

Regulatory bodies have been aware of the significance of social media as an important communication tool, and many regulatory bodies have been using them or considering their usage. However, many regulatory bodies are unclear about how to proceed with developing social media content, and how to integrate the platforms into existing public communication programs.

As a matter of fact, Indonesia has nearly 74 million active social media fans. It is easy to predict that younger population (age: 12-34) dominates this digital native demographic. This number increases more than 19% in one year only (January 2015 – January 2015) [4]. Facebook takes the lead in social media platform which makes Indonesia as the 4th largest Facebook population in the world. After many years of delivering classic website and learning from the above fact, BAPETEN needs to integrate social media engagement into existing public communication program. Technically, we should create a public communication service based on age differentiation. The option is to use major social media platforms (e.g. WhatsApp, Twitter and LinkedIn).
Due to our lack of competent human resources to heavily involved in social media, this initiative is done by third party RSS (Really Simple Syndication) feed mechanism that allows us to syndicate material across the web (from one to many). Every half an hour, all new information available in our website is transmitted to third party website that handle RSS feeding. Seamless integration created in this scheme allows us to focus only to the content of classic web site. As long as the system works, the information created in the web will be automatically posted to the social media platforms. We started this so-called “BAPETEN Goes Social Media Initiative” in October 2013.

Using respective built-in analytics and metrics, our record shows slow but increase activities from those social media platforms, including post reach and engagement (likes, comments, and shares). Analytics from Facebook (Fig. 2), for example, shows that 66% engagement rate coming from age 18 to 34, while Fig. 3 tells us that the most commented news is achieved in October 2015, when we post a TV talk show regarding medical patient dose.
FIG. 2. Facebook analytics on facebook.com/bapeten.

FIG. 3. Total Likes on facebook.com/bapeten.

Reviewing the complete social media analytics brings a new understanding on how to perform a better way to communicate with parties. This is in turn will satisfy the requirement to establish and maintain the confidence and trust of interested parties in order to be identified as an independent, transparent, reliable and competent regulatory body.

5. FUTURE WORKS

Despite of lack in man power, the demand for involving social media in public communication remains high in BAPETEN. A simple yet effective mechanism has been introduced to overcome challenges in social media engagement. Although there is a slow response at the initial stage, built-in Facebook analytics show an increase trend in the public engagement (likes, comments, and shares). Future works include how to have rich-content social media, personal engagements, etc.
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ENHANCING BAPETEN REGULATORY SYSTEM THROUGH STRENGTHENED INTERNATIONAL AND REGIONAL COOPERATION IN SAFETY, SECURITY AND SAFEGUARD ASPECTS

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Abstract

Nuclear energy development in implementation is currently in speedy progress. Researches and developments in national level should always be in line with international trends and paradigms. In term or regulatory system of which the role is borne by the regulatory agency, the dynamics of standards and guidance set by international agencies or any world-wide associations as well as by other advanced countries shall provide the various nuances in national regulatory system application. Further published results of research and publications released by the counterparts are utilized as references in drafting new regulations and amending several other old regulations that need to be revised. International collaborations can technically support and enhance the effectiveness in regulatory system as the beneficial shared knowledge and best practices. Several countries may have more advanced experiences in regulatory process for their nuclear energy implementations, such condition can be taken as advantages for other emerging countries in nuclear plans.

1. INTRODUCTION

BAPETEN as Nuclear Energy regulatory Agency in Indonesia has three main functions in playing its important role of regulating nuclear energy implementation through regulation making, licensing and inspection. The process is supported by internal technical supporting organization as part of its working units; two assessment centres for radiation facilities and radioactive materials and for nuclear material installation. There are as well three other non-technical supporting organizations: the planning bureau; legal and organizational bureau; and general affairs bureau. Apart from that, BAPETEN is equipped with a training and education division in charge for human resources competency and development.

2. INTERNATIONAL COOPERATION SECTION

The international cooperation which is affiliated within the Planning Bureau has the responsibilities of providing the umbrellas for all types of required cooperation both internationally and regionally. The memorandum of understandings being prepared for the enhanced regulatory system can be established either in bilateral or multi-lateral collaborations. Benefits and advantages
of such cooperation and collaborations will be mutual for the parties signing the agreement or arrangement. Scope of the international cooperation covers the safety, security and safeguard aspects which will be directly implemented in future regulation whenever an amendment is considered required. Indonesia has committed to fully implement the Non-Proliferation Treaty as a support for Peaceful Uses Initiatives launched by IAEA later on in 2010.

3. INTERNATIONAL COOPERATION ACTIVITIES IN BAPETEN

Several MoUs have existed even before BAPETEN was independently established. For example in term of Arrangements with the US-NRC for the collaboration within safety aspects of nuclear energy implementation, it has been initiated since 1992 when BAPETEN was still part of BATAN as the Nuclear Energy Agency. When finally BAPETEN was independently established in year 2000, the Arrangements were then renewed periodically in every five (5) years. Recently BAPETEN and US NRC have renewed the Arrangements during the IAEA General Conference in Vienna September 2015. The implementation of the Arrangements itself will cover the possibility for a fellowship as in on-the-job training (OJT) program for BAPETEN employee in US NRC, where a fellow of junior staff in BAPETEN can apply to get the OJT in US NRC for a duration of six (6) months up to two (2) years. For this particular matter the financial supports will be borne by either of the parties or even by a third party like TC Programme of IAEA. Apart from that US NRC has as well committed to provide supports for nuclear power plants embarking program in Indonesia by sharing its computer code to be used by the Assessment Center for Nuclear Material Installation for thermal hydraulic and neutron production calculation in any newly design nuclear reactors which will be submitted by the licensees for their licensing application.
Some other MoUs for bilateral cooperation are also well-maintained like the MoU with KINS (Korea Institute for Nuclear Safety), KINAC (Korea Institute for Nuclear Nonproliferation and Control), ASNO (Australian Safeguard and Nonproliferation Office), Nuclear Regulatory Authority of Slovak Republic, AELB (Atomic Energy Licensing Board, Malaysia), Arrangements with US DoE (United States Department of Energy), Arrangements with ARPANSA (Australian Radiation Protection and Nuclear Safety Agency). Apart from that due to the strong demands for regulatory system for new generation of nuclear reactors, BAPETEN is initiating some new proposed collaboration with some counterparts in regulatory agencies like Rostechnadzur (Russian Nuclear Regulatory Agency), GRS (Germany Technical Supporting Organization for Nuclear Regulatory Control), China NNSA (China National Nuclear Safety Administration). It is expected that BAPETEN can enhance the regulatory system to support the national plan to employ the Non Commercial Nuclear Power Plant in Serpong, Jakarta.

Regional cooperation for nuclear energy regulators are to be formed in ASEANTOM as an official organization of nuclear energy regulators in South East Asian region to further support the ANSN (Asian Nuclear Safety Network) and other regional network that have been established in earlier phase.

Considering that Indonesia does not yet have an advanced technology in term of nuclear energy implementation, the cooperations and collaborations with other international regulatory agencies can contribute benefits in developing capacity building for the human resources as regulators.

### 3.8. Cooperation in Nuclear and Radiation Safety

Most of the existing international cooperation established by BAPETEN are covered within nuclear and radiation safety. It concerns with the nature of safety term existence in the past. It relates as well with the basic idea that safety information will not be treated as confidential. Bilateral cooperation initiated and maintained by BAPETEN cover the scope of reactor design and safety analysis; probabilistic risk assessment (PRA) activities; digital instrumentation and control (I&C); human and organizational factors (HOF); operating experience; specific topic; radiation protection; nuclear fuel, fuel cycle facilities; decommissioning, waste management, final disposal; as well as other fields.

In implementing the international cooperation activities, BAPETEN and its counterpart can do exchange of documents and information (through correspondence, newsletter, technical reports); mutual visits, joint meetings and exchange of experts; assignment of personnel; supply of computer codes; and other activities as agreed upon by the parties.

BAPETEN has been recognized as a leading nuclear regulatory agency in regional area covering South East Asian countries. Its independence from the promoting body since 2000 has put a significant influence to its counterparts. BAPETEN has gathered experiences in radiation safety regulatory system in particular as the number of radiation facilities for industrial and medical purposes in Indonesia registered as its licensees can reach 2,325 institutions with number of
licensees can be accounted for as many as 11,897 covering industrial, medical and research facilities at the end of 2015.

3.9.  **Cooperation in Nuclear Security**

Security term associated in nuclear energy implementation was introduced in later period. Being the nuclear energy regulatory agency BAPETEN has been able to incorporate the security requirement along with the safety requirement for some implemented level of regulation as stated in its BAPETEN Chairman Regulation. In enhancing the agency’s capacity, series of trainings and workshops are attended by its employees that in return they can contribute their added knowledge to the progress of regulatory system for nuclear energy in Indonesia. International supports have improved a great deal of fields for the development of nuclear security in Indonesia.

Border detections equipment and trainings for the front line officers get a special attention from the IAEA program to improve the nuclear security system in Indonesia.

3.10. **Cooperation in Nuclear Safeguard**

Indonesia has ratified the Non Proliferation Treaty for peaceful use initiatives of nuclear energy. Being a part of ASEAN and as a member state which has held the chairmanship in 2011, Indonesia initiated that ASEAN revised the Southeast Asian Nuclear-Weapon-Free Zone Treaty (SEANWFZ) Protocol for ASEAN member states and Nuclear-Weapon States (NWS). Indonesia has ratified the Comprehensive-Nuclear –Test-Ban Treaty (CTBT) through Act No 1/2012 and has submitted its instruments of the ratification to the United States Secretary General in February 2012.

Indonesia’s accession to International Convention for the Suppression of Acts of Nuclear Terrorism (ICSANT) by Act No 10/2014 is believed to support existing legislation regarding nuclear security.

Indonesia ratification on Convention on the Physical Protection of Nuclear Material (CPPNM) along with its amendment through Presidential Decree can support the national achievement in nuclear security and safeguard.

Indonesia’s role in international for nuclear safeguard application has been considered significant and important in keeping up the peaceful use initiatives of nuclear energy.

4.  **CONCLUSION AND RECOMMENDATION**

Implementation of international cooperation can strengthen and improve effective regulatory system for nuclear energy utilization. It definitely can help develop the capacity building and informal peer review for some cases.

Action plans for the international cooperation should be intensively followed up for the success of objectives accomplishment.
Shared experiences and additional knowledge can significantly enhance the dynamics changes and development of regulatory system as required by the updated international standards and guidance.

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USE OF OPERATIONAL EXPERIENCE FEEDBACK FOR IMPROVING THE NUCLEAR REGULATORY FRAMEWORK IN ROMANIA

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Abstract

The paper presents the latest developments of the nuclear safety regulatory framework in Romania, based on the use of lessons learned from operational and regulatory experience feedback. Significant improvements of the regulatory framework after the Fukushima Daiichi accident, using lessons learned from this event as well as updates of the international standards, include the issuance of a National Strategy for Nuclear Safety and Security and new regulations on the nuclear power plants response to transients, accidents and emergency situations, the protection of nuclear installations against external events of natural origin, the nuclear safety policy and the independent nuclear safety oversight for nuclear installations, the operational limits and conditions for nuclear installations.

1. INTRODUCTION

Following the Fukushima Daiichi accident, CNCAN (the National Commission for Nuclear Activities Control – the nuclear regulatory authority of Romania) focused initially on the technical reviews of the protection of the plant against extreme external events and of beyond design basis accident analysis, severe accident management and emergency response. After more information became available on the organizational factors that have contributed to the accident, CNCAN has used the lessons learned to improve the national regulatory framework.

The paper presents an overview of the recent regulatory developments in Romania, including new regulatory requirements issued by CNCAN, using input from peer review missions, international standards and the international operational experience, including lessons learned from the Fukushima Daiichi accident.

2. ENACTMENT OF THE NATIONAL STRATEGY FOR NUCLEAR SAFETY AND SECURITY

In July 2014, the National Strategy for Nuclear Safety and Security was officially approved by the Romanian Government and by the Supreme Council of
National Defence, has been published and has come into force.

The work on a national strategy for nuclear safety and security started from a recommendation received from an Integrated Regulatory Review Service (IRRS) mission, organized by the International Atomic Energy Agency (IAEA) in January 2011. The scope of the review covered the nuclear regulatory framework for all types of facilities. The aim of the review was to compare the national regulatory framework with the requirements in the IAEA Safety Standard GSR Part 1, issued in September 2010 [1].

The IAEA IRRS Mission to Romania recommended that "The Government of Romania should issue the national policy and the strategy for safety, and implement them in accordance with a graded approach" and suggested that "The government should consider all fundamental safety objectives and principles, established in the IAEA Fundamental Safety Principles document, when finalizing the national policy and strategy".

The above mentioned recommendation was based on IAEA GSR Part 1 Requirement 1, which states that “The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.” It further requires that the “National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government’s intent. The strategy shall set out the mechanisms for implementing the national policy [...]”

Although most of the elements required by such a strategy were considered to be already in place, it was recognized that a national strategy may bring better coordination and coherence in addressing all the aspects and measures that have an impact on nuclear safety and security. Therefore this work has been considered of added value and all the national authorities with roles and responsibilities related to the nuclear field, as well as the organizations owning and operating the major nuclear facilities, have participated in the development of the strategy, which was coordinated by CNCAN.

The development of the national strategy started in the beginning of 2013. At first, the strategy addressed only nuclear safety (including radiological protection and emergency preparedness and response), but the scope of the strategy was later expanded to cover also nuclear security (including physical protection, nuclear safeguards and cyber security). Based on the current regulatory framework and on the trends observed at international level with regard to the improvement of the synergy between safety and security, it was decided that a national strategy addressing both nuclear safety and security is justified, taking into account also the provisions in the IAEA Safety Standards.

The strategy includes a policy statement with nuclear safety and security principles, including the ten fundamental safety principles outlined in the IAEA SF-
1 Publication, and takes account of the relevant provisions of the IAEA GSR Part 1 
Publication.

The strategy will be reviewed and revised as necessary, at least every 5 years. 
A process will be established to monitor the implementation of the strategy and of 
its corresponding action plan, and the results would be presented annually to the 
Government.

It should be mentioned that the work on this strategy was briefly presented at 
the 6th Review Meeting of the Contracting Parties to the Convention on Nuclear 
Safety and Romania received a recognition of a "good practice" because it 
"Established a consolidated, high-level, National Strategy for Nuclear Safety and 
Security". The acknowledgment of this good practice was supported by 4 countries 
in the Country Group 2.

3. REGULATION ON RESPONSE TO TRANSIENTS, ACCIDENT 
MANAGEMENT AND ON-SITE EMERGENCY PREPAREDNESS AND 
RESPONSE FOR NUCLEAR POWER PLANTS THE 

Acting upon the lessons learned from the Fukushima Daiichi accident and 
from the safety reviews performed, CNCAN issued the regulation “Nuclear safety 
requirements on the response to transients, accidents and emergency situations at 
nuclear power plants”. The regulation came into force in April 2014. The new 
regulation on accident management and on-site emergency preparedness and 
response provides requirements on:

— objectives, principles and factors to be taken into account for the response 
to transients, accidents and emergency situations on-site;
— transient and accident scenarios to be addressed in / covered by the EOPs 
(Emergency Operating Procedures);
— severe accident scenarios to be covered by the SAMGs (Severe Accident 
Management Guidelines);
— emergency situations to be covered by the on-site emergency response plan 
and emergency response procedures;
— establishment of the minimum number of staff with necessary qualifications 
to manage all scenarios required by the regulation (including combinations 
of events and scenarios in which multiple units on site are affected by 
accidents initiated by extreme external events beyond the design basis of 
the plants);
— facilities and equipment to be available for accident management and on-
site emergency response, including in situations caused by extreme external 
events;
— habitability analyses to demonstrate de feasibility of human actions for 
severe accident management;
— development, validation and documentation of the technical basis for the
procedures, taking into account human factors;
— configuration management in relation to the procedures and systems credited for accident management and emergency response;
— training programs and exercises;
— use of operational experience for the improvement of accident management and emergency response and records from exercises and from real events.

Since accident management and on-site emergency response are intrinsically coupled, it was decided that both should be addressed in the same regulation. It is expected that this approach would contribute to a better correlation between activities pertaining to the development of EOPs, SAMGs and emergency response procedures and plans as well as to the effectiveness of regulatory review and inspection activities. Cernavoda NPP has already taken actions to comply with the new regulatory requirements. Review and inspection activities for assessing compliance with the new regulation are still ongoing. As actions resulting from the enforcement of this regulation, so far, we can mention the re-assessment of the minimum shift complement, the re-validation of the EOPs and the review and improvement of the EOPs addressing events occurring during shutdown states. The development of SAMGs to cover shutdown states had already been committed as part of the post-Fukushima action plan.

4. REGULATION ON THE PROTECTION OF NUCLEAR INSTALLATIONS AGAINST EXTERNAL EVENTS OF NATURAL ORIGIN

The new regulation “Nuclear safety requirements on the protection of nuclear installations against external events of natural origin” – NSN-06 was published in January 2015. The regulation is based primarily on the new WENRA (Western European Nuclear Regulators Association) Reference Levels - Issue T: Natural Hazards, published in 2014.

The regulation NSN-06 does not prescribe the external events to be considered, but provides the following generic categories:

(a) Geological hazards;
(b) Seismotectonic hazards;
(c) Meteorological hazards;
(d) Hydrological hazards;
(e) Biological phenomena;
(f) Vegetation fires.

The regulation provides general requirements on the identification, screening, selection and analysis of external events on natural origin, for the purpose of establishing the design bases for the nuclear installations. The regulation also provides general requirements on the hazard analyses and on the definition of the
design basis events.

The regulation includes general requirements on the protection of design basis events of natural origin, as well as on the protection against events that exceed the design basis. CNCAN has not yet issued any regulatory guides in relation to this regulation, but it has endorsed the general guide issued by WENRA / RHWG (Reactor Harmonization Working Group to support the implementation of the reference levels in Issue T.

The licensees have submitted to CNCAN self-assessments of the compliance with the new regulation. These are under review and the regulatory inspections are planned for 2016.

CNCAN plans to revise the regulation to extend its scope to cover also human-induced external events.

5. REGULATION ON THE OPERATIONAL LIMITS AND CONDITIONS FOR NUCLEAR INSTALLATIONS

A new regulation on the operational limits and conditions (OLCs) for nuclear installations has been published in 2015. Previously, the general requirements on OLCs for nuclear power plants and research reactors have been set in a regulation issued in 1975, as well as in licensing basis documents and license conditions.

New requirements introduced by this regulation include:

— the provision of an operator to staff the SCA (secondary control area) on a permanent basis, for each shift (this requirement has been already implemented by the licensee on a voluntary basis, based on lessons learned from the safety reviews post-Fukushima);
— the provision of two licensed control room operators for each operating shift;
— the establishment of administrative controls, as part of the OLCs, for the systems and equipment credited to support the implementation of the severe accident management guidelines.

5.1. Regulation on the Nuclear Safety Policy and Independent Nuclear Safety Oversight

In September 2015, CNCAN issued a new regulation, “Requirements on the nuclear safety policy and on the independent nuclear safety oversight”, which applies to all licensees and applicants for a license for the phases of construction, commissioning and operation of nuclear installations (including nuclear power plants). The regulation has come into force in September 2015 and the licensees have 1 year to ensure compliance with it.

The first part of the regulation establishes requirements on the nuclear safety policy, covering all the current WENRA safety reference levels in Issue A. The
second part of the regulation establishes requirements on the independent nuclear safety oversight.

The requirements on independent nuclear safety oversight have been established by CNCAN taking account of the international experience available in this area, including the information from various countries that have a long tradition in this practice (e.g. UK, France, Belgium, etc.) and the conclusions in the Summary Report of the 6th Review Meeting of the Contracting Parties to the Convention on Nuclear Safety. The requirements are aimed at establishing an organizational unit, inside each licensee’s organization, having as an exclusive and full-time job the independent oversight of nuclear safety.

This function of internal independent nuclear safety oversight is different / separate from the independent audit of the management system (which is nevertheless recognized as a form of internal independent oversight). It cannot be considered fulfilled by external independent oversight units / organizations (such as Nuclear Safety Review Boards) and external review missions.

The intent of these regulatory requirements is that the independent nuclear safety oversight function is performed on a continuous basis. In other jurisdictions, this function is referred to informally as an “internal regulator” function.

The implementation of the new requirements on independent nuclear safety oversight is not aimed to decrease the regulatory oversight effort but to provide additional assurance to the regulator that the licensee is taking all the reasonably practicable measures to find and correct any safety significant issues in a timely manner, taking account of the best practices in this area at international level.

5.2. Regulatory Requirements on the Prevention of Use of Counterfeit, Fraudulent and Suspect Items In Nuclear Installations

In December 2014, CNCAN issued some modifications / updates to the regulations on quality management system for nuclear installations and activities, to include provisions on the prevention of use of counterfeit, fraudulent and suspect items in systems, structures, components and equipment important for nuclear safety and for nuclear security. CNCAN requested Cernavoda NPP to develop the procedure(s) necessary for the implementation of these new requirements. These have been submitted for regulatory review at the end of 2015. Compliance with the new regulatory requirements and procedures will be verified through routine inspections. The need for these new requirements was identified based on international experience regarding counterfeit, fraudulent and suspect items in the nuclear industry.

5.3. Regulatory Guide on Industrial Codes and Standards for Nuclear Power Plants

In 2014, CNCAN started to work on a regulatory guide (GSN-01) on the industrial codes and standards for nuclear power plants. After consultation with the
stakeholders, the guide was published in March 2015. This guide is aimed to improve the regulatory control over the entire set of industrial codes and standards used for safety-related systems, structures, components and equipment and associated activities, for the stages of siting, construction, commissioning and operation of a nuclear power plant, as well as for the process of periodic safety review. It provides a list of recommended codes and standards, including the ASME code and CSA, IEEE, IEC and ISO/IEC standards. Cernavoda NPP has to develop its own list, taking account of the standards recommended in this guide, and submit it for regulatory review.

5.4. Regulatory Guide on the Independent Verification of Nuclear Safety Analyses and Evaluations

The regulatory guide on the independent verification of nuclear safety analyses and evaluations for nuclear installations (GSN-02) was published in September 2015. This guide was issued in relation to the general requirements on independent verification that already existed in the nuclear safety regulations and in the regulations on quality management systems for nuclear installations and activities.

The independent verification in this context refers to the independent verification referred to in the IAEA safety standard GSR Part 4 - Requirement 21 and paragraphs 4.66 – 4.71 [2]. The provisions of the GSN-02 guide apply to the independent verification activity for the following categories of nuclear safety analyses & evaluations (NSA&E):

a) NSA&E which are part of the licensing basis for the nuclear installations, including analyses and evaluations supporting the initial, preliminary and final nuclear safety analysis reports that are submitted to CNCAN in the licensing process.

b) NSA&E which are at the basis (which support) the proposals for design modifications of a nuclear installation already licensed by CNCAN, for the systems, structures, components and equipment with nuclear safety functions and / or for the technical limits and conditions for operation (operational limits and conditions / technical specifications).

NSA&E include deterministic safety analyses, probabilistic safety assessments and hazard analyses. The provisions of the guide apply to both NSA&E performed by the licensee’s / applicant’s own staff and to those performed by external organizations for the licensee / applicant.

The guide includes a recommendation that the licensee / applicant establishes policies, principles and requirements on the objectives, scope, depth and degree of detail of the independent verification of NSA&E, to reflect a graded approach, taking account of the following factors:

(a) the specificity and complexity of the nuclear installation;
(b) the importance of the NSA&E, taking account of the intended application / use and of the impact on the design basis and / or licensing basis for the respective nuclear installation;
(c) complexity of the NSA&E;
(d) novelty or unicity of the NSA&E or of the methods of analysis and evaluation used.

It is recommended that the licensee/applicant plans and establishes the necessary procedures for the systematic approach to the independent verification of NSA&E, including for documenting the results of the independent verification in specific reports. It is recommended that the independent verification reports present at least the following information:

(a) purpose and objectives of the independent verification;
(b) limitations of the independent verification;
(c) verification methods, tools and criteria used;
(d) any non-conformities identified and the corrective actions implemented to ensure the adequate quality of the NSA&E.
(e) conclusions on the fulfillment of applicable requirements and on the acceptability of the NSA&E.

For ensuring a systematic approach to the independent verification of NSA&E, it is recommended that the licensee/applicant uses checklists with acceptance criteria. The annex to the guide presents a checklist with generic acceptance criteria, which are not exhaustive. It is recommended that the licensee/applicant develops its own checklists, specific for the respective nuclear installation and for the type and intended use of NSA&E and updates them periodically to take account of the accumulated experience, results of research activities and of the newest standards and good practices recognized at international level.

5.5. Regulatory Guide on the Format and Content of the Final Safety Analysis Report for Nuclear Power Plants

The new regulatory guide on the format and content of the Final Safety Analysis Report for Nuclear Power Plants (GSN-04) has been published in October 2015, following consultation with the stakeholders. The provision of GSN-04 applies to the FSAR editions submitted in the licensing process for the commissioning and operation stages of a NPP. Cernavoda NPP has to submit to CNCAN a plan for aligning their FSAR documents for Unit1 and Unit 2 to the recommendations in the new guide. Up to date, the structure and content of the FSARs have been established taking into account the provisions of US NRC RG 1.70 - Standard Format and Content of Safety Analysis Reports for Nuclear Power
Plants (17 Chapters). The main change from the existing practice is the addition of 2 new chapters (18 and 19 – with the scope similar to the corresponding chapters in US NRC NUREG-0800).

5.6. Conclusions and Further Work

The recent developments of the regulatory framework in Romania prove that CNCAN is committed to the effective use of operational experience feedback, new standards and peer reviews to identify and implement improvements to its requirements and practices. Work is ongoing to ensure alignment to the latest IAEA safety standards, issued in 2016, and the transposition of the EU directives [3] relevant for nuclear safety.

REFERENCES


NUCLEAR SAFETY AND SECURITY CULTURE WITHIN THE REGULATORY BODY IN ROMANIA

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Abstract

The paper presents the activities implemented in the Nuclear Fuel Cycle Division of the National Commission for Nuclear Activities Control - CNCAN - for promoting nuclear safety and security culture. CNCAN started to define its own organizational culture model and identifying the elements that promote and support safety and security culture.

1. INTRODUCTION

Starting with July 2014, Romania has a National Strategy for Nuclear Safety and Security, which includes strategic objectives, associated directions for action and concrete actions for promoting nuclear safety and security culture in all the organizations in the nuclear sector.

In 2015, CNCAN started to define its own organizational culture model and to identify the elements that promote and support nuclear safety and security culture. This action has been taken based upon a recommendation received from the 6th Review Meeting of the Contracting Parties to the Convention on Nuclear Safety, to have assessments of the safety culture of the regulatory authority, acknowledging that the culture of the regulator may have an influence on the safety culture of the licensees.

2. REGULATORY MODEL OF ORGANIZATIONAL CULTURE

The nuclear safety culture is an integral part of any organization in the nuclear sector. License holders for nuclear installations and activities, as well as the nuclear regulatory authority and other authorities and institutions with roles and responsibilities in the nuclear sector have to establish and implement management systems that continuously promote, support and improve nuclear safety and security culture.

For describing the elements of organizational culture and more specifically of safety and security culture, we have used the model developed by Edgar Schein for organizational culture [1].
Several training sessions have been conducted with the staff of the Nuclear Fuel Cycle Division of CNCAN, to present Edgar Schein’s organizational culture model, to identify and discuss the artifacts, espoused values and basic assumptions that are common to organizations in the nuclear sector, to public authorities and more specifically to CNCAN. The concept of organizational sub-cultures has also been presented. Also, the dynamics between basic assumptions, espoused values and artifacts have been debated, as well as the role of the basic assumptions in the discrepancies that appear when artifacts are not aligned with the espoused values, i.e. when the actual regulatory processes and activities do not reflect the commitments and values declared.

3. ARTIFACTS, ESPOUSED VALUES AND BASIC ASSUMPTIONS

The organizational culture model provides several examples of elements, some of them specific to the activities of CNCAN. These items do not represent an exhaustive inventory of all the relevant artifacts, espoused values and basic assumptions that characterize the organizational culture of CNCAN and are listed only for illustration purposes.

Examples of Artifacts (visible elements) include:

— The legislation applicable to CNCAN activities; the responsibilities of CNCAN; the authority given to CNCAN by the Law;
— The organizational structure of CNCAN; its position in relation to other authorities and to the organizations in the nuclear sector; the independence from the organizations that produce, utilize or promote nuclear energy;
— The management system, the work processes and the related procedures; the policy declarations;
— The regulations and guides issued by CNCAN;
— The assessment and inspection reports; the decision-making processes; the regulatory letters sent to licensees and license applicants; the action plans;
— The activity reports, the reports on the fulfillment of the obligations to the international Conventions ratified by Romania in the nuclear field;
— The involvement of CNCAN in the international activities in the areas of nuclear safety, nuclear security and nuclear safeguards;
— The competence of CNCAN staff; the training and qualification programs;
— The availability and adequacy of resources, in terms of qualified staff and financial resources;
The work spaces; the equipment; the conduct of staff at all levels; the flow of information; the management of classified and sensitive information; Interactions with the licensees during meetings and inspections; The press releases; the website.

Examples of Espoused Values (declared) include:

— Mission and vision of the organization;
— Strategies of the organization;
— Regulatory philosophy and approach;
— Principles and values of the organization: priority to nuclear safety, competence, transparency, integrity, independence, cooperation

Examples of Basic Assumptions include:

— Nuclear safety has first priority in all activities of CNCAN;
— Nuclear security is essential for nuclear safety; safety and security measures have to be analyzed and implemented in a synergistic manner;
— The license holders have the prime responsibility for nuclear safety and security;
— CNCAN’s independence from the license holders and applicants and from the organizations that promote the use of nuclear energy;
— The transparency of the decision-making processes is essential for demonstrating their correctness;
— The regulatory decisions shall be based on concrete and complete data, on clear criteria and objective assessments;
— Every employee may and can contribute to the continuous improvement of the management system of CNCAN;
— Our regulatory activities are important for the society;
— We do not tolerate corruption, conflicts of interest and abuse.

4. USE OF SURVEYS

A limited exercise for a safety climate survey has been implemented for CNCAN staff involved in the regulatory review and inspection activities for nuclear installations. The 37 attributes of a strong safety culture promoted by the IAEA [2] have been used, in a slightly adapted form, as part of this safety climate survey. The aim of the survey was not to represent assessment of the safety culture of the regulator, but to identify assumptions that support a strong safety culture as well as assumptions that may undermine it. The survey will be expanded with security
culture indicators [3].

5. PLANNED WORK

Work will continue on the better definition and understanding of the organizational culture model of CNCAN and on the elements that are particularly relevant to nuclear safety and security, using the most recent international standards and publications, such as the new NEA report on the safety culture of an effective nuclear regulatory body [4]. Training sessions and use of surveys will also continue and any new self-assessment methods developed at international level will be taken into account, for the purpose of identifying opportunities for improvement.

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REGULATORY BODY OF EGYPT: PRACTICES AND CHALLENGES

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Abstract

In past, Egypt issued the law No. 59 of year 1969 for regulating the use of ionizing radiations inside the country, this law assigns the responsibilities of Egypt Atomic Energy Authority EAEA to control reactors, open sources, and all nuclear and radiation facilities inside its premises, while the ministry of health was responsible for controlling x-ray machine, sealed sources and accelerators. In 1982 EAEA established within its structure a regulatory body called national center for Nuclear Safety and radiation Control NC-NSRC which is dependent on EAEA. On 30 March 2010 Egypt issued the nuclear law No 7 of year 2010, followed by its executive regulation in October 2011, the new law replaced the old law 59 of year 1969, in addition, the prime minister issued a decree on march 5th 2012 of establishing an independent regulatory body reported directly to him, it has the name of Egypt Nuclear and Radiological Regulatory Authority ENRRA, it is responsible for regulating all nuclear and radiation facilities and activities inside the country, except X-ray machines and linear accelerators for the medical uses, which still remains under the control of ministry of health. ENRRA is managed by a board of directors, which is the supreme committee of the dominant, conduct of ENRRA affairs, and take decisions within the framework of the national plan of Egypt, ENRRA consisted from the old NC-NSRC staff. It organized from three regulatory sectors, and a Technical Support Organization TSO includes three main divisions, besides departments of public communication, center labs, radiation network monitoring, emergency, security, and administrations. ENRRA do a lot of efforts for building and improving its personnel’s capacity and skills.

1. INTRODUCTION

Nuclear Authorities In Egypt

Law no 7 of year 2010 defines the following Egyptian nuclear authorities (Fig 1 below) and assigns their objectives as stated in the following articles:

(Third Article of law No 7): “The nuclear power plants authority is responsible for establishment, operation, and management of nuclear power plants”.

(Forth Article of law No 7): “The Atomic Energy Authority, the nuclear power plants authority, and nuclear material authority continue their direct activities in accordance with the laws and regulations in force, in conformity with the provisions of the attached law”.

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Egypt Regulatory Body: Related Articles of the Law

On 30 March 2010 Egypt issued by the general assembly a new nuclear law named law 7 of year 2010 for regulating & controlling all nuclear and radiation facilities and activities inside the country, it replaced the old law No.59 of year 1969.

The law assigns the responsibility of the government to establish an independent regulatory body, support it, and define its authorization and responsibilities. Also assigns the new RB to control all activities and facilities using ionizing radiation except X-ray machine and linear accelerators for medical uses. Following, in October 2011 the prime minister issued the executive regulation of the law. The new RB come into force by the prime minister decree in March 2012, in which he assigns the chairman and vice chairman and the board council, The New Egyptian RB (Nuclear and Radiological Regulatory Authority” ENRRA) organized from the old NC-NSRC as a Technical Support Organization TSO, in addition to three regulatory sectors: (a) nuclear installation safety sector, (b) radiation installations and radiation sources safety sector and (c) security and safeguard safety sector, in addition to departments and labs (Fig. 2 below). The following articles of the law contain the assignment.

(Item 1): ENRRA is responsible for managing and controlling all nuclear and radiation activities in Egypt except x-rays machine and linear accelerators which are using in medical applications, they still under the controlling of the ministry of health.

(Second Article): “The Ministry of health continues to direct regulatory and supervisory functions regarding the uses of x-ray devices in the medical field including spatial and personal licenses of doctors and radiologists in medical diagnostic and therapeutic.”
(Article 2): “The provisions of this law applies on enterprises, activities, nuclear and radiological practices in various areas, which lies under the control of ENRRA”; including in particular the following:

— All stages of the nuclear fuel cycle;
— Nuclear power reactors for various purposes and research and test reactors;
— Critical and Subcritical Assemblies, and various types of accelerators;
— Safe transport of radioactive materials;
— Approval of the export and import of radioactive materials;
— Nuclear and radiological applications for various purposes, including medical, industrial, agricultural and research;
— Disposal of naturally occurring radioactive materials, NORM, and that resulting from extraction of oil and raw materials.

2. ENRRA STRUCTURE

2.1. Organization

The nuclear law in article 11 established the RB by “It is decided to establish an independent body called nuclear and radiation regulatory authority ENRRA, enjoying legal personality, reporting directly to the Prime Minister, its headquartered shall be in Cairo, or one of its neighboring provinces, and may by resolution of the Board of Directors, to establish branches or offices in other places in the country”.

2.2. Resources

The government took the responsibility of funding, supporting, enhancing the ENRRA to fulfill its objectives. The nuclear law defines the resources of ENRRA as given in article 13 by ENRRA resources:

— The allocation of funds in the State budget;
— Toll fees for permits and licenses issued by the Commission;
— Fees for work and services performed by the body to others at home or abroad, provided that such third party is not subject to control by the Commission;
— External grants that are accepted by the Board Council from the non-controlled organization which are not inconsistent with the authority purposes.
3. ENRRA MANAGEMENT

ENRRA is managed by a board of council, appointed by the president of the country, the members of the council and authorizations are described in the following articles:

Article 16: “ENRRA is managed by a board of council, the President of the Arab Republic of Egypt appoints the members of the board by a decree, upon the presentation from the Prime Minister, for a period of four years”.

Article 17: “The Board of Directors is the Supreme authority of the dominant, and the conduct of its affairs, and take decisions within the framework of the national plan for the State, as it deems necessary to achieve the objectives for which the authority was established”, and in particular the following:

— The policy of the RB;
— Issuing binding decisions, evidence and guided help for the security and safety;
— Issuance of licenses and permits for nuclear and radioactive facilities;
— Issuing standards and requirements related to the security and safety of the peaceful uses of atomic energy in all areas;
— Issuance of rules that ensure the confidentiality of information;
— Making decisions and standards for ingredients and products which are imported, concerning radioactive content;
— Arrangements with the regulatory bodies of other States;
— Determine the license fees and permits of various types;
— Select the monetary equivalent that it deserves the body for work and services performed by third parties at home and abroad;
— Produce an annual report to the President and to the President of the Council of Ministers and to the Presidents of both houses of Parliament
— Adoption of the draft annual budget and final accounts;
— Transfer of appropriations of item to another part in the annual budget;
— Adoption of the organizational structure of the body and the adoption of regulations related to technical, financial, and administrative.
4. ENRRA RESPONSIBILITIES AND AUTHORIZATION

The law 7 states the responsibilities and power of ENRRA in article 12 as “ENRRA is responsible for all regulatory actions and regulatory functions relating to nuclear and radiological activities”. All necessary powers and authorizations are:

— Assuance, amendment, suspension, restoration, withdrawal and cancellation of all license types of nuclear and radiation installations
and activities, in addition to personnel's licensing of dealers with ionizing radiation;
— Administrative closure of places where ionizing radiation is not used safely,
— Issuing and binding rules;
— Access to all documents and information relating to the functioning of all nuclear and radiation installations and activities;
— Regulatory and supervisory functions, including:
  o Review and assessment;
  o Regulatory inspection;
  o Development of the rules.
— Regulatory and supervisory functions in planning, preparedness and response to nuclear and radiological emergencies;
— Public awareness of the regulatory process for nuclear and radiation activities;
— Coordination with other governmental and non-governmental organizations;
— Contact the regulatory and supervisory authorities of foreign States;
— Systems development of permitted activities and doses for human uses;
— Develop systems for the allowed radiation levels, in the importation or bringing in, production or export of any food or other material for human use;
— Inspection of sites or through the supply of products or services;
— Request for opinion and assistance from international bodies and technical advisory or supporting organizations;
— Develop systems by requiring operators to conduct assessments of nuclear and radiological safety including safety reassessments, periodic safety reviews;
— Comment on draft laws on nuclear and radiological activities;
— Issue quarterly reports for the public about the position of national radiation situation, published in the Official Gazette, newspapers and the media;
— Reporting of the offence provisions of the law;
— Research related to nuclear and radiological safety.

5. LEGAL AND DOCUMENTARY FRAMEWORK

5.1. Legal Pyramid

ENRRA legal framework comprises two pyramids: (1) legislative pyramid which is the responsibility of the government, which is binding (see Fig.3 below), and (2) documentary pyramid which is the responsibility of the RB. The Legislative
pyramid consists of treaties at the top, conventions, constitution, nuclear law, the environmental protection law. The presidential decree, board of directors decrees for issuing regulations.

5.2. Documentary Pyramid

At the top is the safety fundamentals, followed by requirements, guides, codes and process regulations. ENRRA board of council published recently in Egyptian gazette the following regulations: (1) a list of rules and procedures governing the activities related to the work of nuclear safeguards, (2) the regulations and standards of the limits of allowable radiation level when import or bring, production, export or sale of any food or other material pertaining to the use by humans and non-human consumption, (3) The duration of the individual licenses in facilities and users of radioactive sources and workers is three years, (4) Determine the amount of insurance or financial security required to license the establishment or operation of a radioactive facility system, (5) Determine the amount of the required insurance or financial security for licensing the establishment or operation of a nuclear facility or transport of nuclear material, (6) On standards, technical regulations, guidelines, and requirements for permits of users of radioactive sources and workers in radiation zones, (7) The issuance of rules of classification of nuclear materials and radioactive sources of nuclear security perspective.

6. REGULATED FACILITIES AND ACTIVITIES

6.1. Facilities

(a) Egypt test and research reactor no 1 ETRR-1.
(b) Egypt test and research reactor no 2 ETRR-2.
(c) Fuel fabrication plant.
(d) Liquid waste treatment plant.
(e) Gamma irradiator plant at Nasr city.
(f) Gamma irradiator plant at Alexandria.
(g) Radio-isotope production factory.

6.2. Activities

(a) Safe transport of radioactive materials through Suez Canal,
(b) Use of radioactive isotopes in all areas such as industries, agricultures, medicine, etc.
(c) Accounting nuclear materials country.
7. HUMAN RESOURCES AND IMPROVEMENT CAPABILITIES

The ENRRA should be ready to regulate the embarked nuclear power plant by training her personnel in review and assessment, licensing, inspection, and updating regulations. The total number of scientists of ENRRA is about 200, 18 of them moved to the three regulatory sectors (6 person /sector). ENRRA started three international projects for capacity building and improvement skill of its regulators, with:

- EU The European Union Instrument for Nuclear safety Cooperation (INSC).
- IAEA.
- South Korea and Korean grant aid programs for developing countries.

Specific fields of training are:

- Establishing/ development of an action plan for the cooperation;
- Support of the establishment of independent nuclear regulatory authority;
- Assistance in the field of regulatory framework;
- Identifications of the basic safety requirements criteria;
- Strengthening and enhancing professional knowledge of ENRRA and its TSO;
- Strengthening and enhancing ENRRA capacity in nuclear safeguard.
8. CHALLENGES

— Continuous training of ENRRA personals in NPP inspection.
— Continuous training in review and assessment, especially at present, the site Evaluation report SER.
— Evaluation of our documentary pyramid.
— Revise of our existing national regulations.
— Assistance in development our national (missing) standards.
— Assistance in development of management system.
— Enhancing, upgrading capabilities of leaderships.
NUCLEAR REGULATORY SYSTEMS IN AFRICA: IMPROVING SAFETY AND SECURITY CULTURE THROUGH EDUCATION AND TRAINING

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Abstract

The purpose of this paper is to address the important issue of supporting safety and security culture through an educational and training course program designed both for regulatory staff and licensees. Enhancing the safety and security of nuclear facilities may involve assessing the overall effectiveness of the organization's safety culture. Safety Culture implies steps such as identifying and targeting areas requiring attention, putting emphasis on organizational strengths and weaknesses, human attitudes and behaviors that may positively impact an organization's safety culture, resulting in improving workplace safety and developing and maintaining a high level of awareness within these facilities. Following the terrorist attacks of September 11, 2001, international efforts were made towards achieving such goals. This was realized through meetings, summits and training course events, with main aim to enhance security at facilities whose activities, if attacked, could impact public health and safety. During regulatory oversight inspections undertaken on some licensee's premises, violations of security requirements were identified. They mostly involved inadequate management oversight of security, lack of a questioning attitude, complacency and inadequate training in both security and safety issues. Using training and education approach as a support to raise awareness on safety and security issues in the framework of improving safety and security culture, a tentative training program in nuclear and radiological safety was started in 2002 with the main aim of vulgarizing the regulatory framework. Real first needs for a training course program were identified among radiographers and radiologists with established working experience but with limited knowledge in radiation safety. In the field of industrial uses of radiation the triggering events for introducing and implementing a training program were: the loss of a radioactive source in a mining site, the terrorist attacks, and the uncontrolled traffic of radioactive minerals and devices under a specific name of “uranium material”. Human resources development program involving more than 250 radiation workers and staff from regulatory body, research reactor facilities, hospitals, mines, customs, intelligence and immigration service’s was implemented. Training topics covered ranged from regulatory framework, regulations, reactor operation and radiation safety issues, radiation protection of patient, security of radioactive sources in industries, emergency preparedness and response, nuclear security, threat assessment and response, sources risks management, illicit trafficking and safety and security culture. The implemented Training program resulted in substantially raising collective awareness about security and safety issues, from staff
members to the management, increasing the level of regulatory inspections and putting more emphasis on the control of radioactive sources and more regulatory requirements on handling orphan radioactive sources. On the other hand, using generated incomes from trainings undertaken, training facilities were gradually upgraded and training syllabuses progressively updated to be consistent with country current and future needs. While important progress has been achieved, future needs have been identified. Extending educational and training program to cope with university and academic requirements in the field of nuclear and radiological sciences, with a view to introducing nuclear power program in the country; strengthening the enforcement and sanctions regime, monitoring of border crossings to detect illegal source movements, increasing the capability and basic knowledge of first responders, collecting and upgrading conditioning and final storage of radioactive sources facility.

1. INTRODUCTION

Today, it is generally recognized that radioactive sources provide great benefit to humanity, primarily through their use in agriculture, industry, medicine, and research, and the vast majority are used in well regulated environments [1]. However, control has been lost over a small fraction of those sources, sometimes resulting in accidents of which some had serious consequences.

One of the best ways to mitigate consequences of such incidents and accidents would consist of improving safety and security culture within organizations involved in using radioactive material and operating nuclear facilities.

Both safety and security have many concepts in common. Enhancing the safety and security of both nuclear facilities and radioactive material users may involve assessing the overall effectiveness of the organization's safety culture. Safety culture is better defined in Reference [2], as “that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance. Put together, these essential elements of safety culture emphasize that Safety Culture is attitudinal as well as structural, relates both to organizations and individuals, and concerns the requirement to match all safety issues with appropriate perceptions and action.”

Safety Culture implies steps such as identifying and targeting areas requiring attention, putting emphasis on organizational strengths and weaknesses, human attitudes and behaviors that may positively impact an organization's safety culture, resulting in improving workplace safety and developing and maintaining a high level of awareness within these facilities [3]. Following the terrorist attacks of September 11, 2001, international efforts were made towards achieving such goals. This was realized through meetings, summits and training course events, with main aim to enhance security at facilities whose activities, if attacked, could impact public health and safety.

On the other hand, as stated in Reference [4], security culture is characterized by the beliefs, attitudes, behavior and management systems, the proper assembly of which lead to more effective security. It puts much emphasis on the role managers
and operators of facilities and activities involving radioactive material, and those regulating these practices and/or activities.

Establishing and maintaining a safety culture directly results in some benefits for both operators and regulators. Radioactive materials are safely and securely used. Licensees and other users of regulated material are primarily responsible to ensure that these materials are used safely and securely. Because weaknesses in safety culture or a deteriorating safety culture appear to increase the likelihood of performance problems and the consequences of those problems, it is important to encourage licensees to maintain a positive safety culture [5].

While all these features supporting the safety and the security of radioactive materials and nuclear facilities are important, approaches and means to correct bad behaviors and obstacles to ensure safety and security culture could be different from one individual or organization to another. Education and training have shown to be essential in supporting changes in cultures. The purpose of this paper is to address the important issue of supporting safety and security culture through an educational and training course program designed for both regulator staff and licensees.

2. METHODS AND RESULTS

2.1. Methods

Between 2002 and 2008, regulatory oversight inspections were conducted on some nuclear operator's and users of radioactive material premises. One nuclear operator and five radioactive sources facilities were concerned. Violations of security requirements were identified. They mostly involved inadequate management oversight of security, lack of a questioning attitude, complacency and inadequate training in both security and safety issues.

The study involved questionnaire, free debates and discussions with management and radiation workers. Major findings comprised regulatory investigations during loss of radioactive sources.

While general non radiological safety issues were given much attention, the survey showed lack of basic knowledge of radiation risks among both management and staff in most organizations involved. Radiation workers were Complacency was assessed in terms of the degree of relevance that safety and security matters were receiving within the organizations.

Response from the regulator could not be comprehensive. Focus was to act on what was paramount, ie, education and training approach as a support to raise awareness on safety and security issues in the framework of improving safety and security culture.

A tentative training program in nuclear and radiological safety was started in 2002 with the main aim of vulgarizing the regulatory framework. Real first needs for a training course program were identified among radiographers and radiologists with established working experience but very limited knowledge in radiation safety. In
the field of industrial uses of radiation the triggering events for introducing and implementing a training program were: the loss of a radioactive source in a mining site, the terrorist attacks, and the uncontrolled traffic of radioactive minerals and devices under a specific name of “uranium material”. Other major findings included lack of awareness about radiological risks and inadequate knowledge of regulatory infrastructure in place.

2.2. Results

Human resources development program involving more than 250 radiation workers and staff from regulatory body, research reactor facilities, hospitals, mines, customs, intelligence and immigration service’s was implemented. Training topics covered ranged from regulatory framework, regulations, reactor operation and radiation safety issues, radiation protection of patient, security of radioactive sources in industries, emergency preparedness and response, nuclear security, threat assessment and response, sources risks management, illicit trafficking and safety and security culture.

Although, in the first instance, training program was professionally oriented and only addressed needs from medical field, efforts were made to cover radiation uses as many and diverse as safety and security issues, regulatory framework, research reactor facilities and non destructive testing. More interests and needs were recorded among mining facilities, customs and security borders and intelligence services. Figures 1 and 2, below, report on the number of training courses organized and the number of trained people between 2002 and 2013.

![FIG 1 and 2. Number of Training events and number of trained people between 2002 and 2013.](image)

The implemented Training program resulted in substantially raising collective awareness about security and safety issues, from staff members to the management, increasing the level of regulatory inspections and putting more emphasis on the control of radioactive sources and implementing regulatory requirements while handling orphan radioactive sources. Radiation safety received now high priority and restrictions on the implementation of training program withdrawn.
On the other hand, using generated incomes from training courses undertaken, training facilities were gradually upgraded and training syllabuses progressively updated to be consistent with country current and future needs.

3. CONCLUSIONS AND PERSPECTIVES

Important progress has been made towards improving safety and security status in the country. As clearly stated that [4] the prime responsibility for safety must rest with the person or organization responsible for facilities and activities that give rise to radiation risks”, the study underlines the key roles of the regulator and that of the Technical Supporting Organization in improving safety and security culture through an appropriate education and training program. While operators and radiation users are expected to foster a strong safety and security culture in their respective organizations, the regulator should ensure that the licensee properly discharges this prime responsibility for safety.

Government commitment to ensuring safety and security and promoting safety and security culture should be also considered as essential in improving safety and security in nuclear sector.

Future needs have been identified. Extending educational and training program to cope with university and academic requirements in the field of nuclear and radiological sciences, with a view to introducing nuclear power program in the country; strengthening the enforcement and sanctions regime, monitoring of border crossings to detect illegal source movements, increasing the capability and basic knowledge of first responders, collecting and upgrading conditioning and final storage of radioactive sources facility.

REFERENCES

INITIAL EXPERIENCE AND CHALLENGES IN
ESTABLISHING AND STRENGTHENING A NEW
REGULATORY INFRASTRUCTURE CONCERNING RADIOACTIVE WASTE
MANAGEMENT

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Abstract

According to an amendment of the Hungarian Act on atomic energy in 2013, the Hungarian Atomic Energy Authority (HAEA) took over the regulatory oversight function over radioactive waste repositories from the previous authority (the radiation health authority) in the middle of 2014. Earlier, HAEA was the regulatory authority only for the Hungarian nuclear facilities (nuclear power plant, spent fuel storage facility, research reactors) and served ‘only’ as a special co-authority in licensing procedures of radioactive waste management facilities. In this sense, a new – now integrated – regulatory system has been formed in Hungary: the NPP, the spent fuel storage facility and both radioactive waste repositories are now under the same licensing authority. In parallel with this, a new Governmental Decree on the safety requirements of interim storage and final disposal facilities of radioactive waste was issued in 2014. Since that time, HAEA has taken several measures in order to determine the present state of the facilities, and to improve the level of safety. During the first year of the operation of this integrated regulatory system, an Integrated Regulatory Review Service (IRRS) mission was organized in Hungary (May of 2015). The IRRS team identified certain issues warranting attention or in need of improvement in developing a long term human resource plan, more procedures and guidelines that would enhance the overall performance of the regulatory system. The HAEA is carrying out the actions needed for this.

1. INTRODUCTION

The Hungarian Act on Atomic Energy specifies that the ultimate responsibility for decommissioning and the management of spent fuel and radioactive waste generated in Hungary is the responsibility of the Hungarian state. However, in 1996 the Act also stated that radioactive waste management facilities (repositories) were not considered to be nuclear facilities which, initially, led to a divided authority and regulatory system. Hungarian Atomic Energy Authority (HAEA) was the regulatory authority only for the nuclear facilities (nuclear power plants, spent fuel storage facilities, research reactors) and contributed to the licensing procedures of radioactive waste management (RWM) facilities as a special co-authority only. This was resolved in an amendment to the Act in 2013; HAEA was designated to take over the task of regulatory oversight of the radioactive waste
repositories from the Office of the Chief Medical Officer of the National Public Health and Medical Officer Services. In this sense, a new – now integrated – regulatory system was formed in Hungary from 1st of July 2014.

The new task of HAEA includes, inter alia; licensing and inspection of site selection, design, construction, operation, modification and closure; and approval of emergency response plans.

2. PREPARATION

In 2013, led by HAEA, the elaboration of a new executive order of the Act on the radioactive repositories was started where special focus was given to the following:

— Taking into account all of the safety reference levels provided by WENRA and other relevant international standards;
— Elaborating a more detailed system of requirements and regulatory processes than earlier in a similar manner as those are in the Nuclear Safety Codes (NSC) for nuclear facilities;
— Introduction of a differentiated regime taking into account all of the specific features of the repositories.

The success of the work is indicated by the promulgation of the Govt. Decree 155/2014. Korm. on the safety requirements of interim storage and final disposal facilities of radioactive waste and the related regulatory activities (Decree). This mandated the HAEA with regulatory supervision of the safe management, storage and disposal of radioactive waste in the two operating radioactive waste repositories in Hungary.

The content of this Decree is similar to a given extent to that for the nuclear facilities (NSC), although the processes of the supervising authority and the related requirements to the licensees were incorporated into the main body instead of the first annex because of a new legislative procedure. The main body of the Decree incorporates the general requirements and those for the waste acceptance criteria and record keeping together with the responsibilities of the licensees as well. As a consequence of this and of the less variety of the facilities belonging to the scope of the Decree it has got only two annexes yet. The first one regulates the management system of licensees; the second one prescribes the safety requirements on design, construction, operation, closure and institutional control life-cycle phases of the storage and disposal facilities.
3. RADIOACTIVE WASTE MANAGEMENT IN HUNGARY, EXISTING FACILITIES

In Hungary, the Public Limited Company for Radioactive Waste Management (PURAM) is the designated organization to perform all of the RWM activities; the final disposal of radioactive waste, interim storage of spent nuclear fuel, closure of the nuclear fuel cycle, decommissioning and dismantling of nuclear facilities (and the development and implementation of the national programme for radioactive waste and spent fuel management).

The national policy reaffirms that Hungarian State takes the ultimate responsibility for the safe management of any radioactive waste and spent fuel (or HLW from its reprocessing) generated in the country. The reference scenario of the national programme relies basically on a future deep geological repository expected to be operational by 2064 in Hungary and on three already existing facilities. These latter ones are:

— the National Radioactive Waste Repository (NRWR) in Bátápáti (in operation since 2012),
— the Radioactive Waste Treatment and Disposal Facility (RWTDF) in Püspökszállás (in operation since 1976),
— the Interim Spent Fuel Storage Facility (ISFSF) in Paks (in operation since 1997)

The final disposal facilities (NRWR, RWTDF) allow PURAM to dispose of LILW-SL arising from the NPP operation & decommissioning, as well as from other institutional producers till the end date of the national programme (2084).

The RWTDF is the oldest Hungarian near surface disposal facility receiving LILW from small scale (non NPP) producers. Here a safety upgrading project is ongoing aiming at retrieval of certain waste packages for which one cannot exclude that some long lived sources might have been placed in. After a demonstration programme few years ago where retrieval technologies were successfully tested, PURAM is ready to start the large scale retrieval.

The NRWR is the newest repository in Hungary, it is a geological (intermediate depth) disposal facility, receives LILW from the NPP. Now it has one chamber (out of 4 already excavated chambers) in operation. In parallel with the mining activities (excavation of the chambers), they have changed the disposal concept (PURAM and the experts of the Paks NPP have revised the system of engineered barriers) in order to make the use of disposal capacities more efficient; to be able to put more radioactive waste into the next chambers now under construction.
4. FIRST MEASURES

The HAEA has begun the on-site inspections soon after the takeover and has taken several measures with the aim to determine and improve the current level of the safety of repositories and to verify the compliance of on-site processes with the relevant legal requirements. In this framework, at first, the authority collected and organized the associated and available documents (licences, resolutions, assessments, etc.) regarding these facilities. The HAEA has facilitated the communications with the licensee, conducting consultations with PURAM about the expectations of the authority regularly, and implemented the practice of weekly reports, under which the licensee shall report to the HAEA about its activities and events occurred in the facilities regularly.

HAEA has also started the establishment of a Performance Indicator System to be applied for the two facilities. Each facility has about 20 indicators with different thresholds of compliance. The repositories were first assessed in accordance with the indicator system concerning the operational experiences of 2014.

5. CHALLENGES FACED

According to the Council Directive 2009/71/Euratom, the HAEA initiated at the IAEA hosting the mission of Integrated Regulatory Review Service (IRRS). During the first part of the task the concerned authorities conducted self-assessment according to the established methodology, while the second part, the IRRS mission was organized in Hungary (May 11-22, 2015). The mission observed among others the following two main items regarding the supervision of the storage and disposal facilities.

5.1. Human factors

With regards to regulatory oversight of repositories, a large set of competencies is needed to assess activities and interconnected processes that occur inside a facility, in the geosphere and the environment. The current situation of the activities developed for deep geological disposal will also soon bring challenging responsibilities for the HAEA. Depending on the different phases of the lifetime of repositories, several competencies are needed by the HAEA [1].

To manage this need, HAEA has reorganized its organisational structure providing specific staff to performance the functions regarding the supervising of the repositories. This new task-allocation makes possible to use the needed skills that are available at the HAEA, after large scale staff recruitment.
5.2. Guidelines

There are several areas where safety guides have not been developed yet, including closure, site characterization process, the development and the update of waste acceptance criteria, safety assessment of overlapping excavation/construction and operation. [1].

The Decree empowers the HAEA to publish guidelines to facilitate the compliance with the requirements. HAEA has already issued three guidelines in this field:

— Inspection of radioactive waste storage and disposal facility;
— Regular and event reports of radioactive waste storage and disposal facilities;
— Survey of the safety culture and the utilization of the results at the repositories.

In order to comply with the Decree, the HAEA has undertaken the elaboration of further guidelines on the following topics (some of them with the support of external company acting as TSO):

— Periodic Safety Review for the Radioactive Waste Treatment and Disposal Facility;
— Periodic Safety Review for the National Radioactive Waste Repository;
— Licensing activities of modification in radioactive waste storage and disposal facilities.

REFERENCES

Abstract

In the mid of 2015 a coordination action project SITEX-II was initiated within the EC programme Horizon 2020. It aims at implementing in practice activities along with the interaction models issued by the SITEX project (carried out within FP7 programme in 2012-13), in view of developing an Expertise function network. This network is expected to ensure sustainable capacity of developing and coordination joint and harmonised activities related to the independent technical expertise in the field of safety of deep geological disposal of radioactive waste.

1. INTRODUCTION

responsibility of the license holder with regards to safety and reinforces the role and independence of the competent regulatory authority.

For this purpose, WMOs in Europe decided to coordinate their efforts to be able, at horizon 2025, to implement the first geological disposal and launched in 2009 the Implementing Geological Disposal of Radioactive Waste Technology Platform (IGD-TP) under the aegis of the EC. This coordination is established through a common vision and strategic research agenda (SRA) that foster exchanges and joint works about the scientific challenges that remain to be addressed before 2025.

In line with this Directive and in consistency with international high level safety standards issued by IAEA and WENRA, and with international approaches developed within the NEA/RWMC activities, waste management organisations (WMOs) are developing a safety case for presenting the technical and organisational arguments that support the development of the national geological repository concept. As safety cases develop, capability of their review by regulatory bodies in the framework of the decision making process develops as well. The assessment of the scientific and technical issues developed by the WMOs requires specific skills from the reviewer in order to evaluate whether they allow compliance with the safety requirements issued by the regulatory authority.

In that context, there is a need at the international level for developing and coordinating activities associated to the regulatory review process of geological disposal. For that purpose, the FP7 EURATOM SITEX (2012-2013) project (www.sitexproject.eu) was launched in order to complement the above mentioned initiatives with the view to characterize at national level the Expertise function activity devoted to the technical review of the safety case with respect to the safety of the geological disposal. This specific Expertise function was characterized as the set of scientific and organisational activities developed in support to regulatory body to review the safety case.

The SITEX project highlighted different needs and missions of the national Expertise function along the decision making process, in relation to: safety case Regulatory Review, Implementation of Research in Safety, Training of Experts in charge of regulatory review and Interaction with Civil Society (CS). Regarding these different tasks, SITEX (2012-2013) project participants identified the potential areas of cooperation, exchanges or sharing of resources that could be developed by a future SITEX network. For that purpose, the sources and issues listed below were considered:

- International and national standards and guides (defining the expectations of regulators);
- An inventory of the Expertise function in SITEX project participants’ countries and an overview of the needs of expertise as part of technical support and inspection for national regulators;
— An overview of the methodologies used in the context of a safety case review and an assessment of the needs of harmonization of these methodologies and of specific training required to implement the safety case review;

— An inventory of Research & Development (R&D) programs implemented, facilities operated and modelling carried out by organisations involved in SITEX, with the view to prepare the development and the implementation of a strategic research agenda (SRA) specific to the Expertise function;

— An overview of the expectations of the other stakeholders in terms of interaction with the Expertise function (notably on the basis of the results of a Workshop organised with CS representatives), and the exchanges organised with WMOs in the framework of IGD-TP regarding the coordination of research programming at European level.

Though the considerable preparatory work carried out within SITEX (2012-2013), some of the above outcomes and key concepts of a future SITEX network require being further developed and/or tested in practice before to validate orientations stated in the former SITEX project and launch the network. There is also a need to reinforce the links between the Expertise function and the CS regarding its engagement in the decision making process and in particular in the identification of research topics relevant for CS that would be integrated in the definition of the strategic research agenda. Considering the above comments, former SITEX participants, Civil Society organisations, and R&D entities decided to build a follow-up of SITEX project. This step ahead toward a SITEX network is the purpose of the coordinated action SITEX-II as described below.

2. SITEX-II OBJECTIVES

The overall objective of the proposed coordinated action is the practical implementation and demonstration of the sets of activities along with the interaction modes issued by the FP7 program SITEX project (2012-2013), aiming at developing at European and international level the Expertise function network ensuring to coordinate joint and harmonized activities related to the independent technical expertise in the field of safety of geological disposal of radioactive waste.

For this purpose, regulatory organisations, TSOs, research groups as well as organisations representing the CS propose a second phase of SITEX as a new 30-month coordination action called SITEX-II, which stands for “Sustainable network for Independent Technical Expertise of Radioactive Waste Disposal – Interactions and Implementation”. The step beyond SITEX (2012-2013) would include:
— The definition of the Strategic Research Agenda based on the common R&D orientations defined by SITEX project participants, the definition of ToR for the implementation of specific topics of from the SRA, and the interaction with IGD-TP and other external entities mandated to implement research on radioactive waste disposal regarding the potential setting up of a respective European Joint Programming;

— The production of a guidance on the technical review of the safety case at its different phases of development, fostering a common understanding on the interpretation and proper implementation of safety requirements for developing, operating and closing a geological repository and on then verification of compliance with these requirements;

— The practical demonstration of experts training that may be provided by SITEX network in the future: the development of training modules at a generalist level, with emphasis on the technical review of the safety case, based on national experiences, practices and prospective views and following pilot training session;

— The commitment of a Civil Society in the definition of the SRA mentioned above, considering the expectations and technical questions to be considered when developing R&D for the purpose of Expert function. Close interactions between experts conducting the review work and CS representatives will enhance establishing the safety culture and, more globally, proposing governance patterns with CS in the framework of geological disposal;

— The preparation of the ‘administrative’ framework for creating a sustainable network of Technical Safety Organisations from EU members states by addressing the legal organisational and management aspects.

3. PROJECT IMPLEMENTATION

3.1. Concept and approach

The different services of the SITEX network to the SITEX members relate to Training and tutoring, Reviewing the safety case, Developing a research strategy and workforce at national and international level and Interacting with the Civil Society.

Three graded modes of interactions of the SITEX network are identified as follows (see Fig.1): (i) the mode of interactions “Programming” aims at identifying specific needs and developing diagnostic and specific programmes and products by sharing national experiences, practices and prospective views and by auditing appropriate stakeholders; (ii) the mode of interactions “Implementing” aims at implementing in
Within the SITEX network, the programmes and products identified in the first mode of interaction by developing joint work and sharing resources; and (iii) the mode of interactions “Harmonizing, linking with external entities” aims at building the collective opinions of the network with the view to reach harmonization where appropriate, as well as promoting and diffusing the SITEX network products and developing interactions and partnerships with external entities.

The SITEX-II project aims at further preparing the launching of this foreseen SITEX network. Accordingly, the project will implement in practice interaction modes and services mentioned above. This involves programming interactions (SRA, guidance), implementing interactions (pilot training session) and harmonizing interactions with external entities. In order to efficiently implement the programme of work of the SITEX-II project, the project consortium consisting of 18 institutions from 12 countries was composed involving representatives of regulatory bodies, technical experts from TSOs and research institutes, as well as organisations that have experience in CS participation. Close cooperation with implementers (via the IGD-TP) will also be a key tool for ensuring success of this coordinated action. Actually, the implementation of the SITEX SRA should be shared, where needed, with the R&D programme carried out by the WMO’s at European level, in line with the orientations regarding the establishment of a European Joint Programming (EJP) by the European Commission. The Figure 2 illustrates the composition of the

**FIG. 1. Framework of the SITEX network.**
SITEX-II project as well as the external entities of interest with regards to SITEX-II, with which interactions are foreseen.

3.2. Overall structure and goals of the project

The work in the project SITEX-II has been designed into six inter-related Work Packages (WPs), with two WPs respectively dedicated to the management of the project and to the integration and dissemination of its outcomes, and four WPs addressing the key topics that would drive the future activities of the foreseen network of expertise. This structure, designed in close collaboration with regulatory bodies, technical support organisations (TSOs), R&D organisations and Civil Society (CS) organisations. The particular WP’s cover the following issues:

WP1 - Programming R&D (Bel V, Belgium)

(a) Based on outputs of former SITEX project (a synthesis of the scientific and technical areas of interest and of the resources) creation of a SITEX SRA defining and prioritizing R&D topics in line with the previously identified R&D orientations;
(b) Defining the ToR for the implementation of R&D topics by the Expertise function alone;
(c) Providing support to SITEX-II representatives in the JOPRAD project (see Section 3.3) by identifying the Expertise function expectations regarding the construction of a potential EJP as well as SITEX-II position regarding the R&D topics that could be shared within programmes in the framework of an EJP.

WP2 - Developing a joint review framework (FANC, Belgium)
Developing a common understanding, among regulatory bodies, TSOs and CS, on the interpretation and proper implementation of selected high-level safety requirements issued by international entities (EC directive, IAEA, ICRP, WENRA…), as well as developing guidance on reviewing the safety case.

WP3 - Training and tutoring for reviewing the safety case (LEI, Lithuania)
Demonstration in practice of training services that may be provided by a future SITEX network together with an existing institute for expert training in nuclear safety (European Nuclear Safety Training and Tutoring Institute, ENSTTI):
   a. Development of training modules for generalist experts, with emphasis on the technical review of the safety case, based on national experiences, practices and prospective views;
   b. Implementation of a pilot training session.

WP4 - Interactions with Civil Society (Mutadis, France)
(a) Promoting CS involvement in the whole decision-making process on radioactive waste management.
(b) Developing the interactions between representatives of the Expertise function and the CS through three thematic activities of this process, dealing with R&D, safety culture / safety case review and more globally, governance related to geological disposal including institutional and legal framework issues.

WP5 - Integration and dissemination (CVREZ, Czech Republic)
(a) The integration and issuing project outcomes;
(b) The development of the legal, organisational and management aspects for the SITEX network development in the form of an Action Plan for its establishing;
(c) Promoting the interaction of SITEX-II participants with external entities, especially stakeholders (CS, WMOs, Research centres, etc.);
(d) Supporting other ways of dissemination of SITEX-II results to larger tribunes and fostering the participations to international events.
WP6 - Management (IRSN, France)
Project management and coordination.

3.3. Participation in JOPRAD

Project JOPRAD (Towards a Joint Programming on Radioactive Waste Disposal) is a coordination action fulfilled within the H2020 EURATOM Work Programme 2014-2015, as SITEX-II. The project is implemented by a consortium consisting of three categories of stakeholders: (i) waste management organisations (WMO) represented by IGDTP members, (ii) technical support organisations (TSO) represented by SITEX members, and (iii) nationally funded Research Entities (RE) involved in the R&D of radioactive waste management, including geological disposal. These representatives are nationally mandated by the “programme owners”, typically the ministries in charge of the setting up of national radioactive waste management programmes.

The ultimate goal of this project is to prepare a proposal for the setting up a system of a “Joint Programming on Radioactive Waste Disposal”. This should bring together, at the European level, those aspects of R&D activities to be implemented jointly where synergy from Joint Programming is expected.

4. SUMMARY

In 2015, the coordinated action SITEX-II was initiated within the EC programme HORIZON 2020 aiming at paving a pathway for establishing a network of Technical Support Organisations and technical experts supporting regulators in reviewing the Safety Case of waste disposal facilities. The action further elaborates outcomes of previous project SITEX performed in 2012-2013 and coordinates its activities towards Joint Programming of R&D regarding geological disposal at European level with IGD-TP platform through the participation of SITEX representatives in the JOPRAD project.

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EFFECTIVE NUCLEAR REGULATORY SYSTEMS 
FACING SAFETY AND SECURITY CHALLENGES

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Abstract

Nuclear regulators should not actively take part in issues concerning nuclear energy policy. Their essential function is to contribute as effectively as possible to nuclear safety. The principal focus will be on the application of this concept since the Fukushima Daiichi nuclear accident. By using a comparative approach, the paper will address the measures taken by various countries to ensure the independence of their respective nuclear regulator, especially in light of the recent nuclear accident.

1. INTRODUCTION

The purpose of the paper is to address the issue of regulatory independence in the nuclear industry. The first part of the paper will discuss the importance of regulatory independence. This section will address the meaning of effective independence, as well as the ways in which regulatory independence can be achieved. The purpose of the second part will be to compare the concept of regulatory independence in the aftermath of the Fukushima Daiichi nuclear accident, as applied and implemented in different countries.

2. THE PRINCIPLES OF REGULATORY INDEPENDENCE FOR NUCLEAR REGULATORS

A number of measures can be taken in order to ensure that the regulatory body is well equipped to meet the challenges to independence in regulatory decision making in matters of nuclear safety. Some of these measures need to be taken by the relevant political decision makers (government and parliament). Others are the responsibility of the senior management of the regulatory body. These measures can be grouped into three tiers:

— The establishment of the legal framework governing regulatory activities and their associated objectives, principles and values, including the legal basis for adequate and stable financing of regulatory activities;
— The establishment and implementation of clearly defined processes for regulatory decision making;
— The establishment and implementation of a clearly defined competence management programme for the regulatory body which includes an internal management programme for human resources and provides the necessary means to secure independent scientific and technical support for the regulatory activities, with international co-operation as an important component.

These measures may be regarded as fundamental components of a regulatory quality management system aimed at ensuring the key features of independent regulatory decision making and the overall quality of regulatory activities.

3. CHANGES BROUGHT TO REGULATORY AGENCIES SINCE THE FUKUSHIMA DAIICHI NUCLEAR ACCIDENT

Whenever a major nuclear accident occurs, the role of the regulatory body often comes under scrutiny. Following the nuclear accident at Fukushima Daiichi in March 2011, many States have reviewed the structure of their nuclear regulator and emphasized the importance of having independent regulators, in order to ensure that such events will not occur again in the future. In this section, I propose to analyze the changes adopted by United Kingdom and Japan.

The United Kingdom

Even though the United Kingdom had commenced the modification of its regulatory authority prior to the Fukushima Daiichi nuclear accident, the event confirmed the need for a modern, independent and flexible nuclear regulator. Prior to the changes, the Health and Safety Executive (HSE) regulated the nuclear industry through its Nuclear Directorate. The HSE was set apart from government and industry, and was therefore independent in its role as nuclear regulator. There were, however, inherent concerns about the HSE’s accountability and transparency in its regulation of the nuclear sector, especially since the HSE carried out certain statutory functions on behalf of the Secretary of State, rather than in its own right as regulator.

In February 2011, the Government of the United Kingdom announced the establishment of the Office for Nuclear Regulation (ONR) to regulate the nuclear power industry; pending legislation, the ONR was set up as a non-statutory agency of the HSE, in April 2011. As such, the ONR is without legal personality, and does not have the right to perform regulatory functions in its own right. Its establishment is a temporary solution, pending the introduction of legislation to establish the ONR more formally as a statutory body. On May 22, 2012, the Department of Energy and Climate Change published its draft Energy Bill 2012, which seeks to establish the ONR.
It is anticipated that the Energy Bill will receive Royal Assent in mid-2013. The provisions set out in the Energy Bill reflect existing legislation, and do not present a significant departure from the status quo. The transition to a statutory ONR is intended to create a transparent regulatory arrangement, and will provide the statutory ONR with an increased flexibility in financial and employment arrangements.

Japan

The Fukushima Daiichi nuclear accident put Japan at the centre of an international controversy on nuclear safety and regulation. Following this event, the Japanese government adopted a new regulatory regime to oversee nuclear safety in the country.

The Atomic Energy Basic Act and other laws regulate nuclear energy in the country. Prior to 2012, the Minister of Economy, Trade and Industry (METI) had jurisdiction over nuclear installations in Japan; METI was in charge of the safety regulation of the nuclear installations, and had the authority to issue licenses for the installment of nuclear installations, after examining sitting, structure, and equipment to ensure that the nuclear installation would not cause any radiological hazard.

4. CONCLUSION

The purpose of this paper was to explain the independence of regulatory bodies in the nuclear sector and to examine the changes that have taken place since the Fukushima Daiichi nuclear accident. Effective independence generally means that the regulatory body must be able to make decisions for the regulatory control of facilities and activities without undue pressure or constraints from the government, from any organization promoting the nuclear industry, those who are opposed to the use of nuclear energy, or those it regulates.

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CONTRIBUTIONS OF THE EUROPEAN OPERATING EXPERIENCE FEEDBACK PROJECT TO SUPPORT REGULATORY BODIES

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Abstract

Operating Experience Feedback (OEF) is one of the ways of improving the nuclear safety of operating nuclear power plants. The EC-Clearinghouse initiative was set up in 2008 to support nuclear regulatory authorities of EU Member States, but also Technical Support Organizations, international organizations and the broader nuclear community, to enhance nuclear safety.

The differing regulatory regimes in the EU member countries and a significant diversity of the nuclear power plant (NPP) designs have been a challenge in the establishment of the European Clearinghouse.

The European Clearinghouse is organized as a Network operated by a Central Office located at the Institute for Energy and Transport (IET) which is part of Joint Research Centre (JRC) of the European Commission. It gathers 17 European regulatory authorities and three major European Technical Support organizations (TSO).

The Clearinghouse aims at providing lessons learnt, raises recommendations and identifies best practices from operational experience of NPPs based on support and commitment from the EU nuclear regulatory authorities. The objectives of the European Clearinghouse help to improve methodologies and capabilities for the assessment of unusual events in NPPs.

The paper presents the main activities of the European Clearinghouse. These include (a) Topical studies providing in-depth assessment of selected topics important for the safe operation of NPPs. Statistical tools help to identify interesting subjects for these studies;(b) Quarterly reports on operating experience; (c) Training courses in the field of root cause analysis and event investigation; (d) Development, maintenance and population of a database for storage of operating experience related information and (e) Collaboration with international organizations such as IAEA and OECD/NEA on all aspects of OEF.
All activities of the Clearinghouse initiative focus on providing an added value to nuclear regulation in Member States.

1. INTRODUCTION

A regional initiative was set up in 2008 in support of EU Member States’ nuclear safety regulatory bodies, but also EU Technical Support Organizations (TSO), international organizations and the broader nuclear community, to enhance nuclear safety through improvement of the use of lessons learned from operational experience of nuclear power plants (NPPs). Good international experience showed that the establishment of a centralized OE Clearinghouse for a particular region in the world can yield significant benefits due to optimized use of resources and improved feedback of lessons learnt. Due to differing regulatory regimes in the EU member countries, significant diversity of the NPP designs and different languages used, the establishment of the European Clearinghouse was more complicated and challenging and needed strong support and commitment from the EU nuclear safety regulatory authorities.

The Joint Research Centre (JRC) of the EC was chosen to play a central role in establishing and running the European Clearinghouse for Operating Experience Feedback (OEF). The choice allowed the use of well-established JRC working mechanisms, means and technical expertise in the field to promote better cooperation and more effective use of the limited national resources and to strengthen the capabilities for OE analyses and dissemination of the lessons learned.

The European Clearinghouse is organized as a Network operated by a Central Office located at the Institute for Energy and Transport that is part of JRC of the European Commission. It involves currently 17 European nuclear safety regulatory authorities and 3 major European TSOs.

The European Clearinghouse was challenged during and in the aftermath of the Fukushima Daiichi accident and provided daily technical updates on the local situation for dissemination in the EU Member States [1].

2. OBJECTIVES OF THE EUROPEAN CLEARINGHOUSE

The main objectives of the European Clearinghouse are set out in the Terms of Reference of the Clearinghouse. Among them are:

- Strengthening co-operation between European safety authorities, TSOs and the international OEF community to collect, evaluate and share NPP operational events data and help to apply lessons learnt in a consistent manner throughout member countries;
- Establishing European best-practices for assessment of unusual events in NPPs;
— Coordinating OEF activities and maintaining effective communication between experts from European regulatory authorities involved in OEF analyses and their TSOs;
— Strengthening European resources in operating experience;
— Supporting the long-term EU research and policy needs on NPP Operating Experience Feedback.

3. SCOPE AND WORKING METHOD

The Institute for Energy and Transport (IET), one of seven institutes making up the Joint Research Centre which is a Directorate General of the European Commission (DG JRC), is the Centralized Office (CO) of the EU Clearinghouse on OE for NPPs. The European Clearinghouse is governed through two main bodies; the Technical Board (TB) and the Steering Committee (SC).

The SC is the decision body of the EU Clearinghouse. The SC’s mandate is to approve the annual work programme proposed by the OA, as well as the final version of the deliverables prepared in the framework of the EU Clearinghouse, before their formal distribution.

The SC has the right to propose areas of special interests on NPP OEF for further development. The SC approves or rejects new candidate members as observers or full members.

The TB is a discussion forum for the working programme and the work performed. It includes SC members and observers, TSOs and international organizations such as IAEA, OECD-NEA and DG-ENER of the European Commission.

The scope of activities of the European Clearinghouse was, inter alia, agreed to:

(a) fostering the collection of operating experience from European nuclear regulators or operators, assessing its potential value for learning lessons, and ensuring that events relevant to global OEF are reported systematically and in consistent manner to the IRS system jointly operated by NEA and IAEA;
(b) distributing selected events to appropriate professional groups in Europe for detailed event analyses;
(c) evaluating IRS reports and alerting the national regulatory bodies on the most relevant events and on significant corrective actions implemented;
(d) providing topical studies of event groups with similar features or causes and facilitating trend analyses to enable better understanding of the main patterns from events with significant operating experience.

The Clearinghouse activities can only be carried out in close collaboration with the international community. Fig. 1 illustrates that Technical Support
organizations or TSOs play a central role in obtaining and analysing information about operating experience: three major European TSOs (IRSN from France, GRS from Germany and Bel V from Belgium) are members of the Technical Board and advise the Clearinghouse about technical issues. In many occasions, JRC and TSO experts work together to elaborate comprehensive topical studies.

4. MAJOR ACTIVITIES

4.1. The activities in the frame of the European Clearinghouse include different approaches Topical studies on selected subjects related to NPP operating experience

Topical Studies provide in-depth assessment of selected safety relevant subjects for which operating experience has been reported. These studies often cover 200 events or more. They typically provide statistical analyses, corrective actions, lessons to be learnt and recommendations to avoid recurrence of events. The Clearinghouse project has finished up to now 18 Topical Studies and for each of them a summary report which are available on the Clearinghouse website. Studies on events related to external hazards in 2012 [2] [3], on emergency Diesel generators in 2013 [4] [5], on events in the cooling chain in 2015 [6] [7] and the study on events related to maintenance activities [8] [9] are prominent examples. A summary of the studies completed in the last years is given in Fig. 2. Two more studies are under preparation; considerations are currently made for two new studies to be finalized in 2017.
FIG. 2. Topics of recent Topical Studies published by the Clearinghouse

The study on external hazards [2] analysed 230 events from several databases classified into different categories according to the initiating event such as extreme weather conditions, extreme heat sink conditions, external flooding, external fires, lightning strikes, fouling, chemical events and man-induced events. In addition to the recommendations and lessons learned specific to each type of external hazard, the study allowed identifying several generic issues. In some cases, multi-unit or even multi-plant consequences of external hazards were not considered as a design basis for plant safety. Some OE reports indicated that the intensity of a phenomenon was much stronger than could have been foreseen from historical data.

The study on emergency Diesel generators [4] applied a similar approach and screened events over a period from 1990 to 2010. Special attention was given to common cause failures (CCF) as observed with the Fukushima Daiichi NPP accident. Several events were assessed which could be considered as important precursor for potential CCF type failures (e.g. icing events compromising cooling, harsh weather conditions, design deficiencies or insufficient qualification for earthquakes). The study concludes with recommendations in six main areas including preventive maintenance and testing, protective devices, reliability and external events.

The study on events related to maintenance activities in NPPs [8] focused on in-depth analysis of causes, root causes, contributing factors and consequences and deduced lessons learned from the events investigated. Events from four databases were scanned and included periodic, predictive, planned and corrective types of maintenance. The statistical analysis of events revealed that valves and electric power components were the most effected technical components. The prevailing root causes identified throughout the analysis were "maintenance performed incorrectly", "deficiencies in written procedures or documents" and "deficiencies in management or organization". The study provides several recommendations and
concludes among others that learning from plant's own maintenance history and a comprehensive human reliability analysis provide useful tools for identifying weaknesses in plant maintenance practices and procedures. Predictive maintenance is the most effective event-free type of maintenance.

Fig. 3 provides an overview of the studies under development or review and the plans for 2017/2018.

As already mentioned the topics of all studies are based on internationally available reported operating experience and were selected according to their safety significance.

![FIG. 3. Topical Studies in progress or under consideration](image)

All Topical Study reports can be found on the Clearinghouse website. For each of these reports a shorter summary report providing the main findings of the respective study in concise form is provided and is freely accessible after registration. The Topical Study reports can also be obtained from the IAEA IRS website.

4.2. Contributions to improve the quality of event reports sent to the International Reporting System

The International Atomic Energy Agency (IAEA) together with the Nuclear Energy Agency (NEA) of the OECD operates the International Reporting System for Operating Experience (IRS). All participating countries share operating experience to improve the safety of nuclear power plants and submit event reports on unusual events relevant for safety.

The Clearinghouse helps ensuring quality and consistency of these event reports to the IRS system by reviewing draft reports upon request of Clearinghouse member countries.

4.3. Quarterly reports on Operating Experience

Quarterly reports are issued by the Clearinghouse and provide timely information to its members and the general interested community about recent significant events with a real or potential impact on nuclear or radiation safety.
Quarterly reports compile NPP events that were reported publicly. Each quarter, around 100 events are screened by a selection committee which decides about five or six more relevant events to be published in the quarterly report. All screened events are uploaded in the Clearinghouse database.

Quarterly reports are published on the Clearinghouse website and are freely available.

4.4. Development, maintenance and population of a database for storage of Operating Experience related information

The Clearinghouse maintains a website and a database which can be found under the following address: https://clearinghouse-oef.jrc.ec.europa.eu/.

This platform provides access to all relevant resources of the Clearinghouse project. It is organized in three layers. The entry level is open to all visitors of the platform and provides comprehensive information about Clearinghouse and its objectives but also latest news, next activities and interesting links including quarterly reports and other documents.

The restricted and confidential levels require special credentials and were established according to the character of documents provided there.

The internet platform provides also access to a database which contains the events screened for the various activities of the Clearinghouse such as quarterly reports.

4.5. Training in the field of Root Cause Analysis and event investigation

Each year, the European Clearinghouse provides a five-days training course about Root Cause Analysis (RCA) and event investigation, designed mainly for regulatory bodies and TSOs.

This training provides detailed knowledge of the RCA methods and tools frequently used in the practice of nuclear events investigation. Emphasis is given to practical use of universal RCA tools such as Event and Causal Factors Charting, Barrier Analysis, Change Analysis, Task Analysis, Interviewing, Management Oversight and Risk Tree Analysis. These methods are applied in all event investigations and are appropriate for analysis of Human and Organisational Factors contributing to nuclear events.

This training combines lectures and practical exercises of event investigation including interviews among participants. The next training course will be held 11-15 April 2016 in Petten, The Netherlands.

RCA courses have been attracting increasing international interest and were acknowledged by participants.
5. CONCLUSIONS

More than eight years of operation of the European Clearinghouse have shown the added value of the initiative. Further areas are being developed such as statistical tools to identify topics which should be on focus in the future.

Numerous Topical Studies on selected safety relevant subjects for which operating experience has been reported and quarterly reports or newsletters have been published by the European Clearinghouse and contribute to further strengthening nuclear safety in the operation of NPPs.

Beyond the tasks carried out by the Centralized Office of the European Clearinghouse, the key aspect of the achievements obtained so far is the successful cooperation of European Regulatory bodies, European TSOs and the JRC.

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MORE EFFECTIVE REGULATORS THROUGH IMPROVED ACCOUNTABILITY

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Abstract

The Fukushima-Daiichi Accident demonstrated the need of assessing and strengthening institutions involved in nuclear safety, including the accountability of regulators. There are a few problems hindering the path towards a greater understanding of accountability systems, the ensemble of mechanisms holding to account the nuclear regulator on behalf of the public. There is no consensus on what it should deliver and no systematic assessment method exists. This article proposes a definition of an effective accountability system and a method of assessment of institutions based on defence in depth concepts and inspired from risk-assessment techniques used in the nuclear industry.

1. INTRODUCTION

Prior to the Fukushima-Daiichi nuclear accident, both the nuclear operator and the regulator were seemingly aware that the plant would be unable to withstand a very large tsunami having predicted by some of having a credible frequency of occurrence [1,2]. The failure of the operator to make the necessary improvements was caused by institutional shortcomings including in the regulatory system.

In the comprehensive investigation led by the IAEA after the accident, it was found that the main regulatory body, the Nuclear and Industrial Safety Authority (NISA) lacked the authority to have the operator make these changes and traces this issue to several institutional failings [3]. First, NISA lacked independence from both the nuclear industry it was charged to oversee and the ministry promoting nuclear power. Second, it lacked formal authority due to the complexity of the regulatory framework. Finally, the government staffing policy and the rule requiring job rotation every few years in particular hindered NISA staff from gaining the expertise needed [3].
Despite these deep-rooted institutional failings being identified as one of the root causes of the accident, the international nuclear community has so far focused predominately on engineering and operational lessons.

In order to identify ways of making a country’s institutions involved in nuclear safety more robust, the concept of institutional strength in depth is particularly useful. Inspired by the engineering principle of the same name, it details the three barriers ensuring sound and risk-informed decision making in the field of nuclear power. They are the nuclear industry, the regulator and the stakeholders. They are represented in Figure 1.

The stakeholders provide the third level of protection. They are of diverse nature and can be divided into two distinct groups [6&7]: The first set is composed of members of the nuclear industry – the workers in the industry. The second set is the general public, its governmental representatives such as the national and local governments, and non-governmental entities such as NGOs and other interest groups.

Little attention has so far been given to the third barrier. Thus, there lies the greatest potential for improvement. In order to be a sound level of defence, stakeholders must be able to have an impact on the regulator’s actions when needs be. Therefore, they must be well informed and have effective means of actions at their disposal. For that they have to rely on diverse mechanisms which hold the
nuclear regulator to account. All together, these mechanisms form what will be referred to as the system of accountability for the nuclear regulator.

It is this area of the overall model of institutional strength in depth that is the prime focus of this paper. The goal is to find a new approach to assessing the impact of these institutions on nuclear safety.

2. BACKGROUND

Definition

The definition of regulatory accountability that will be used in this paper is the following: For a regulator, to be accountable is to be required to justify both its decisions and actions and to make the necessary changes should the explanation given be judged unsatisfactory.

Accountability mechanisms

In most countries, the mechanisms through which the nuclear regulator is held to account typically include the following:

— Stakeholder consultations such as NGO forums public consultations, public meetings, consultation with the nuclear industry etc.
— Parliamentary oversight in the form of annual reports, committee hearings, parliamentary questions etc.
— Oversight by the executive branch (i.e. by a ministry or a governmental agency).
— Financial and performance audits.
— Appeal processes.
— Appointment process for leadership role within the regulatory body.

Stakeholders and regulatory accountability

Whilst stakeholders may not know what the regulatory framework should look like or how the regulator should manage its activities, they can always provide valuable input on its decisions as they are directly affected by them and thus may perceive issues the regulator overlooked.

The report of the House of Lords’ Select Committee on the Constitution entitled The Regulatory State – Ensuring its Accountability, identifies three key elements to allow the stakeholders to have an impact on a regulator’s actions [8].

— The duty to explain: Regulators must provide information on its activities to interested parties and explain the basis of the decisions they take.
— Exposure to scrutiny: Regulators must provide the means through which stakeholders can enquire about regulatory activities and decisions.
— The possibility of independent review: Stakeholders must be able to ask for an independent review of a regulatory decision so that it may be overturned or altered.

3. PROBLEM DESCRIPTION

Regulatory accountability is not a very active field of study. Accountability is mentioned in myriads of books and articles on public administration [9 to 14] and on regulation [15 to 18] as it is seen as a democratic requirement and a necessity to ensure an effective public administration and effective regulators. However the chapters dedicated to accountability only skim the surface and readers must content themselves with a basic explanation of its concept and brief descriptions of the various accountability mechanisms in place in the country in question.

In Regulatory Policies in OECD Countries, From Interventionism to Regulatory Governance, the OECD provides details on what constitutes an effective system of accountability. These can be divided into two parts.

Firstly, a strong set of legal requirements for regulators to uphold is needed to foster transparency and accountability. It must include:

— A law setting explicitly the objective(s) of the regulator [19].
— Laws on information disclosure [20] and requirements on responsiveness to information requests [21].
— Requirements for the regulator to seek the opinion of the stakeholders on regulations that affect them [22].
— Requirements governing regulation-making processes to ensure fair and transparent regulatory procedures [23].
— Secondly, an effective system of accountability comprises the following features.
— An appeal process that is clear, predictable, consistent and independent from the original decision-maker [24].
— An audit office that is in charge of checking the quality of the implementation of the regulations [25]
— Oversight of the regulator’s activities by the parliament [26]
— A regulatory oversight body in charge of regulatory reform [27]

Only a few studies focus exclusively on accountability systems [28,29,30]. Furthermore, they all use different methods of assessment, each lacking a systematic approach. They use few, if any, quantitative performance indicators to assess accountability systems. As a result the studies cannot be used to compare these
systems. Additionally, this helps maintaining a certain amount of subjectivity which is detrimental to the accuracy of the assessment.

Finally, the focus of these studies is not on the accountability system in question but rather on its individual parts. The objectives the system of accountability should achieve are never clearly stated. As a result these studies were unable to consider neither the relative importance of each mechanism in achieving them nor the combined effects of all the system’s parts put together. Whilst the importance of balancing accountability with efficiency was recognised, neither the OECD nor the three studies talked about the costs of the various accountability mechanisms.

Objective:

The objective of this work is to take the first step towards overcoming these shortcomings. It will propose a flexible method of assessment that would be able to evaluate different systems of accountability whilst providing quantitative results allowing their comparisons. Finally, it will present a simple simulation depicting a much-simplified version of the method of assessment. The aim of the simulation is to illustrate the inner workings of the method of assessment and demonstrate the kind of results it will be able to supply. Sensitivity studies were performed to check the impact of the assumptions made on the results obtained.

4. PROPOSAL FOR A NEW METHOD OF ASSESSMENT

Objectives of an accountability system

In order to build a method of assessment on strong foundations, it is necessary to first address an issue that has never been tackled head on and define the objectives of an accountability system.

It can be argued that the fundamental purpose of the system of accountability is to ensure that the nuclear regulator is achieving its objective, that is, ensuring that nuclear licensees operate their facilities in a safe manner.

Additionally, the system of accountability should help foster a strong safety culture within the regulator as well as trust and respect between the regulator and the stakeholders and finally encourage their involvement in the framework of accountability.

New approach

The approach proposed to provide a sound foundation to the method of assessment revolves around two key ideas. The first is to use risk assessment techniques used in the nuclear industry as an inspiration for the assessment method as the two issues share similar traits. The nuclear safety case, which has long been
used in the nuclear industry to demonstrate the safety of a nuclear facility or activity, is of particular interest. Based on solid scientific foundations, it uses a systematic approach and offers both a qualitative and quantitative risk-assessment to provide assurances that the risks posed by the facility or activity in question have been reduced to reasonable levels and as low as reasonable practicable (ALARP).

The second idea is to model accountability mechanisms and nuclear regulators as well as their decision-making processes. The assessment of systems of accountability would thus rely less heavily on the observable behaviour of these organisations and would be able to assess the contribution of each individual accountability mechanism in the achievement of the system of accountability’s fundamental objective. Indeed, as most countries rely on similar mechanisms to provide some regulatory accountability, and since real-life experiments are not a possibility, modelling how they function is the only approach that can accomplish this goal.

**Nuclear safety case**

A nuclear safety case is a set of documents describing the potential sources of danger, or hazards and the systems put in place to prevent these from causing harm, or should it come to it, to mitigate the harm done. The safety case may relate to a site, a facility - or part of one –, an activity, or a modification to a facility or to an activity [31].

The first aim of a safety case is to demonstrate that all credible hazards and risks associated with the activity or facility in question have been identified and understood, and that limits and conditions of operation and adequate safety systems have been identified and put in place for the risks to be at acceptable levels, and ALARP. Its second objective is to provide the necessary information for the nuclear facility to be run, or the activity to be undertaken, safely.

In order to achieve these objectives, a nuclear safety case must first provide an analysis of normal operating condition to demonstrate that the radioactive doses to nuclear workers and to the public are below regulatory limits and ALARP.

Secondly, the safety case must include a risk assessment analysis of the activity or facility in question. The objective of a risk analysis is to predict what adverse events might happen [32]. As a result, for a plant, a risk analysis must cover the undesirable events that could occur and the consequences they could lead to taking into account the facility’s safety systems and their likelihood to fail on demand.

Therefore, the risk assessment must go through the following steps [31]:

- Identify all the possible hazards using systematic and thorough identification processes.
- Identify all possible faults that could trigger an undesirable event using systematic and thorough identification processes. For instance
combustible material is a hazard, and a spark is a fault associated with it as this would ignite the material and start a fire.

— Identify the failure modes of the plant using systematic and thorough fault sequence identification processes

— Perform both deterministic and probabilistic analyses of the plant design against these failure modes. The analyses must demonstrate that the facility conforms to sound safety principles such as defence in depth and that equipment important to safety is going to work during its expected lifetime so as to prove the design’s strong tolerance against these failure modes.

Structure and rational of the method

The IAEA provides a list of requirements for nuclear regulators to follow whilst the NEA detailed the characteristics they must possess. As both organisations compiled these results thanks to substantial research on regulatory effectiveness, it can be inferred with some confidence that any deviation from these standards would impede regulators from performing effectively.

Ensuring the effectiveness of the regulatory authorities can thus be thought as an effort to systematically detect and fix these deviations, or regulatory failures, and mitigate the negative impact these may eventually have on the safety of nuclear facilities. This occurs when the regulator fails to undertake its regulating duties adequately, such as taking decisive action when an unacceptable risk arises.

As a result, the assessment of the effectiveness of a system of accountability can be done by evaluating the response of the nuclear regulator to combinations of regulatory failures. In particular, the negative impact the nuclear regulator has on safety can be used as a scale of effectiveness for its system of accountability.

Analogy with the nuclear safety case:

Table 1 presents the different analogies that can be drawn between the risk-assessment method used in the safety case and the method for assessing the effectiveness of a system of accountability.

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Safety case</th>
<th>Accountability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source of danger</td>
<td>Hazards and associated faults</td>
<td>Regulatory failures</td>
</tr>
<tr>
<td>Impact on system</td>
<td>Fault sequences</td>
<td>Failure sequences and their impact on regulatory processes</td>
</tr>
</tbody>
</table>

TABLE 1. Analogies between the risk assessment used in a safety case and the proposed method for assessing the effectiveness of a system of accountability
<table>
<thead>
<tr>
<th>Consequences for safety</th>
<th>- Probability of incident/accident</th>
<th>- Probability of poor regulatory decision-making</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Damages incurred</td>
<td>- Increase in risk incurred</td>
</tr>
<tr>
<td>Safety systems</td>
<td>- Protective safety measures</td>
<td>- Mechanisms detecting and fixing regulatory failures</td>
</tr>
<tr>
<td></td>
<td>- Mitigating safety measures</td>
<td>- Appeal mechanisms</td>
</tr>
</tbody>
</table>

*Failure sequences describe how regulatory failures may trigger or worsen the gravity of other regulatory failures*

These analogies suggest that the proposed method should have the following steps which are represented in figure 2:

- Systematic identification of regulatory failures
- Systematic identification of failure sequences
- Modelling the regulatory processes associated with each regulatory activity
- Using research on human and organisational factors in probability safety assessments to infer the impact regulatory failures have on regulatory processes
- Modelling the processes of accountability mechanisms
- Identify measurable indicators for the principles for effective accountability
- Using research on human and organisational factors in probability safety assessments to infer the performance of the processes of accountability mechanisms using the data gathered
FIG. 2. Diagram representing the method used to assess the impact of a regulatory failure on the safety of nuclear facilities.

The first step deals with identifying the undesirable events that may occur within a regulatory body. The second, third and fourth aim at exploring the potential consequences these events may have on the regulator’s performance and thus on the safety of the facilities it oversees. The three final steps look at the ‘safety systems’ and their characteristics.

Once these steps have been carried out and all the necessary data on the regulator and the system of accountability have been collected, we can then assess the robustness of the entire system – nuclear regulator and its system of accountability – against regulatory failures.

Modelling the processes of both the regulator and the mechanisms that hold it to account will allow us to perform a simulation of the nuclear regulator’s behaviour over the years, after it has been afflicted with a combination of regulatory failures. We will thus be able to observe, year after year, the spread of regulatory failures, and their growing impact on the quality of the regulator’s output. Most importantly, we will be able to assess the capacity of the system of accountability to prevent the regulator from degrading the level of safety in nuclear facilities.

5. TEST-CASE MONTE-CARLO SIMULATION

The work presented here is a Monte-Carlo simulation run on MATLAB.
Organisation and failure modelling

For the simulation, five organisations were modelled: a nuclear regulator, one stakeholder and three accountability mechanisms. For simplicity, and to ensure rapid convergence of the Monte-Carlo simulation, all the organisations but the regulator are modelled as a single-working unit. Each possesses a set of characteristics which impact how well it performs the tasks it has been assigned. Details on how these organisations were modelled can be found in Accountability feedback assessments for improving efficiency of nuclear regulatory institutions [33].

The sequence of regulatory failures chosen for the Monte-Carlo simulation is a budget cut which impact the training quality of the regulatory staff resulting in a gradual decrease in its expertise.

Simulation

Time is discretised in time steps of 1 year. The state of the system at time t is represented by the expertise score of each regulatory staff, the quality of the initial training and the status of continuous training.

Initially the regulator is effective. Each staff is assigned an initial expertise score using a triangular probability density function. The average expertise score is set at 65% and 88% for junior and senior staff respectively.

There are two mechanisms which impact the evolution of the expertise of the regulatory staff. The first is staff turnover: each year, every junior staff has a probability of 8% to leave whilst every senior staff has a probability of one sixteenth to leave. Thus, on average, 1.6 junior staff leaves per year and one senior staff leaves every eight years. A junior staff leaving is replaced by a new recruit. A senior staff leaving is replaced by one of the three best junior staffs of the appropriate field (inspection or regulation), chosen at random. The junior staff taking over as senior staff is in turn replaced by a new recruit.

New recruits are trained and assigned an expertise score using the same triangular probability density function, with the average expertise equal to the quality score of the initial training.

The second mechanism is continuous training. All regulatory staff are continuously trained to ensure they progressively gain expertise. Every year, the expertise score of each regulatory staff changes by a certain amount, assigned using the triangular probability density distribution. The average expertise variation is dependent on the status of the continuous training described below (boosted, not failing, less failing and failing).

It is assumed that the initial training is run by the junior regulatory staff, thus the quality of the training is impacted by the expertise of the junior staff. The quality of the initial training is set at 75% of the average expertise score of the junior staff. When the budget reduction is introduced, the quality of the initial training drops to 45%. It remains there until 75% of the average expertise score of the junior staff
falls below this value, at which time the former relationship between the two variables is restored. Both senior and junior staff expertise score cannot drop below 15%.

The regulator has two main activities to undertake: inspections and rule-making. A drop in regulatory expertise impacts safety in the following ways: Firstly, the expertise of inspectors impacts the probability for them to detect when an operator fails to comply with safety standards. In the simulation, it is assumed that any safety standard violation is associated with an increase in risk, expressed in core damage frequency, from ALARP levels. Secondly, the expertise of the rule-making staff affects their ability to identify the areas where safety standards could be strengthened and to gather international experience, expert opinion and new scientific findings in order to maximise the risk reduction. Thus the impact on safety of the rule-making staff is the difference between the risk reduction the new regulations would ideally achieve and the risk reduction actually obtained.

The simulation runs for 60 years. At \( t = 0 \) the budget reduction is introduced, causing an immediate drop in the quality of initial training and the continuous training status is switched to failing.

The stakeholder can appeal any regulatory decisions made during the year whilst poor regulatory performance may trigger an audit the same year or several years in the future.

If the audit office determines the cause of the regulator’s poor performance and successfully implements tangible improvements, the status of continuous training switches from failing to less failing. In addition, the regulatory staff must attend an intensive course which increases their expertise score by 10%.

Should the audit office solutions be found insufficient to adequately restore the effectiveness of the regulator, the third appeal mechanism may launch a more in-depth investigation which may eventually result in an act of parliament solving the budget issue.

When the budget issue is solved, the continuous training status changes from less failing to boosted, as training becomes a priority. Only when the average junior expertise score reaches 65% does its status switch to not failing.

Results

Ten thousands independent iterations were performed to reduce the statistical errors of the results. However, as this simulation is merely a proof of principle, statistical uncertainties will not be discussed in this work.

Figures 3-5 illustrate the impact of the three different systems of accountability (SoA) on regulatory expertise and on nuclear safety. System A is only made of an appeal mechanism, system B is made of the appeal and the audit mechanisms whilst system C is made of all three accountability mechanisms.

Figures 3 and 4 present the probability density function (pdf) of the average expertise of the junior regulatory staff, at three times, 20, 40 and 60 years for
accountability systems B and C respectively. The pdf is used to calculate the probability $P(t)$ that for a random simulation run, the regulator will have an average junior expertise at time $t$ between $E_1$ and $E_2$:

$$P(t) = \int_{E_1}^{E_2} p(E, t) dE \quad (eq. 1)$$

Where $p(E, t)$ is the pdf of the average expertise of the junior regulatory staff.

Only equipped with an appeal mechanism, the accountability system A cannot impact the expertise of the regulatory staff. As a result, in Figure 3, the pdf of the average junior expertise is the same as for a failing regulator without an accountability system. Expertise decreases continuously until it reaches its lower limit of 15%. After 20 years, the average expertise of the junior regulatory staff is comprised between 15% and 35%. At later times $t=40$ and 60 years, in all the simulation run, the staff has the minimum possible expertise and the pdf of the average expertise is thus a Dirac delta function.

With system B, at time $t=20$ years, the pdf is formed of two bell curves, one with a peak at 27%, and another, with a smaller peak at 39% but larger width. This shows that in the simulation, one of these two scenarios happened: either the audit office detected the failings of the regulator and took action to resolve the issue which resulted in an average junior expertise between 32 and 50%. Or the audit office failed to detect any regulatory failures, and the average junior expertise continued to fall as with system C. Using equation 1, the probability of each scenario was found to be 50:50. At time 40 and 60 years, the pdf is only formed of one bell curve that becomes growing taller and thinner with time and whose peak gradually approaches 15%. At time 60 years, the pdf peaks to 94 at an average junior expertise of 15%. This emphasises that the audit office, as it does not possess the power to tackle the real root cause of the issue, can only slow down the inexorable loss of regulatory expertise.

With system of accountability C, at time $t=20$ years, the pdf is formed of three bell curves. The first one is identical to the one found for system B. This is hardly surprising as their respective audit office have the same characteristics and thus have the same chance to have detected the regulatory failure during the first 20 years. The second bump in the pdf peaks at 39% whilst the third and smallest peaks at 66%. The shape of the curve indicates that three possible scenarios can occur, either the audit fails to identify any regulatory failures, either the audit office does act but the third accountability mechanism does not, or both mechanisms act and the root cause for the poor performance of the regulator is found and fixed. Using the pdf to calculate the probabilities of each outcome, the split was found to be 50:40:10. Pdfs at times 40 and 60 years indicate that the chances for the regulatory failure to go unnoticed becomes slimmer as time goes by. After 60 years, there is still a 15% chance that the accountability system has yet to resolve the issue however.
Figure 5 shows the pdf of the cumulative difference between ideal and actual core damage frequency decrease achieved by the regulator.

As expected, the system A is the least effective. The cumulative core damage frequency increase per plant has a 95% chance to be comprised between $0.8 \times 10^{-3}$ and $1.1 \times 10^{-3}$ years$^{-1}$. Compared with the pdf obtained without any accountability mechanism, it is simply shifted $4 \times 10^{-4}$ years$^{-1}$ to the left, which gives the direct impact of the appeal mechanism on nuclear safety.
With system B, the spread of the cumulative core damage frequency increase is much wider. There is a 90% chance for it to be between 2 and $7\times10^{-4}$ [years]$^{-1}$. Indeed the faster a successful audit is made, the more impact it will have. Its action marginally improves the regulator’s continuous training program thus attenuating the yearly drop in expertise which in turn impacts the quality of its work.

With a full accountability system, there is a 8% chance for the cumulative core damage frequency per plant to be at the level of a healthy regulators at $10^{-5}$ [years]$^{-1}$, and a 45% chance to be below $10^{-4}$ [years]$^{-1}$, less than the most optimistic scenario for a failing regulator with accountability system B. The probability density then decreases slowly between 0.2 and $1.0\times10^{-3}$ [years]$^{-1}$. Again, the explanation for this behaviour is that the sooner the audit office and the third accountability mechanism successfully act to resolve the regulatory failures, the greater the impact on the core damage frequency increase is.

These numbers may seem quite high, especially for a healthy regulator, but in the simulation, it is assumed that a regulatory error cannot be rectified later on. As a result, even after the accountability system resolves the budgetary issues of the regulator, the damage done cannot be undone.

FIG.5. Pdf of the cumulative difference between ideal and actual decrease in risk per plant achieved by the regulator.

**Costs and benefits of accountability systems**

The simulation also provides the average costs and benefits of the different systems of accountability. The costs of the system are simply the sum of the costs of each accountability mechanisms.
In order to provide an estimate of the benefits, the increase in risk experienced due to the poor performances of the regulator were multiplied by the cost of an accident. In this simulation, it was assumed that this cost is merely the loss of revenue for the operator due to the plant’s early closure. Thus, the cost of an accident is, on average, the average revenue of a nuclear plant per day times the average time left before closure.

It was assumed that the 10 plants in the simulation have a lifetime of 60 years, that they all have been constructed 6 years apart and that every time a plant closes, a new one comes online. The average revenue of a plant per day was chosen to be M£1.

The results are displayed in Table 2. It displays the average cumulative cost for the system of accountability, the average cumulative risk increase per plant and the average cost due to early plant closures over the duration of the simulation. Finally, it displays the cost benefit ratio where the cost is the cumulative cost of the accountability system while the benefit is the avoided costs due to early plant closures thanks to the accountability system.

Based on these numbers – which are not meant to be taken literally - each additional accountability mechanism results in a better value for money.

The cost benefit ratio drops from 0.59 with only one appeal mechanism to 0.3 with all three accountability mechanisms.

As previously mentioned, the simulation does not allow the regulator to rectify errors it has done in the past. It results in a higher risk increase, especially for healthy regulators as they are more likely to notice a past regulatory error and take the necessary actions. Thus the increase in core damage frequency and in cost due to early plant closures are overestimated.

<table>
<thead>
<tr>
<th>TABLE 2. Costs and benefits of the three systems of accountability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>No SoA</strong></td>
</tr>
<tr>
<td>Cost of the accountability system (M£) over 60 years</td>
</tr>
<tr>
<td>Cumulative increase in risk per plant (10⁻³y⁻¹) over 60 years</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
</tr>
<tr>
<td>Cost benefit ratio</td>
</tr>
</tbody>
</table>
This section highlights that this very simple Monte-Carlo simulation can be used for studying a wide range of scenarios. For instance, one could explore the effect of stakeholder funding on the performances of the system of accountability, or compare a system of accountability having a quick and inexpensive appeal mechanism with a system having a long and expensive one.

It is important to note that some the simplifications used unfortunately reduce the potential uses of the simulation in its current form.

For example, since there is only one regulatory failure sequence, only one audit and one investigation performed by the third accountability mechanism are required to solve the problem. As a result, the simulation cannot be used to study the impact of different amounts of funding for the audit office and the third accountability mechanism.

In addition, the possibility of exploring the relative importance of each accountability mechanism is greatly reduced by two key assumptions:

An audit can only be launched following the overturn of a regulatory decision by the appeal mechanism and an investigation by the third accountability system can only be launched once it has been warned by the audit office. In reality, these audits can be triggered by many other events, such as the claims of a whistle-blower.

However, this simulation is merely a proof of principle, the actual method will be able to address these questions.

Results of the sensitivity studies

Most variables used in the simulation were chosen arbitrarily as the research needed to make an informed choice has yet to be performed. Sensitivity studies were performed to analyse the impact of the average junior expertise for a healthy regulator and of the discount rate on the results obtained.

Impact of the junior expertise for a healthy regulator

A sensitivity study was done to observe the impact of a change in the average junior expertise of a healthy regulator on the results obtained. The change thus affects both the initial average junior expertise and the average junior expertise after the regulator has been restored to its healthy condition by the system of accountability. For simplicity, in this section, the average junior expertise of a healthy regulator is referred as the initial expertise.

Figures 6 displays the probability density function for the average junior expertise at time $t = 60$ years. The pdf curves are all formed of two bells which represent the two possible scenarios: If the third accountability mechanism has fixed the root cause of the poor performances of the regulator, it is either healthy or quickly improving and has an average junior expertise close to the initial one. If the third accountability mechanism has yet to resolve the budgetary issue, the average junior expertise is close to the minimum.
For an initial expertise between 60 and 70%, the pdf curves are nearly identical. All three have the same bell curve, centred at an average junior expertise of 17% and their second bell curve have the same shape, albeit centred on their respective initial expertise.

For higher initial expertise, the first bell curve becomes wider and shifts to higher expertise, from 19% for an initial expertise of 75% to 30% for an initial expertise of 80%. The second bell curve keeps the same width as for lower initial expertise and continues to be centred on the respective initial expertise; however the peak value of their pdf slowly decreases from 5.5 for an initial expertise of 70% to 4.3 for an initial expertise of 80%.

Regarding the probabilities for each scenario to happen, for an initial expertise between 60 and 70%, the probability for the third accountability system to have resolved the regulatory failure after 60 years is constant at 85%. For higher initial expertise, the probability drops sharply to only 65% for an initial expertise of 80%.

Figure 7 displays the impact of the initial expertise on the increase in risk for each plant resulting from the budget cuts imposed to the nuclear regulator.

The curves of all probability density functions have the same shape. They peak at a very low core damage frequency and sharply decrease with increasing risk.

The peak value of the pdfs rises and the peak position shifts to lower core damage frequency as the initial expertise is increased. With an initial expertise of 60%, the pdf reaches its maximum of 4.6 at $4 \times 10^{-5}$ years$^{-1}$ and with an initial expertise of 80% the pdf reaches its maximum of 11.5 at $2 \times 10^{-5}$ years$^{-1}$.

In addition, the higher the initial expertise is, the sharper is the fall in the value of the pdf with increasing core damage frequency.

In terms of probabilities, the cumulative increase in risk per plant has only a 50% chance of being smaller than at $2 \times 10^{-4}$ years$^{-1}$ for an initial expertise of 60%. The probability reaches 90% for an initial expertise of 80%. There is a 99% chance that the cumulative increase in risk per plant is below $10^{-3}$ years$^{-1}$ and at $5 \times 10^{-4}$ years$^{-1}$ for the former and latter case respectively. Thus, increasing initial expertise from 60 to 80% on average halves the increase in risk due to budget cuts.
FIG. 6. Pdf of the average junior expertise at time $t = 60$ years for different values of initial junior expertise.

FIG. 7. Pdf of the cumulative difference between ideal and actual decrease in risk per plant achieved by the regulator for different values of initial junior expertise.

Table 3 summarises the costs and benefits of the system of accountability for each simulation made. The cost of the system of accountability decreases only marginally when the initial junior expertise is increased. However both the cumulative increase in risk and the cost due to early plant closure plummet with an increasing initial junior expertise. Naturally, maintaining a higher level of expertise would incur greater expenditures for the regulator. However, this simple model only focuses on the effectiveness of the system of accountability, not the regulator itself. Thus, whilst the cost of the regulator should significantly rise with an increased junior expertise, the cost of the accountability system falls marginally.
TABLE 3. Costs and benefits of the system of accountability for different values of initial junior expertise.

<table>
<thead>
<tr>
<th>Initial junior expertise</th>
<th>60%</th>
<th>65%</th>
<th>70%</th>
<th>75%</th>
<th>80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>60.4</td>
<td>58.9</td>
<td>56.8</td>
<td>53.5</td>
<td>49.9</td>
</tr>
<tr>
<td>Cumulative increase in risk per plant (10^{-3} yr s^{-1}) over 60 years</td>
<td>0.251</td>
<td>0.216</td>
<td>0.172</td>
<td>0.127</td>
<td>0.085</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
<td>87.2</td>
<td>68.5</td>
<td>49.7</td>
<td>34.6</td>
<td>22.5</td>
</tr>
</tbody>
</table>

This sensitivity study shows that increasing the initial junior expertise delays the action of the system of accountability. Thus, a regulator with higher initial junior expertise takes, on average, more time to recover from budgetary cuts. However, increasing the initial junior expertise has a very beneficial impact on the increase in risk and the cost due to early plant closure. Indeed, with an increase in initial junior expertise from 60% to 80%, the latter is divided by more than 3.

In the simulation, the simplification was made to have only one feature characterising the regulatory staff, one that therefore encompassed all characteristics that impact regulatory performance. This sensibility study hence emphasises how crucial it is to identify these characteristics and to choose their value to best represent a healthy regulator.

Impact of the discount rate

Five different discount rates were used in this study to investigate the sensitivity of the results to the constant discount rate chosen: 0%, 1%, 3%, 5% and 10%.

The results of the study are summarised in Table 4. It displays the average cost of the accountability system over 60 years, the cost of early plant closures over 60 years and the cost benefit ratio for systems A, B and C using the five discount rates.

The results show that the cost due to early plant closure is slightly more affected by an increase in the discount rate than the cost of the accountability system is. This is because the undiscounted cost of systems of accountability increases fast for the first twenty years before slowing down and even decrease for system C. On the contrary, the cumulative risk due to poor regulatory performance can only increase with time since the model does not allow the regulator to correct past mistakes. As a results, the chances of a nuclear plant closing down early are highest
at time $t = 60$ years which in turn explains why an increase in the discount rate has a greater impact on the cost due to early plant closure.

**TABLE 4. Costs and benefits of the systems of accountability for different discount rates.**

<table>
<thead>
<tr>
<th>Discount rate</th>
<th>No SoA</th>
<th>SoA A</th>
<th>SoA B</th>
<th>SoA C</th>
<th>Healthy regulator</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>NA</td>
<td>164</td>
<td>216</td>
<td>189</td>
<td>68</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
<td>2390</td>
<td>1673</td>
<td>787</td>
<td>508</td>
<td>42</td>
</tr>
<tr>
<td>Cost benefit ratio</td>
<td>NA</td>
<td>0.23</td>
<td>0.13</td>
<td>0.10</td>
<td>NA</td>
</tr>
<tr>
<td>1%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>NA</td>
<td>121</td>
<td>157</td>
<td>142</td>
<td>51</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
<td>1495</td>
<td>1056</td>
<td>495</td>
<td>328</td>
<td>29</td>
</tr>
<tr>
<td>Cost benefit ratio</td>
<td>NA</td>
<td>0.28</td>
<td>0.16</td>
<td>0.12</td>
<td>NA</td>
</tr>
<tr>
<td>3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>NA</td>
<td>72</td>
<td>91</td>
<td>87</td>
<td>32</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
<td>610</td>
<td>426</td>
<td>206</td>
<td>144</td>
<td>14.5</td>
</tr>
<tr>
<td>Cost benefit ratio</td>
<td>NA</td>
<td>0.39</td>
<td>0.23</td>
<td>0.19</td>
<td>NA</td>
</tr>
<tr>
<td>5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>NA</td>
<td>48</td>
<td>58.5</td>
<td>58.9</td>
<td>22.7</td>
</tr>
<tr>
<td>Cost due to early plant closures (M£) over 60 years</td>
<td>265</td>
<td>184</td>
<td>92.3</td>
<td>67.8</td>
<td>8.0</td>
</tr>
<tr>
<td>Cost benefit ratio</td>
<td>NA</td>
<td>0.59</td>
<td>0.34</td>
<td>0.30</td>
<td>NA</td>
</tr>
<tr>
<td>10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of accountability system (M£) over 60 years</td>
<td>NA</td>
<td>23.2</td>
<td>27.3</td>
<td>29.0</td>
<td>12.8</td>
</tr>
</tbody>
</table>
As a result, the cost benefit ratio increases with the discount rate. However, increasing the discount rate has no impact on the relative efficacy of the different accountability systems. System C conserves the lowest cost benefit ratio regardless of the discount rate used. Thus, it can be concluded that for comparing the effectiveness of different systems of accountability, the choice of the discount rate has only a limited impact.

**Conclusion**

In this paper, it was argued that the field of regulatory accountability is held back by the absence of systematic method to assess systems of accountability and allow their comparison as well as a lack of consensus regarding what the objectives of such systems should be.

To resolve these issues, the article proposes a method of assessment of accountability systems based on defence in depth concepts and inspired from risk-assessment techniques used in the nuclear industry.

Finally, the article presented a simple Monte-Carlo simulation to demonstrate the principles of the method of assessment and display the kind of information and results it would eventually be able to procure.

**ACKNOWLEDGEMENT**

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CHALLENGES IN IMPLEMENTING IAEA NATIONAL NUCLEAR SAFETY KNOWLEDGE PLATFORMS

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Abstract

The Integrated Nuclear Security Advisory Services (INSServ) and the Integrated Regulatory Review Service (IRRS) took place in Cameroon in April and October 2014. The main objective was to further improve the effectiveness of the Cameroon governmental, legal and regulatory framework for safety and security. NRPA became a member of Forum for Nuclear Regulatory Bodies in Africa (FNRBA) in 2009. FNRBA organized with IAEA a workshop from 14th to 18th October 2013 in Nairobi, Kenya on Knowledge Safety Network. NRPA of Cameroon created the first National Nuclear Portal under FNRBA. This was linked to other national websites. During the IAEA review missions, most counterparts took opportunity from the thematic site to share information and develop advance reference materials. The IAEA IRRS team also shared materials that could not be transferred through email with national counterparts using the GNSSN SharePoint website due to large file sizes.

Results: Revision of the legal and regulatory framework so that all international safety and security standards are addressed in laws and statutes have been done with documents downloaded from Nuclear portal sites found in GNSSN. Establishment and implementation of integrated management systems by NRPA is being done with documentation under the National Nuclear Portal with lessons learned from the IAEA review missions.

1. INTRODUCTION

The Integrated Nuclear Security Advisory Services (INSServ) took place in Cameroon from 21st to 25th April 2014 and the Integrated Regulatory Review Service (IRRS) from 12th to 21st October 2014. This was after the government requested the Director General of International Atomic Energy Agency (IAEA) through an official correspondence on 11th June 2013, for these missions. The main objective was to further improve the effectiveness of the Cameroon governmental, legal and regulatory framework for safety and security. Triggered by the expansion of national economic and social sectors, the demand for nuclear science and technology applications in Cameroon is marking an ever growing trend in scale and scope. Consequently, there is an increasing use of radioactive sources in various socio-economic developmental activities and the above development calls for
organized and coherent measures to regulate and control the applications of radioactive sources from a safety and security perspective without impeding on the beneficial application thereof.

National Radiation Protection Agency (NRPA) of Cameroon activities started with inventory program in 2009, decree to control radiation (Decree 250/2002) and nuclear material exist and currently in the process for its enhancement to a Comprehensive Nuclear Law. Existing laws that were sufficient to provide basis for respecting the current IAEA standards and requirements require further consultation among their designated authority for effective implementation. National coordination to address the following areas like existing legislation, identifying gaps in legislation, identifying capabilities, defining responsibilities, identifying contact points with definition of communication lines with identified lead authorities commenced in December 2010. As of February 2016, 162 radioactive sources have been identified to be extensively in used for beneficial purposes in Cameroon in medical, industrial, agricultural, research and educational applications. Ensuring their safety and security has been done for the past three years by National Radiation Protection Agency (NRPA) and significant improvements have been made in this respect. However, proper legislative framework and adequate resources remain major concerns. Many efforts are being put in place to review the current situation and to identify the means of maintaining the highest possible level of safety and security of radioactive sources throughout their lifecycle everywhere in Cameroon.

The primary foundations through which valuable regulatory exercise could be ensured is by developing and sustaining sound national regulatory infrastructures which is equipped to effectively and efficiently implement regulatory control over the application of nuclear technology and practices involving the use of radiation sources at a national level and by promoting regional cooperation among Regulatory Bodies. In the context of the above development, NRPA has been part of the Forum of Nuclear Regulatory Bodies in Africa (FNRBA) since 2009 and the AFRA Projects on Self-Assessment of Regulatory Infrastructure for Safety and Networking of Regulatory Bodies (RAF 9038) and Sustaining the Regulatory Infrastructure for the Control of Radiation Sources (RAF 9042 and RAF9049).

2. PROGRESS MADE, NEEDS AND PRIORITIZED AREAS IDENTIFIED

- Legislative framework, Regulations and Codes of Practice
- Regulatory Body functions: Inventory of radiation sources, Authorization, Inspection
- Safety and security of radiation sources
- Regulatory Control on Uranium Mines Activities
- Coordination and Cooperation at National Level
- Regional and International Cooperation
- Quality Management
A committee was setup at NRPA to develop strategy to share knowledge in the different departments. Overview of the radiation safety infrastructure in Cameroon was presented by National Nuclear Regulatory Portals (NNRP) coordinator after the IAEA workshop in Nairobi, Kenya in 2013. The recommended actions that came from this meeting to address these were:

— To adopt a strategic approach. NRPA should have a strategy for the strengthening of radiation safety infrastructure. NRPA should develop their own strategy in line with the IAEA strategy;
— A policy ensuring that NRPA website have clear objectives, achievable outputs and adequate funding, should be developed and applied;
— High priority should be given for developing regulations on radiation safety and sharing knowledge after attending IAEA events;
— To provide assistance for NNRP and website to be regularly updated and validated;
— To create nucleus accounts and seek access to FNRBA portal. Existing network should continue to share experiences;
— Outreach and high level sensitization. Outreach activities to sensitize and to enhance awareness on importance of radiation safety should be carried out;
— The Following Procedures are in place:
  o Administrative and Financial Procedure
  o Publication of news on website
  o Notification and Authorization Systems
  o Inspection System
  o Orphan Source Search

3. ACHIEVEMENTS AND BENEFITS OF NNRP

(a) Successful implementation of most of the planned activities (90.6% of the total allocated information was filled). Cameroon was the first country in Africa to appear on National Nuclear Portal of IAEA that was presented at AFRA-Nest in June 2015 [3].

(b) Organise 16 restitution training courses, 9 expert missions and 8 meetings/workshops, notably:
  a. on authorization, inspection and enforcement,
  b. School of drafting regulations,
  c. on regulating uranium mining and milling activities,
  d. on Staff Organisation and Competence for regulators.

(c) Overall improvement of the management system.

(d) Enhanced skills of participants at events led to an increase in the usage of national experts.
(e) Promoted the sharing of experience and lessons learned between the participating staff.

(f) Better understanding of the regulatory functions as a result of the IRRS mission uploaded into NNRP.

(g) Facilitated the use of RAIS and SARIS by consulting the FAQ under GNSSN of Thematic Network.

4. CONCLUSION

With IRRS and INSServ missions done in 2014, various recommendations ditched out, NRPA is improving its Information Management System, defining measurable quantities to monitor the performance of the authorization process, inspection and enforcement systems. Keep an electronic copy of all process documentation into RAIS and NNRP, so that it can readily be accessible to the management and all staff of the regulatory body with connection to IAEA GNSSN knowledge management principles [1]. Regulatory Body staffing and training will continue, especially new recruits, as sharing of nuclear knowledge management is concerned. The regulatory documents have been uploaded on the platform and can be accessed through FNRBA and NRPA website (www.anrp.cm). UN organizations implementing projects in Cameroon are also linked to the platform. The action plans and progress reports for IAEA/AFRA projects are also available. Moreover, NRPA regulatory activities and licensing sources are available on this platform. NRPA is continuously developing the National platform as an instrument in enhancing networking at national and regional levels. The platform is part of Integrated Quality Management System which was recommended by the IRRS mission of October 2014. Other developing countries not having a management system yet can learn from this practice.
REFERENCES


INNOVATIONS IN THE DELIVERY OF REGULATORY SERVICES IN AUSTRALIA

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Abstract

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the country’s primary authority on radiation protection and nuclear safety. ARPANSA promotes safety, security, and emergency preparedness through efficient and effective regulation of nuclear installations, controlled facilities, and radiation sources. Recent initiatives to improve regulation by ‘cutting red tape’ and reducing regulatory burden have been introduced. ARPANSA’s Regulatory Delivery Model emphasizes the key elements to good regulation and describes initiatives such as promulgation of a baseline inspection schedule, use of Performance Objectives and Criteria, and identification of performance deficiencies. These and other initiatives have streamlined inspection efforts, increased risk-based oversight and risk-informed decision making, and led to increased efficiencies for both regulator and licence holder. In addition, ARPANSA has introduced 12 key performance indicators in its self-assessment of regulatory performance.

1. INTRODUCTION

In January of 2015, ARPANSA implemented a new model for delivering regulatory services. This Regulatory Delivery Model emphasises several key elements to good regulation. Prominent among the changes was the use of risk-informed decision making to optimise the allocation of limited regulatory resources. A keen focus was placed on planned inspections, which included the development and use of performance criteria, and the use of performance indicators to promote continuous improvement.

2. DISCUSSION

In January of 2015, the agency implemented a new model for delivering regulatory services. This Regulatory Delivery Model emphasises several key elements to good regulation. As an independent regulator, ARPANSA must place a premium on openness, clarity, reliability, and efficiency. Because we carry out the public’s business, we must communicate openly. Our approach and positions should be logical and practical, such that they are understood by our stakeholders. Our regulatory actions should be predictable and timely. To achieve efficiency, we must use risk to inform our decision making.
Independence requires us to be objective and unbiased, but it does not imply isolation. Assessment of licence holders requires RSB staff to have an understanding of how the licensed entity conducts its business. Visits to licensed facilities are essential for this understanding.

As described in ARPANSA’s Strategic Directions FY2014-2017, the regulatory approach assures safety by:

(a) Emphasising to licence holders their special responsibility with respect to safety and security;
(b) Communicating with stakeholders in an open and transparent manner;
(c) Fostering a healthy and robust safety culture through collaboration with licence holders;
(d) Applying risk-informed approaches to licensing, inspection, and compliance activities;
(e) Taking appropriate and timely enforcement actions.

3. INSPECTIONS

Under the agency’s new delivery model, a long-term schedule of licence holder inspections was developed taking risk into consideration.

The baseline interval for facilities is three years. The complexity and risk inherent in each facility determines the scope and duration of each inspection. There are eight inspection areas that must be covered during the baseline inspection period. For example, a single inspection may last two weeks and involve just one of the eight areas; it may, on the other hand, involve four areas and last only two days. This is what is meant by a graded approach to inspection scheduling.

A slightly different approach is used for scheduling source inspections, although it too is graded. The approach for sources makes use of the inherent hazard categorisation of sources to establish a priority. The approach to scheduling of source licence holders is in line with IAEA recommendations and is similar to the approach used by the US Nuclear Regulatory Commission. It aims to optimise regulatory efficiency in light of the wide variety of sources that are inspected. The baseline interval for sources is five years.

All ARPANSA inspections require considerable planning by a lead inspector, typically weeks in advance. Planning is always conducted by a team of two or more. A notification, which documents who, what and when, is sent to the licence holder at least two weeks before the inspection.

An inspection includes an entrance and exit meeting involving appropriate licence holder personnel. The entrance meeting marks the formal commencement of the inspection; it is an opportunity for the licence holder to better understand the inspection process and what to expect. During the inspection, the lead inspector keeps the licence holder apprised of any findings of fact, issues, or concerns. At the exit meeting, findings of facts are presented – both positive and negative. The goal
of the exit meeting is to agree on the facts, which should also include any steps that
the licence holder has taken to address the findings or underlying issues.

The inspection culminates in a written report which is issued within 10
working days of the exit meeting. The licence holder is consulted with respect to the
content of the report. ARPANSA strives for ‘no surprises’. In general, only those
findings discussed at the exit meeting appear in the final report.

Feedback from the licence holder is collected from an independent online
survey approximately a month after the inspection. The feedback is reviewed
periodically through self-assessment so that improvements can be made.

The baseline inspection program is based on the inherent risk of the facility;
this risk is not expected to change unless the facility is modified in a significant way.
The following inspection areas, which are comprised of more specific modules,
collectively known as the Performance Objectives and Criteria, constitute the
baseline schedule for each licence:

(a) Performance Reporting Verification
   Modules address the reporting culture, both internally and externally,
   including discrepant or unreported performance data, performance
   indicator verification, and compliance with operating limits and
   conditions.
(b) Configuration Management
   Modules include evaluation of changes (made under Regulations 51 &
   52), equipment alignment, operability determinations, temporary facility
   modifications, and safety system design and capability.
(c) Inspection, Testing, and Maintenance
   Modules include post-maintenance testing, in-service testing and
   inspection, surveillance testing, and maintenance and work control.
(d) Training
   Modules address personnel training, the use of a systematic approach to
   training, accredited operator training, etc.
(e) Event Protection
   Modules include adverse weather, fire protection, flooding, bush fires,
   land management, etc.
(f) Security
   Modules include aspects of security arrangements and requirements.
   Modules also include infrequently conducted tests or evolutions, outage
   performance, etc.
(g) Radiation Protection
   Modules include access control, dosimetry, ALARA planning, radiation
   monitoring instrumentation, effluent system monitoring, radioactive
   material processing and transportation, etc.
(h) Emergency Preparedness and Response
Modules include exercises and drills, emergency response organisation testing, notification testing, etc.

These eight inspection areas are broad in scope and are intended to cover all aspects of licence holder performance. Note that security is woven into the inspection areas, and inspectors with security expertise are included in inspection teams. Of course not all modules or areas apply to every facility. Using a graded approach, the scope of each inspection is determined based on risk.

There are also three cross-cutting aspects that may be addressed in each inspection:

(a) Human performance
(b) Safety Culture
(c) Performance Improvement

Consistent with ARPANSA’s holistic approach, these three aspects are not explicitly called out in any inspection area. Instead they are inherent to all inspections regardless of the scope.

The difference in approach between facilities and sources is one of degree. There are fewer inspection areas, fewer inspectors involved, and the time required for assessment is generally less for a source licence. In addition, the geographic separation of sources under one licence necessitates an ‘alternate inspection’ approach. A variety of inspection methods are used to assess safety and security of sources. For example, the inspection may involve a representative sample of sources only.

4. PERFORMANCE INDICATORS

In 2015, the Australian Government committed to reducing the cost of inefficient or unnecessary regulation imposed on individuals and businesses by $1 billion per year. Although ARPANSA does not regulate private businesses, the agency was required to establish an approved set of performance indicators to measure performance in the area of efficiency.

Regulatory costs do not just come from the design of the regulations. Poorly administered regulation can impose unnecessary costs that reduce productivity. These costs inevitably flow through to business more widely and to the community even where their initial impact is on a particular business. These costs may negatively impact the viability of the business or divert scarce resources.

ARPANSA plays an important role in managing risk and protecting the interests of the community. In addition to ensuring safety, properly administered regulatory frameworks can also improve efficiency for both ARPANSA and licence holders. As set out in the Australian Government’s Regulator Performance Framework, ARPANSA’s delivery of regulatory services strives to:
(a) Avoid unnecessary intervention in the operations of regulated entities
(b) Communicate with regulated entities clearly and effectively
(c) Take action proportionate to the regulatory risks being managed
(d) Choose an approach to compliance and monitoring that is streamlined and coordinated
(e) Remain open and transparent in dealings with regulated entities and the public
(f) Perform frequent self-assessments in order to improve our delivery model

To measure regulatory performance against these goals, ARPANSA created and is using the following 12 performance indicators:

4.1. Percentage of inspections conducted in accordance with established inspection schedule (schedule adherence)

ARPANSA measures the percentage of inspections conducted in accordance with an established long-term inspection schedule. Each of eight inspection areas is undertaken at least once during the three-yearly (facility) inspection cycle. A long-term risk-informed inspection schedule is maintained and updated regularly to reflect the compliance maturity of the licence holder. Adherence to the schedule promotes trust, predictability and efficiency and allows the licence holders to plan their work. It also supports ARPANSA’s ability to deliver quality regulatory services with minimal disruption to licence holder operations.

4.2. Percentage of applications assessed within agreed licence holder expectations (timeliness)

ARPANSA assesses applications for licences and amendments to licences as well as requests for special approvals under the ARPANS Regulations. The complexity of applications varies widely. Using a risk-informed approach, and in consultation with licence applicants or licence holders, regulatory staff prioritise resources and establish a ‘need by’ date for completion of the application assessment, thereby assisting the licence holder with business planning and avoiding impediment to operations. Approval of an application of a satisfactory standard by the agreed date is deemed to be timely.

4.3. Percentage of stakeholder feedback where the positive outweighs the negative (customer satisfaction)

ARPANSA issues an inspection report within 10 working days of the exit meeting. Soon afterwards, the Office of the CEO requests feedback on the inspection, independent of the RSB. The options for response from the licence
holder range from ‘strongly agree’ to ‘strongly disagree’. Negative feedback is an opportunity to improve systems of interaction. If the average response is neutral or better, then the feedback is taken to be favourable. This serves as an indicator of how effectively the key performance indicators are being put into practice by regulatory staff.

4.4. **Number of information sharing meetings with licence holders (effective communication)**

Meetings are held with licence holders to exchange information on regulatory matters such as upcoming legislative changes, licence applications or licensing and compliance issues. Examples of such established fora are the Defence-ARPANSA Liaison Forum (DALF) and ARPANSA Licence Holders’ Forums. Regular information exchange meetings on regulatory matters improve licence holder understanding of regulatory expectations, ultimately improving compliance standards and reducing regulatory burden. The number and quality of meetings in a year and the feedback from these meetings indicates if communication is effective.

4.5. **Ratio of performance deficiencies to non-compliances (graded approach)**

Potential non-compliances may arise when licence holders do not meet licence conditions or the requirements of the ARPANS Act or Regulations. In contrast, performance deficiencies may occur when a licence holder does not follow accepted international best practice or does not meet self-imposed standards. By distinguishing between performance deficiencies and potential non-compliances, regulatory staff adopts a risk-informed graded approach to compliance, hence reducing regulatory burden. ARPANSA implements formal enforcement measures only when a breach has been determined by the CEO of ARPANSA and the licence holder’s remedial actions (if any) are deemed unsatisfactory.

4.6. **Ratio of site visits to inspections (performance monitoring)**

ARPANSA inspectors monitor performance of licence holders on a regular basis outside of the inspection process through site visits. Frequent site visits are undertaken to observe licence holder operations. Unlike inspections, no detailed advance planning is required for site visits, and observations are shared verbally with the licence holder. Frequent site visits improve regulatory oversight of licence holder operations, increase the visibility of the regulator/inspectors among licence holders, and are expected to contribute to minimising the incidence of potential non-compliances through enhanced communication.
4.7. Percentage of inspections of licence holders with a medium to high risk ranking (risk informed regulation)

ARPANSA’s risk ranking methodology published on the ARPANSA website informs the licence holder and enables regulatory staff to gauge the risk of an undertaking based on the inherent risk of the facility or source, recent compliance history, quality of the licence holders’ procedures, and history of incidents and accidents. The risk ranking of each licence is reviewed annually and following inspections and incidents. Establishing a transparent and planned inspection program based on the risk ranking of the licence holder’s operation allows ARPANSA to streamline its compliance monitoring program as necessary to take account of any changes in licence holder risk profile, and reduces regulatory burden.

4.8. Percentage of time that actions are initiated within three months of an identified performance deficiency (light touch regulation)

When a performance deficiency is identified, either as a result of an inspection or other monitoring, there is an expectation that the licence holder will take corrective action in a timely fashion to address it. As the objective of identifying performance deficiencies is to reduce regulatory burden by improving compliance without formal enforcement action, the time taken for a licence holder to implement corrective actions, accompanied by communication of the timeliness expectations, is a measure of the transparency and effectiveness of the inspection/compliance monitoring program.

4.9. Percentage of RSB time devoted to regulatory activities (core business efficiency)

Direct regulatory activities are those which can be attributed to a particular licence holder. Activities include inspections, site visits, compliance monitoring, application assessments, enforcement activities and development of specific guidance. As regulation is core business for ARPANSA, increased percentage of time spent in direct regulatory activities is likely to improve ARPANSA’s understanding of licence holders operations, resulting in better compliance outcomes and transparency in its dealings with its licence holders. Carefully recording direct regulatory activities reduces regulatory burden in a transparent manner, as it is the legislated basis for the annual licence charges.

4.10. Percentage of instances where licence holders are consulted on the development of guides, codes and standards (transparent development of standards)

ARPANSA publishes guides, codes and standards on a range of regulatory topics which set out expectations for the safety of sources and facilities. These
guides, codes and standards typically adopt international best practice and hence their adoption in Australia reduces unnecessary regulatory burden. Consultation with licence holders for feedback on draft guides, codes and standards improves transparency and promotes continuous improvement.

4.11. Number of improvements, identified through self-assessment or external reviews, that were implemented (continuous improvement)

Areas for improvement in the regulatory framework are identified through various means such as annual self-assessments. Additional opportunities include procedure and policy reviews as part of the RSB Quality Management System, external audits of ARPANSA such as international peer review missions, and stakeholder feedback from surveys and licence holder forums. The number of regulatory improvements identified and implemented measure ARPANSA’s actions to continuously improve the regulatory framework.

4.12. Percentage of inspections that used expertise external to RSB (judicious use of regulatory expertise)

ARPANSA may utilise external experts in its inspection program. Such persons may have experience in a particular field and/or regulation of particular sources or facilities. Judicious use of certain expertise promotes efficiency and improves regulatory results. The use of external experts provides a valuable source of independent advice in specialised areas which can actively contribute to improvements in the regulatory framework. In addition, the use of external personnel when inspecting licences issued to other ARPANSA branches avoids conflicts of interest.

1. CONCLUSION

ARPANSA provides independent oversight of facilities and sources to gain assurance that activities are being conducted in a safe manner. Where this is not the case, the regulator calls for the operator to take corrective actions to bring the facility or sources into compliance with requirements, licence conditions, and the safe operating envelope. ARPANSA’s Regulatory Services Branch promotes safety, security, and emergency preparedness through efficient and effective regulation of nuclear installations, controlled facilities, and radiation sources. Recent initiatives have been implemented to improve regulation in this regard.
REFERENCES

DETERMINATION OF PROBABILISTIC INSPECTION FREQUENCY OF STRUCTURES, SYSTEMS AND COMPONENTS OF THAI RESEARCH REACTOR 1- MODIFICATION 1 (TRR-1/M1)

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Abstract

In this work, the probabilistic inspection frequencies of selected Structures, Systems and Components (SSCs) for TRR-1/M1 reactor were determined using Monte Carlo simulations technique. This research assumed that (a) IAEA safety classification is somewhat comparable to the safety integrity level referenced in ISO standards number 13849-1 [5] and (b) the probability of failure of SSCs per hour is constant over time. The failure data was obtained from the IAEA reliability database for research reactor and assumed to be a Chi-Square distribution with degree of freedom equal to number of actual failure components. The results from this research will be used as guidelines for evaluating the TRR-1/M1 operator’s inspection and maintenance plan.

1. INTRODUCTION

One of the most challenging tasks in nuclear research reactor operation is to determine the inspection frequency of Structures, Systems and Components (SSCs). For the inspection and maintenance of TRR-1/M1 SSCs, a conservative deterministic approach has been employed to determine the frequency; however it was not based on safety significant of the SSCs. The current inspection and maintenance scheme for TRR-1/M1 is divided into three types: (a) yearly major inspection, (b) weekly minor inspection and (c) daily inspection before starting up the reactor. That means each individual SSCs will be maintained and inspected either yearly, monthly or daily respectively. This information is defined in TRR-1/M1 operating organization’s (Thailand Institute of Nuclear Technology (TINT)) inspection plan. It is submitted to its regulatory body, Bureau of Nuclear Safety Regulation, Office of Atoms for Peace, for reviewing and planning regulatory inspection. The current regulatory inspection is 4 times per year and this is also based on conservative deterministic approach. Due to stricter inspection norms,
international best practices, and more detailed regulatory inspection guidelines, the inspections have been consuming excessive resources such as budgets, time and inspection personnel. To maximize safety through inspection while optimizing budgets, time, and personnel, some of the scheduled inspections and maintenance works can be adjusted to match the safety significant to the SSCs by utilizing the failure data of the SSCs combining with statistical technique such Monte Carlo simulation. Maintenance and Inspection period can be related to time to the next failure or mean time between failures (MTBF). In a typical component failure analysis, one would usually expect a number, i.e. time to the next failure or MTBF, which is usually given by manufacturer. Unfortunately, in many cases including the TRR-1/M1 case, this data is not available because the reactor was designed in the past when such data was not provided. One of the solutions is using the component reliability database collected by IAEA [2]. The database composes of failure data of reactor components from a total of 12 research reactors from 9 participating countries. The data collection period varied according to the facility, ranging from 2 to 28 years. Reactor-power ratings varied from 100 kW(th) to 135 MW(th).

2. EQUIPMENT FAILURE RATE AND AVAILABILITY

The failure rate ($\lambda$) for continuously operated failure rate) is the expected number of failures of a given type in a given time interval (failures per hour, per year). This parameter is applicable to components in an operating or running condition. In most cases, components are assumed to be in the useful life phase (i.e. having a time independent failure rate). That means wear in or wear out failures, which are time dependent, are not included. In practice, it is not always possible to distinguish between these different phases. Hence all failures are, therefore, assumed to be time independent, and the average failure rate is given by equation (1):

$$\lambda = \frac{n}{T}$$  \hspace{1cm} (1)

Where $\lambda$ is the total failure rate in occurrences per component operating time (i.e. hours) $n$ is the total number of observed failures of the component type $T$ is the total component operating time (i.e. hours). The operating time is the accumulated time period during which an item, component or a system performs its intended function within specified limits.

For zero failures the average failure rate $\lambda_0$ is calculated by equation (2):

$$\lambda_0 = \frac{n-0}{T}$$  \hspace{1cm} (2)
Where \( \chi^2 \) is the Chi-Square distribution, 50th percentile with 2 degrees of freedom. This Chi-Square distribution will also be used in the simulation in the research. For other cases that number of actual failure is not zero, then the degree of freedom will equal to that actual failure number.

3. STATISTICAL APPLICATION AND MONTE CARLO SIMULATION

In statistical application, any given continuous parameter can be expressed in any mean or average number with its corresponding standard deviation. Further, the population of the parameter can also be distributed with normal distribution or distribution of different characteristics. Examples of continuous distributions are log-normal, exponential, logistic and Chi-Square distributions. Examples of discrete distributions are binomial and Poisson distributions. In common, they all have mathematical expressions for mean, standard deviation, distribution function, kurtosis, 5th percentile, 95th percentile and etc. In general deterministic method tends to use just one parameter, the mean value, as a representative of the population. Since different circumstances may have different types of distribution which can affect the relevant analysis, probabilistic approach was then introduced to characterize the parameter that is considered importance. One example of using a probabilistic parameter is “if 95th percentile of total effective dose equivalent (TEDE) equals to 1 mSv and the mean TEDE equals to 10 nSv” this generally means 10 nSv average with 95 percent of the population have TEDE lower than 1 mSv. This is more of a global approach rather than an individual one. Another example is on the average of time to the next failure. Failure rate of a component is usually derived from the failure of many components with similar type over a certain period of time. This is somewhat probabilistic approach because the ideal that one would like an infinite number of failures to represent the true mean failure rate but in reality that is not happening. Hence just using a limited set of failure data with corresponding statistical definitions will help define the failure rate in a more representable way. And this approach can be also applied to other importance parameters such as public dose, occupational dose and radiation releases activity.

In this research, a computational tool name @Risk was used in repeating the simulation according to the distribution or the uncertainty data of interest that is predefined. All one needs to do with this software is: first, define a working model, i.e. simple mathematical formula such as \( A = k \times X \); second, define statistical data or uncertainty data for \( X \) such as, mean, standard deviation and distribution data (range, normal, Chi-Square, or etc.); third repeat the calculation for many times (so called simulation) until the result is reasonable and representable such that the parameter \( X \) were sampled from the defined distribution evenly. The way that parameters were sampled randomly is also known as Monte Carlo sampling. For this simple \( A = k \times X \) model (with constant \( k \)) which is linear equation, parameter \( A \) should have the same statistical distribution as parameter \( X \); if \( X \) is normally
distributed then A must be also normally distributed. And how parameter A was calculated is called Monte Carlo simulation.

4. RESEARCH ASSUMPTIONS

International Atomic Energy Agency has divided SSCs in to 3 categories [7]; SR-A, SR-B and NSR. SR-A represents an item that performs the safety functions which include:

— Shutting down the reactor and maintaining it in a safe shutdown state for all operational states or all designed basis accidents (DBAs);
— Providing for adequate removal of heat after shutdown, in particular from the core including in DBAs;
— Confining radioactive material in order to prevent or mitigate its unplanned release to the environment

SR-B represents an items that does not meet the criteria for SR-A, but having functions that must be accomplished to achieve proper reactor operating conditions, prevent accidents, or mitigate accident consequences, thereby resulting in protection of site personnel, the public, and the environment from undue radiation hazards. NSR represents an item that does not meet the criteria for SR-A or SR-B.

Currently, there is no legal requirement posted on the availability of SSCs of any safety class for nuclear research reactor in Thailand. The availability (A) is defined as a fraction of time for which a system is capable of fulfilling its intended purpose [3]. Hence to utilize the concept of availability of different classification of SSCs, this research assumed that the IAEA safety classifications are comparable to the safety integrity levels (SIL) referenced in ISO 13849-1 [5]. To employ failure rates of different components provided in the IAEA reliability database [2], a simple methodology given in Marek DZWIAREK’s research [1] was adopted in order to evaluate the issue in determining of inspection and maintenance frequencies of SSCs of TRR-1/M1. Table 1 shows the relationship between probabilities of failure rate (\(\lambda\)), Safety Integrity Level (SIL), Performance Level (PL), and the assumed match-up of the IAEA safety class with ISO 13848-1 SIL.

<table>
<thead>
<tr>
<th>PL</th>
<th>(\lambda) (per hour)</th>
<th>SIL</th>
<th>IAEA Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>(10^{-5} - 10^{-4})</td>
<td>No corres</td>
<td>NSR</td>
</tr>
<tr>
<td>b</td>
<td>(3 \times 10^{-5})</td>
<td>1</td>
<td>SR-B</td>
</tr>
<tr>
<td>c</td>
<td>(10^{-6} - 3 \times 10^{-6})</td>
<td>1</td>
<td>SR-B</td>
</tr>
<tr>
<td>d</td>
<td>(10^{-7} - 10^{-6})</td>
<td>2</td>
<td>SR-A</td>
</tr>
<tr>
<td>e</td>
<td>(10^{-8} - 10^{-7})</td>
<td>3</td>
<td>SR-A</td>
</tr>
</tbody>
</table>
Another assumption is that the failure rate of component being considered is independent of time, i.e. it follows a bathtub model (that is, wear in, or wear out failures are not included). This research also assumes that the time to failure is exponentially distributed. This assumption also means the availability of the system will remain unchanged over the period when the bathtub expands. The availability of the system under this condition is given by the following formula:

\[
\theta = \frac{1 - e^{-\lambda t}}{\lambda t}
\]  

(3)

Taking into consideration the values of acceptable failure rate given in Table 1 and the required availability of the system per year, the required availability can be determined using equation (3) as the values shown in Table 2.

**TABLE 2. REQUIRED AVAILABILITY OF DIFFERENT SAFETY INTEGRITY LEVELS**

<table>
<thead>
<tr>
<th>PL</th>
<th>A(t)</th>
<th>SIL</th>
<th>IAEA Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>0.957451434</td>
<td>No correspondence</td>
<td>NSR</td>
</tr>
<tr>
<td>b</td>
<td>0.986974354</td>
<td>1</td>
<td>SR-B</td>
</tr>
<tr>
<td>c</td>
<td>0.995632762</td>
<td>1</td>
<td>SR-B</td>
</tr>
<tr>
<td>d</td>
<td>0.999562128</td>
<td>2</td>
<td>SR-A</td>
</tr>
<tr>
<td>e</td>
<td>0.999956201</td>
<td>3</td>
<td>SR-A</td>
</tr>
</tbody>
</table>

In this application, time to the next failure \(t\) is a desired value in order to estimate an inspection interval based on given parameters such as required availability and observed/actual failure data for component. Let’s consider equation (3), \(t\) could not be analytically solved easily. One way to approximate the value \(t\) in equation (3) is that when the value \(\lambda t\) is much less than 1.0 (which is often the case), then Taylor’s approximation could be utilized as shown in equation (4);

\[
\theta \approx 1 - \frac{\lambda t e^{-\lambda t}}{2} \approx 0.5 e^{-\lambda t}
\]

(4)

With this expression, \(t\) can be solved using simple quadratic solver formula as the result shown in equation (5) [1].

\[
t = \frac{1 - \sqrt{1 - 6\theta^2}}{2\lambda} \approx \frac{\log(\theta)}{\lambda}
\]

(5)

If one knows failure data for a component (\(\lambda\)) and its corresponding required availability (A(t)), one can approximate the value \(t\) using equation (5).

Considering IAEA safety class along with its corresponding availability \(A\) and by utilizing a measured failure rate from IAEA database (\(\lambda\)), a time to failure (t) can be determined using equation (5).
Now, recalling the Monte Carlo Simulation using $A = k \cdot X$ model, we replace the left hand side of the equation with $t$, and the right hand side of the equation is function of availability and failure rate. From Table 2, required availability ($A(t)$) were calculated according to safety classification. Next, failure rate ($\lambda$) and its statistical distribution, i.e. Chi-Square distribution were obtained from IAEA database and used as input parameters in a computational tool called @Risk. In the process, the software would sample the failure rate values from the Chi-Square distribution data given by user and would give the result such as mean time to next failure, its standard deviation, 5th percentile, 95th percentile, and if required user can file the simulation results in to predefined distribution. Note that this model is not linear so that one cannot assume the same distribution on both sides of the equations.

In this work, a software, @RISK [6] was utilized in order to obtain a probabilistic data for time to the next failure $t$ for component of interests. The major processes include; (1) assigning the required availability $A$ to a component with matching SIL and IAEA class that was done and shown in Table 2, (2) assigning probability distribution to the failure rate of components of interest which can be obtained from the IAEA reliability database [2], (3) conducting a calculation, (4) obtaining a probabilistic data for time to the next failure $t$. This implies that the inspection time must be less than $t$ in order to ensure the availability of the component of interests.

5. DATA ACQUISITIONS AND ANALYSIS

In research reactor business, it usually involves lacking of actual failure data for systems and components, however, an attempt were made by the IAEA characterizing these data [2]. The first data set used in the calculation was obtained from either Vienna research reactor or Indonesian research reactor located at Bundung and Yogjakarta or Slovenian research reactor since their types are the same as the TRR-1/M1’s type, TRIGA type reactor. Since these data do not cover all type of SSCs failures for TRR-1/M1, an alternate data from other types of reactors was used in the calculation for similar component type. Table 3 shows examples of failure rate of different SR-A components gathered from the database. These data were calculated based on Chi-Square distribution as shown in equation (6) to (7) [3]. This Chi-Square distribution was also used in the software to tabulate the failure rate data for the simulation.

$$P_L = \frac{\chi^2}{2\alpha}$$

Where $\alpha = 0.10$ for 90% confidence interval
$n$ is number of equipment failure
$T$ is cumulative time in hour
$PL$ is 5th percentile
TABLE 3  FAILURE RATES FOR SSCTS OF INTERESTS [2]

<table>
<thead>
<tr>
<th>SSCs (SIL)</th>
<th>Failure Rate (per hour)</th>
<th>Mean Value ((\lambda))</th>
<th>(P_L) (5th percentile)</th>
<th>(P_U) (95th percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactor core and structures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel element TRIGA, stand LEU (3)</td>
<td>5.00E-07</td>
<td>2.00E-07</td>
<td>9.00E-07</td>
<td></td>
</tr>
<tr>
<td>Beam tube (2)</td>
<td>5.40E-06</td>
<td>3.00E-07</td>
<td>1.63E-05</td>
<td></td>
</tr>
<tr>
<td>Reactor Safety System</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactor SCRAM system (3)</td>
<td>7.20E-05</td>
<td>3.70E-06</td>
<td>2.16E-04</td>
<td></td>
</tr>
<tr>
<td>Reactivity Control System</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control rods (3)</td>
<td>6.70E-06</td>
<td>1.20E-06</td>
<td>1.59E-05</td>
<td></td>
</tr>
<tr>
<td>Control rods drive (2)</td>
<td>8.30E-06</td>
<td>2.80E-06</td>
<td>1.60E-05</td>
<td></td>
</tr>
<tr>
<td>Control rods position indication (2)</td>
<td>1.00E-04</td>
<td>7.79E-05</td>
<td>2.37E-04</td>
<td></td>
</tr>
<tr>
<td>Emergency Core Cooling System (ECCS)</td>
<td>4.50E-06</td>
<td>1.80E-06</td>
<td>8.20E-06</td>
<td></td>
</tr>
<tr>
<td>ECCS Pump (3)</td>
<td>2.84E-05</td>
<td>9.70E-06</td>
<td>5.50E-05</td>
<td></td>
</tr>
<tr>
<td>Pressurized level switch (2)</td>
<td>9.00E-06</td>
<td>1.60E-06</td>
<td>2.14E-05</td>
<td></td>
</tr>
<tr>
<td>Other Systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactor confinement system (3)</td>
<td>1.01E-05</td>
<td>5.00E-07</td>
<td>3.02E-05</td>
<td></td>
</tr>
<tr>
<td>Emergency power supply (3)</td>
<td>3.48E-05</td>
<td>1.64E-05</td>
<td>5.90E-05</td>
<td></td>
</tr>
</tbody>
</table>

6. CASE STUDY-SIMULATION OF INSPECTION FREQUENCY OF SAFETY CLASS (SR-A) SSC’S OF TRR-1/M1

The first priority of this research work was devoted to the SSC’s that are important to safety (SR-A) of TRR-1/M1 as shown in Table 3 [4]. As seen in Table 2, SR-A component can be divided into two safety integrity levels with their required availabilities. Table 3 also shows this categorization.

The result from a simulation reveals probabilistic data for mean time to the next failure of the SSCs of interests. For this research, one simulation composes of one hundred thousand trials or data samplings according to the Chi-Square distribution specified by user. The analytical results were based on these data. This time value implies the minimum time interval that the particular SSC must be inspected to ensure its availability. Table 4 shows probabilistic data, i.e. mean, standard deviation (SD),

5th percentile and 95th percentile values, for the inspection time interval of certain SSCs.
TABLE 4. TIME INTERVAL TO THE NEXT INSPECTION OF TRR-1/M1’S SSCS THAT ARE IMPORTANT TO SAFETY (SR-A).

<table>
<thead>
<tr>
<th>SSCs</th>
<th>Inspection Time Interval (hr)</th>
<th>Mean</th>
<th>SD</th>
<th>P_L (5th percentile)</th>
<th>P_U (95th percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactor core and structures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel element TRIGA, stand LEU</td>
<td>2.46E+02</td>
<td>1.73E+02</td>
<td>9.52E+01</td>
<td>5.40E+02</td>
<td></td>
</tr>
<tr>
<td>Beam tube</td>
<td>4.40E+03</td>
<td>6.12E+05</td>
<td>3.58E+01</td>
<td>3.14E+03</td>
<td></td>
</tr>
<tr>
<td>Reactor Safety System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactor SCRAM system</td>
<td>1.41E+01</td>
<td>4.24E+02</td>
<td>4.09E-01</td>
<td>2.39E+01</td>
<td></td>
</tr>
<tr>
<td>Reactivity Control System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control rods</td>
<td>2.61E+01</td>
<td>6.67E+01</td>
<td>5.48E+00</td>
<td>7.32E+01</td>
<td></td>
</tr>
<tr>
<td>Control rods drive</td>
<td>1.41E+02</td>
<td>1.02E+02</td>
<td>5.46E+01</td>
<td>3.10E+02</td>
<td></td>
</tr>
<tr>
<td>Control rods position indication</td>
<td>1.76E+01</td>
<td>4.65E+01</td>
<td>3.69E+00</td>
<td>4.93E+01</td>
<td></td>
</tr>
<tr>
<td>ECCS System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solenoid valve for ECCS</td>
<td>2.43E+01</td>
<td>1.40E+01</td>
<td>1.06E+01</td>
<td>4.94E+01</td>
<td></td>
</tr>
<tr>
<td>ECCS Pump</td>
<td>4.12E+00</td>
<td>2.89E+00</td>
<td>1.59E+00</td>
<td>9.04E+00</td>
<td></td>
</tr>
<tr>
<td>Pressurized level switch</td>
<td>1.94E+02</td>
<td>4.25E+02</td>
<td>4.10E+01</td>
<td>5.47E+02</td>
<td></td>
</tr>
<tr>
<td>Other Systems</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reactor confinement system</td>
<td>1.57E+02</td>
<td>1.51E+04</td>
<td>2.89E+00</td>
<td>1.69E+02</td>
<td></td>
</tr>
<tr>
<td>Emergency power supply</td>
<td>2.93E+00</td>
<td>1.31E+00</td>
<td>1.49E+00</td>
<td>5.36E+00</td>
<td></td>
</tr>
</tbody>
</table>

An average inspection time interval for some of the SR-A SSCs ranges from 14 to 4400 hours. A relevant application for this interval could be the maximum allowable time to have SR-A, SSCs maintained and inspected. For example reviewer can either take either mean or 95th or 5th percentile value, which is depended on regulatory basis, as a guideline for review maintenance frequency for components specified in maintenance plan submitted by reactor operating organization. The reason for this wide inspection interval range is the range of failure rates of components themselves are relatively different. It was found that the more numbers of equipment failure, the better statistics of the results, i.e. Lower standard deviation value. Another topic that needs further research is that how the operating time and hour for each component was obtained in order to get more reasonable failure data.

7. SUMMARY

In this research work, probabilistic inspection and maintenance intervals/frequency for some of TRR-1/M1’s SSCs that are important to safety were determined. The results from the research can be used as a regulatory guideline for reviewing operator inspection and maintenance plan. Future work will be performed in the area of revalidating the failure rate data. If necessary the actual repair data from the TRR-1/M1 logbook for could be used to revalidate the failure rate data such as failure type and failure mode. Once the failure rate data is revalidated, the next step is recalculation of this case study and the expansion to other TRR-1/M1’s SSCs that is less safety significant.
REFERENCES

[6] Palisade Co. Ltd. @Risk Software version 6.1.2
FORUM OF NUCLEAR REGULATORY BODIES IN AFRICA (FNRBA) STRATEGY TO SUSTAIN IMPROVEMENT OF REGULATORY SYSTEMS

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Cameroon
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Abstract

The first five-year term of FNRBA, 2009 - 2014, concentrated on increasing membership and the number of operational national regulatory bodies for control of radiation sources in Africa. Networking of regulatory bodies was launched and the Forum gained credibility outside the continent. FNRBA objectives for its second five-year term, 2016 - 2021, are to strengthen the regional networking, enhance capacity building, implement self-assessment and address common regional issues.

This communication presents the following five strategic priorities identified for implementation during the target period to achieve these objectives:

(a) “Create awareness of, and coordinating activities amongst political and policy makers and other regional forums and organizations;
(b) Establish an efficient and effective network of human resources supported by an IT platform to ensure sustainable regional cooperation and to align national strategies for capacity building with IAEA methodologies;
(c) Ensure understanding, develop, promote and implement high standards of radiation protection, nuclear safety and security in Members States;
(d) Implement capacity building activities at the national and regional level in radiation protection, nuclear safety and security regulatory infrastructure and framework and promoting and supporting sustainable regional cooperation in developing needed human resources;
(e) Harmonize national plans for emergency preparedness and response, transport and security in line with international requirements to facilitate exchange of information and sharing of experience”.

1. FNRBA OBJECTIVES

In March 2009, the Forum of Nuclear Regulatory Bodies in Africa (FNRBA) was established as a response to the following challenges:

— Legislation and regulatory framework non-consistent with the international standards;
— Non-effective nuclear regulatory bodies;
— Poor communication network among regulators in the region;

The objectives of FNRBA are to:

— Provide a platform for fostering regional cooperation;
— Provide for the exchange of expertise, information and experience;
— Provide opportunity for mutual support and coordination of regional initiatives; and
— Leverage the development and optimization of resource utilization.

2. ACHIEVEMENTS DURING THE FIRST TERM (2009-2014)

In 2009, FNRBA approved five strategic goals to be implemented during the first five years of its existence [1].

— **Goal 1**: To promote the establishment of regulatory infrastructure in all countries of the Region.

Out of 55 countries in the region, about 65% have regulatory infrastructure established in 2015.

No information is available for the following countries: Benin, Burundi, Cap-Verde, Comoros, Congo (Brazzaville), Djibouti, Eritrea, Gambia, Guinea, Guinea Bissau, Equatorial Guinea, Lesotho, Liberia, Sao Tomé-et-Principe, Seychelles, Somalia, Swaziland, and Togo.

— **Goal 2**: To enhance the national regulatory systems to be compliant with or compatible with IAEA standards.

Efforts are being made to review the existing national regulatory body infrastructure in order to comply with international standards. FNRBA partners, the IAEA in particular, assist to this end through regional training courses and workshops, and expert services to review legislation and regulation.

FNRBA encourages its members to request Integrated Regulatory Review Service (IRRS) missions to assess the effectiveness of the national regulatory body. Between 2009 and 2015, a good number of IRRS missions were implemented in Africa. From 2007 to 2014, 11 countries hosted IRRS missions.

— **Goal 3**: To develop and promote a framework for capacity building in areas of radiation and nuclear safety and security.
Member States (MS) participated in several workshops and training courses on capacity building which provided the concept details and helped in the identification of the activities to be implemented. Education and training component is still to be developed in the region, and especially in embarking countries. Other MS took advantage of regional Master degree programmes established with the IAEA assistance in some of the countries. Postgraduate courses in radiation protection were established in Morocco, Algeria, and South Africa with IAEA supports. These helped to acquire effective workforce needed by newly established regulatory bodies.

However, the capacity to assess their competency needs according to the nature and scope of the nuclear programmes of their respective countries remind a challenge to the majority of FNRBA members.

The Forum is promoting pools of experts in ten (10) thematic areas, although these Thematic Working Groups (TWG) are yet to be effective. The main FNRBA network tool available is its website established under GNSSN with IAEA support. Each member state has its own page on this platform. Members of TWG can easily share their views on this site. The effective use of the platform is another challenge. Members of the Forum need to be trained in this regard.

— **Goal 4:** To create an opportunity for mutual support and coordination of regional initiatives by leveraging the development and utilization of regional and international resources and expertise.

To optimize the use of the available resource, FNRBA signed formal agreements with key partners and coordination mechanism is in place through the existing FNRBA’s Focal Point at the IAEA to avoid duplication. The following partnership agreements formally exist:

— KINS (Korean Institute of Nuclear Safety): MoU signed in 2010; implemented since 2012 on the basis of 2 training events organized each year.
— IAEA: Practical Arrangements signed in Vienna, Austria, on 17th September 2013 to support the enhancement and strengthening of the radiation protection, nuclear safety and security, and regulatory infrastructure in MS which are members of FNRBA.
— TAMU (Texas Agricultural and Mechanical University): LOI signed in Vienna, Austria, on 18th September 2013.

These formal agreements come to complement assistance received by FNRBA since 2009 from IAEA TC through regional projects RAF9038 on promotion of establishment of Regulatory Bodies in Member States and RAF9049 on sustaining Regulatory Bodies in Africa; US-NRC through Several training activities related to NPP, emergency preparedness, nuclear safety, inspection, etc.
3. PRIORITIES OF THE SECOND TERM (2016-2021)

The Strategic Action Plan (SAP) [2] for the period 2016-2021, adopted by the extraordinary Plenary Meeting of the Forum held on 14th September 2015 in Vienna, is underpinned by the need for competent human capital in the field of nuclear regulation. According to this plan, five (5) priorities (Pi) are selected to be implemented during the term of reference. They are:

**P1:** Create awareness of, and coordinating activities amongst political and policy makers and other regional forums and organizations

FNRBA missions and objectives have been presented at the African Union (AU) meetings, the conference of States Parties to Pelindaba Treaty, the African Commission for Nuclear Energy (AFCONE), and the Resolution 1450 meetings organized at the AU headquarter. Some African Heads of Permanent Missions of IAEA Member States assisted in the ceremony of signature of the Practical Arrangements between IAEA and FNRBA in September 2013. It is foreseen that Permanent Missions will vehicle the FNRBA’s SAP to the policy makers of their respective countries to seek for its greater support.

**P2:** Establish an efficient and effective network of human resources supported by an IT platform to ensure sustainable regional cooperation and to align national strategies for capacity building with IAEA methodologies

Nine principal areas of human resources development were listed by IAEA [3] to support nuclear power programme: workforce planning, training and education, recruitment, succession planning, performance management, career management and retirement. The link between regional experts in various thematic safety and security areas through TWG web pages allow sharing of experiences and the development of teamwork spirit among them contribute to sustainable human resource and capacity building in the field of radiation safety and security in Africa. FNRBA Members are encouraged to get familiar with IAEA methodology for Self-assessment [4] in their efforts to develop their respective national strategy for capacity building. Information about capacity building activities conducted via knowledge networks can be used to facilitate national capacity building programmes. Individual Regulatory Body participation in regional or international knowledge networks provides a support to the Regulatory Body capacity building activities.

**P3:** Ensure understanding, develop, promote and implement high standards of radiation protection, nuclear safety and security in Members States
FNRBA seeks to minimize nuclear safety and security gaps between MS by encouraging the implementation of international instruments and cooperation with other regional networks. (Implementation of: Self-assessment, Peer review missions, IRRS, training on safety standards and security guidelines).

IRRS missions were conducted in six (6) FNRBA Member States in 2007 (Gabon, Uganda, Kenya, Cameroon, Mauritius, Niger), four (4) in 2008 (Côte d’Ivoire, Botswana, Namibia, Sierra Leone), and two (2) in 2014 (Cameroon, Zimbabwe) [5]. Increased number of peer review missions in the region is expected in the period 2016-2021.

P4: Implement capacity building activities at the national and regional level in radiation protection, nuclear safety and security regulatory infrastructure and framework and promoting and supporting sustainable regional cooperation in developing needed human resources.

Academic and on-the-job training modalities are to be combined in the regional capacity building strategy in order to address the development of human resource needed to sustain radiation protection and nuclear safety and security infrastructures (need for e-Learning courses, Assessment of training need in various TWGs and per country; Increase the use of regional training facilities).

GNSSN provides opportunity for Harmonization of global initiatives in nuclear safety and security; it also facilitates exchange of expertise between regions. FNRBA link to GNSSN constitutes a tool offered to its members to implement activities relating to capacity building and development of competences in nuclear safety and security [6].

P5: Harmonize national plans for emergency preparedness and response, transport and security in line with international requirements to facilitate exchange of information and sharing of experience. FNRBA members in each Sub-region are encouraged to establish agreements for transport of radioactive materials and emergency preparedness and responses. Several countries in Africa have approved their Integrated Nuclear Security Support Plan (INSSP). Effective implementation of these plans constitutes a real challenge to be addressed by the Forum and its partners.

4. CONCLUDING REMARKS

The FNRBA Strategic Action Plan for 2016-2021 is a key reference document made available with IAEA’s assistance to monitor the accomplishment of the Forum during this period. The priorities listed constitute the activities of FNRBA’s roadmap for this period. Upgrade of the national regulatory infrastructure, effective network of FNRBA members, sharing of information and knowledge among members and among countries, increase awareness of national
and regional stakeholders on nuclear safety and security are dominant features of the regional regulatory network strategic plan.

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[5] IRRS Mission Worldwide; gnssn.iaea.or/Regnet  