

Technical Meeting on Regulatory Oversight of Human and Organizational Factors (HOF)

Vienna, Austria, 14-18 December | VIC – M7

MINUTES OF THE MEETING AND CONCLUSIONS

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1. Introduction

It has been noted at various regulatory forums, including the Sixth Review Meeting of Contracting Parties to the Convention on Nuclear Safety in 2014 and the International Conference on Effective Nuclear Regulatory Systems: Transforming Experience into Regulatory Improvements in 2013, and in the findings of International Atomic Energy Agency (IAEA) review missions that there is room for improvement in the current regulatory assessment capabilities of licensees' programmes in the area of HOF and in the conduct of oversight, including inspection. Based on exchanges with countries with mature nuclear power programmes as well as with countries embarking on such programmes for the first time, the IAEA was made aware of the importance of sharing Member States' experiences related to the regulatory oversight of HOF.

A technical meeting was held from 14 to 18 December 2015 on Regulatory Oversight of Human and Organizational Factors (HOF) to contribute to the achievement of this goal. Its objective was to assist Member States in understanding: The importance of the regulatory oversight of HOF; Regulatory strategies for the oversight of HOF; Regulatory approaches and methods used, including regulatory inspection, to verify that the licensee effectively manages HOF in order to ensure that these factors contribute positively to safety; and Other provisions of the regulatory body to promote the positive contribution of HOF to safety and to mitigate possible adverse effects. The meeting provided an opportunity for participants to share their experience related to the effective oversight of HOF.

To achieve the objective of the technical meeting, plenary discussions based on participants' presentation were organized along with discussions during breakout session on two specific topics: *"HOF concept and what areas need for oversight on HOF"* and *"Content of a HOF regulatory oversight programme"*. The results of breakout session groups were discussed during plenary sessions in order to finalize the conclusions and recommendations of the group. In addition, a panel discussion was held on *"Developing and strengthening a regulatory oversight programme"*. This report and the conclusions of the meeting were discussed in plenum the last day.

The meeting was chaired by Christopher Kopish (Germany). Ram Prakash Gupta (India) was the Rapporteur of this technical meeting. The Scientific Secretary was Mr Jean-René Jubin.

2. DAY 1 – 14 December 2015

2.1. Opening Session

Mr. Greg Rzentkowski, the IAEA NSNI Director, delivered welcome and Opening remarks. He highlighted that the Chernobyl accident in 1986 pointed out the importance of HOF and the Fukushima accident reinforced the need for HOF in the reactor design, operation, and regulation. Indeed Analysis in nuclear industry pointed out that 70 % of problems in a nuclear power plant can be attributed to HOF failures. He referred to the Fukushima accident report by the Director General of the IAEA in mentioning that cross-cutting nature of HOF: systematic human organization and technical factors need to work together and reinforce each other and should not be considered as stand-alone elements. Those factors need to be duly considered and adapted to the entire life cycle of the nuclear power plant. He also mentioned that: HOF aspects in safety analysis are important but are not still fully incorporated; knowledge management is important; and the right behaviour can be promoted not forced! There should be proper balance between promotion and enforcement action by the regulatory bodies. Mr Greg Rzentkowski concluded that this technical meeting will form the basis for a new technical document on Regulatory Oversight of HOF in order to further assist the IAEA Member States in this area.

After the Chairperson welcome remarks and the introduction of the participants, the technical meeting objectives and expected outcomes were presented by Mr Jean-René Jubin (IAEA / Scientific Secretary). Following this presentation, upon proposal of the Chairman, the agenda of the meeting was adopted.

2.2. Presentations

Ms Alice Salway from Canada delivered a presentation to introduce to the participants basic concepts of HOF and the benefits to consider them as part of the regulatory oversight programme. Her presentation included:

- Overview of HOF considerations, with examples;
- There are factors other than culture that influence human performance, in 5 categories: equipment and system, task related, organizational, environmental, and individual factors;
- Two misconceptions about HOF were presented and discussed. Firstly, the myth that HOF is just opinions and it is too soft and not rigorous for using in the real world is countered by the fact that the HOF domain having an extensive evidence-based body of knowledge and methodologies for analysis and design. Secondly, the myth that people will not make mistakes if we watch them closely and if they pay attention was countered by explaining that the flexibility and variation that humans bring to their work is a positive thing for the majority of the time, but this sometimes leads to errors;
- Practical examples of HOF were presented. This included the HOF-related causes of incidents/ failures and the contribution of various HOF elements such as deficient procedures, lack of knowledge, failure to follow procedures;
- HOF other than culture are generally easier to control and improve than culture;

- The importance of considering HOF was described. Firstly, HOF are ultimately involved in all incidents and accidents. Secondly, HOF can be managed by licensees to support desirable human performance;
- A human-centred, systemic view of HOF was described;
- Oversight by regulatory bodies includes setting requirements and expectations for HOF, carrying out regulatory activities such as inspections, reviews and taking regulatory measures where there are non-conformances
- Promotion to educate licensees is an important part of regulation of HOF;
- Identification of HOF elements and arrangements for regulatory oversight.

Q&A

- Question: Newcomers RB face lack of staffing. How can RB ensure oversight HOF?
- Answer: Use consultants and contractors to help. Train up RB staff with systems thinking abilities who are interested in the domain
- Question: Has Canada developed any new regulatory reviews/inspections/documents after Fukushima?
- Answer: Unrelated to Fukushima, but Canadian Standards Association has produced a new standard on human factors in design for nuclear power plants CSA N290.12-14, which licensees will be implementing.
- Question: Whether regulatory oversight of working environment aspects are provided by other regulatory bodies or same RB.
- Answer: work health and safety is considered by the Canadian Regulator outside of HOF as a separate topic. However there is overlap. The physical environment and safety of workers is considered by HOF specialists in making system modifications and designing new systems and equipment.
- Question: How RB supervises HOF in the utility? Do the Utility inform regulatory body about changes made in the organization? How regulatory oversight is implemented to assess individual fatigue?
- Answer: Requirements and expectations exist regarding HOF and these are regulated through review, inspections, performance monitoring and regulatory measures where needed. Depending on the type of change, the licensee may or may not need to inform the RG. Licensees have processes in place to assess fitness for duty e.g., fatigue, in individual workers.
- Question: What does Systemic approach mean?
- Answer: This refers to holistic approach which is a fluid and dynamic approach. Everything relates to one another, e.g., systems thinking. Systemic approach should not be confused with Systematic approach.

Mr Jubin provided the audience with an *Overview of HOF-related IAEA Safety Standards*. Given their important contribution to safety (positively or adversely), the human and organizational factors are addressed at Safety Fundamental Level under the safety fundamental principle 3. It was recalled that the IAEA safety standards are a sound basis to develop a regulatory system including an effective regulatory oversight programme on HOF. Numerous requirements and guidance related to human and organizational factors provide a good basis to identify what and how to look at. Performance of regulatory functions aims

at determining whether the licensee comply with regulatory requirements and conditions. All of these functions are opportunity to oversee HOF. However, the findings should be considered in an integrated way to identify trends and make knowledge conclusions. These results should be addressed as part of a constructive and professional dialogue with the licenses.

Q&A

- Question: New HOF guide to be developed? When?
- Answer: Several initiatives have been undertaken on Safety Culture and HOF. From this meeting, our intention is to develop a Technical Document on Regulatory Oversight on HOF. So far, the publication is schedule in early 2017
- Question: Is there a formal IAEA requirement to establish a programme on HOF?
- Answer: No IAEA requirements exist as such asking the licensee to have an HOF programme but this regulatory approach is largely considered as a key by numerous IAEA Member States.
- Question: Is there a difference between safety and security HOF in relation to the Technical Document?
- Answer: HOF should also be considered by security. The new Technical Document will only focus on safety but might be useful to security and other areas.

The first national presentation was delivered by Mr Botsoev from Bulgaria. He presented the provisions used or under development to oversee Licensees' human and organizational factors in Bulgaria. His presentation addressed the followings:

- HOF-related requirements outlined, for example, procedure for notification about events in nuclear facilities, procedure for inspection activities in nuclear facilities, oversight of safety culture in nuclear installations (not yet used properly in Bulgaria);
- Systematic strategy of Regulatory Oversight of HOF is missing in Bulgaria;
- HOF information collection: discussion with personnel, review and assessment, for example;
- Individual licenses issued for performance of activities in nuclear facilities, for example;
- Inspections aspects of HOF: Mostly technical inspections are done, for example operating experience feedback;
- Safety assessment and analysis: analysis of operational events related to human error;
- Second legislation is being developed: strong requirement for Regulatory Oversight of HOF;
- Challenges: lack of systematic oversight process including all aspects of HOF; requirements are mainly preventing human errors, economic aspects; regulatory requirements need to be revised; no human factor experts, etc.;
- Solve problems: new requirements and guidance on how to oversight HOF; training needs on HOF to be included; allocation of sufficient resources; experience exchange on the international level;
- Planning to include HOF aspects in training program of regulatory staff.

Q&A

- Question: Does BNRA review the operating procedures?

- Answer: The operator has an obligation when changes in safety-related documents are implemented to provide the documents for regulatory assessment.
- Question: Safety culture and oversight procedure in place? Is there a national standard?
- Answer: Procedure for safety culture oversight exists but not used properly. Procedure is based on the IAEA safety standards.
- Question: Incident related to HOF, does the RB get involved in investigating it or does the RB leave it to the license holder?
- Answer: RB can participate in the analysis but the current practice is to review submitted reports only. INES level also plays a role.

Mr Alvarenga from Brazil presented Experience in the use of human factors engineering for ANGRA 1-3 Nuclear power plant. In this regards, he explained that the regulatory body imposed a new chapter. His presentation covered:

- The regulatory body has adopted USNRC and IAEA documents to verify human factors and organizational factors of ANGRA 1, 2 and 3 NPP. In this regards, the chapter 18 related to human factors engineering was introduced in the safety assessment review (SAR) in 1998;
- The implementation of acceptance criteria of these documents (USNRC-NUREGS, IAEA safety guides, etc.) are being monitored in the ten years periodic safety review (PSR) evaluation for ANGRA-1 and ANGRA-2;
- The proposal of design and procedures modifications are dependent on the acceptance of licensee's PSA in level 2 combined with PSA level 1;
- Regulatory body intends to adapt NRC oversight program to evaluate licensee's safety culture;
- The assessment to improve standards to deal with the digital instrumentation and control failures and to detail the criteria of nureg-0711.

Mr Duchac (IAEA/SAS) presented the current status of the development of the IAEA safety guide, DS492, on human factor engineering. He provided the rationales which support the development of DS492 with the intention to address existing and relevant IAEA requirements established, for example, in SSR-2/1, SSR-2/2, GS-R-3 and GSR part 4. It has been drafting considering the Fukushima Daiichi accident and the interface with other international standards such as IEC, NUREG, and IEEE. It is expected to cover the following topics: Operation and maintenance; Accident conditions; Design of control and display navigators; Equipment layout; etc. Possible sections will be:

- HFE programme management;
- Analysis;
- Human system interface design;
- Human factors verification and validation;
- Design implementation;
- Human performance monitoring.

So far, DS492 is expected to be endorsed by the CSS in November 2017.

Q&A

- Question: Research reactor not covered by the document?

- Answer: Research reactor not specifically covered. This document focuses on specific safety requirement for the design of a nuclear power plant. But human factor engineering is applicable to research reactors.
- Question: Simulators information included?
- Answer: Will be covered under validation.
- Question: Are behavioural factors going to be included?
- Answer: Yes. But please remember that these are recommendations. The IAEA does not promote specific technologies.
- Question: Guide is being reviewed by technical people. What about non-technical people who are experts in human behaviour?
- Answer: Safety guide will be provided to Member States so they can add their input. Behavioural aspect will only be mentioned but not in detail.
- Question: What is the main difference between requirements and safety guides? Should requirements have more details about human factors?
- Answer: Requirements have a specific meaning, shall statements. There are many design safety requirements. Human factor engineering is included in three of these requirements. The safety guide will focus on these three requirements and will make recommendations how to realize these requirements.

Mr Hata from Japan presented the current situation of Japan on regulatory oversight of the licensee's HOF activities. He described the significant changes of the legal and regulatory system in Japan with the establishment of an Independent Regulatory body, NRA. He also provided information related to the content of the regulation. He highlighted the focus was on the erroneous operation prevention related to Man-Machine-Interface and the requirement for person responsible for operation. Since 2011, NRA developed new regulations with a better consideration of HOF and Safety culture. Regarding Safety culture, it was initially addressed in 1994 with the release of the 1st white paper on the topic. Since then, NRA developed "Code of conduct" on safety culture and NRA started evaluating safety culture fostering activities of the licensee in 2014. It is required that the licensee to submit plan for safety culture enhancement. In 2015 NRA Commission issued "*Statement on Nuclear Safety Culture*". The Mihama accident in 2004 results in changes the regulatory oversight system, e.g., Implementation of root cause analysis; establishment of safety culture and human factor analysis; production of guidelines in 2007 and 2008 respectively; organization of more than 20 lectures and training courses to train regulatory staff. So far around 800 events managed thanks to the NUCIA database have been analyzed to identify direct and root causes.

Q&A

- Question: What are the 14 elements of safety culture in Japan? Root cause analysis can identify one of these elements with deficiencies. How is this done in Japan?
- Answer: Mr Hata provided all of the elements.
- Question: Were problems experienced in Fukushima the same as in Mihama?
- Answer: In Mihama, safety culture was the problem. As a consequence, the regulatory body enhanced the regulations. In Fukushima, hardware was the main problem due to the earthquake and the Tsunami.

Ms Retfalvi from Hungary presented the regulatory oversight of HOF at Hungarian Nuclear Facilities. HAEA, the Hungarian regulatory body, has developed several safety guidelines which has HOF relations, and several internal inspection procedures to support regulatory staff to oversee HOF. Hungary developed new inspection planning process, from the annual planning to assessment and follow up action. The goal was the systematic planning. The one of considerable main topic is HOF. Specific HOF inspections are organized; in 2015 they have focussed on: managerial briefing before work; near miss and low importance event investigation; measures to increase the safety culture; organizational structure transformation in the IT security field. The HAEA implemented an auxiliary method for the safety assessment of events, with special attention to the events showing different variants of human factors. In 2014, 18 events have been reported. Human failures were identified by investigation in 14 events, which can refer mostly to problems in written procedures or in safety culture. Ms Retfalvi outlined also real cases of human error events. She also explained the use by HAEA of performance indicators system (one of the main area are safety culture, with 22 low level indicator) and the project to upgrade them.

Q&A

- Question: Are there any English or German publications of the Hungarian procedures?
- Answer: Only few available in English. Swiss and IAEA documents are used for developing inspection planning process. The extract of annual report of regulatory assessment of the hungarian nuclear facilities are available in English online at http://www.oah.hu/web/v3/HAEAportal.nsf/web?openagent&menu=04&submenu=4_3.
- Comment: there is a strong interest in the structure of the Hungarian safety performance indicator system.
- Question: Performance level indicator: what does “no data” indicate?
- Answer: There are several possible reasons, but it is occur very rare. For example in the case of the new facilities. Indicators system for radioactive waste disposal and not all data does yet exist for new facilities, mostly which come from trends or change of data. Assessment done once per year.

3. DAY 2 – 15 December 2015

Main conclusions of Day 1 were presented by Scientific Secretary before the Chairman introduced the day 2.

3.1. Presentations

Ms Aude Geniaux from France presented the ASN strategy on HOF evaluation. She described the individual (the worker) is part of a socio-technical system. Many factors influence the activities pertaining to: worker, working environment, material and technical systems, and organization. The licensees are responsible to ensure that workers have adequate working conditions and have the possibility to adapt the way they are carrying out their task at an acceptable cost. She highlighted that an operating situation in which performance is satisfactory but in which this was obtained at very high human cost is a source of risk: Only a slight variation in the context or change of an individual can be enough to prevent the required performance level from being reached. ASN conduct dedicated inspections on HOF. They usually last one day. However, ASN organizes also team inspections during days to conduct deeper and detailed inspection on a specific topic. The ASN oversight system is also based on the strong support from its technical support organization, IRSN, and advisory committees. ASN has also established a steering committee on socio, organizational and human factors to reflect on some topics with regards to HOF and encourages, through a constructive dialogue, operators to develop HOF consideration. Ms Geniaux concluded:

- HOF is a high concern for ASN;
- HOF are essential to safety;
- HOF are still difficult to oversee;
- ASN uses wide and diverse regulatory oversight mechanisms;
- Based on a constructive and professional dialogue, licensees are encouraged to take over the HOF topics and to recruit relevant HOF specialists.

Q&A

- Question: What level of control of contractors by ASN?
- Answer: ASN does not directly control contractors but control the surveillance actions on contractors put in place by the operator.
- Question: Does ASN oversee the management for safety?
- Answer: Inspection on safety management process.
- Question: Topical HOF inspections are applied for every NPP in France?
- Answer: Yes, every year in every NPP.
- Question: Operators knows about topical HF inspections?
- Answer: Licensee is informed in general, except for inspections of safety events.
- Question: Do licensees come voluntarily to RB for problems? Can RB be contacted for problems?
- Answer: Yes.

- Question: What is mandate of HOF Steering committee?
- Answer: HOF SC comprises representatives and experts from different organizations. Its objective is to improve the considerations of HOF by the licensee. It produces reports with recommendations in this respect.

Mr Lee from the Republic of Korea presented the regulatory oversight activities and issues on HOF in South Korea. The emphasis on HOF started in early 80' after the TMI accident. They established at that time legal basis on HOF focussing on Human Factors Engineering (HFE) design in safety assessment report (SAR) and periodic safety review (PSR): qualification, training, activities, and management of HOF. In the design aspects, the application of human factors engineering are specifically addressed in chapter 18 of SAR but also considered in other chapters such as 7 on instrumentation. Several regulatory standards and guides on HFE, Conduct of operation. Since then, KINS has ensured through its review and assessment process that HOF are properly considered in construction and operation of NPP. He concluded that: HOF should be approached in an integrated manner as done by KINS.

Q&A

- Question: Details on licensee reports on near-misses (examples, incentives, quality and quantity of info, how is info used)
- Answer: Any near-misses should be reported as required by RB. The focus of the RB is the licensee activities to correct and reflect the lessons learned from the near-misses.
- Question: Methodology to treat human actions in safety analyses?
- Answer: This is mainly done by the PSA team in KINS.
- Question: How is fitness for duty observed during inspections?
- Answer: Documented reviews (education& training, working time...) and interviews with selected personnel.
- Question: Are operators required to perform self-assessment?
- Answer: No, but they do it internally.
- Question: What does the "Stress Test" mean?
- Answer: This refers to evaluation of plant arrangements for beyond design basis accident (BDBA) caused by HOF.

Ms Salway presented the CNSC's regulatory oversight of HOF, current approaches and future vision in Canada. She described the Regulatory framework and policy developed by CNSC. CNSC has established a safety and control area (SCA) framework for oversight, which is a set of technical topics. This enables an integrated approach for collecting, managing and presenting information for all regulated facilities and activities (18 items). The regulatory documents are structured according to SCA framework. Details of the full SCA framework can be found on the CNSC website. The current approach is based on: HOF is cross-cutting and apply across the SCA framework (CNSC P-119, Policy on Human Factors); the use of HOF specialists in HOPD (Directorate of Safety Management and its divisions, including the Human and Organizational Performance Division); and the conduct of multidisciplinary reviews and inspections. Ms Salway explained the vision for human performance: HOF is considered formally in the first 5 SCAs (Management Systems, Human Performance

Management, Operating Performance, Safety analysis, Physical Design). HOF is considered less formally, but often in a further set of SCAs. For any of the SCAs, HOF is considered where needed, e.g., in response to a particular concern or event. She provided information on Human performance programmes. She indicated that a discussion paper on Human Performance is in progress and should be published in 2016. She listed the following objectives of licensees' human performance programs:

- Active support of human performance through considering HOF, with the aim of achieving safe and effective outcomes
- Integration of good practices for managing human performance throughout the licensee organization's activities
- A human-centred focus, that considers and supports people carrying out their work
- A systemic approach to managing human performance across the whole organization
- A maintained focus on considering the people in the organization when managing organizational, operational, and technical matters.

She also provided the following good practices regarding management of human performance by licences:

- Consideration of human performance as it is actually carried out by individual workers (not necessarily the same as work as anticipated in procedures or by designers)
- Providing appropriate resources to support human performance
- Continual system improvement through considering and managing the broad range of HOF across the organization
- Considering the roles of all levels and all departments in achieving the desired human performance
- ensuring that human error is considered as a potential symptom of deeper issues, instead of the sole cause of failure
- Identifying the sources of human performance problems using a variety of methods, and correcting them
- Continually striving to improve organizational system that governs, manages and guides human performance

Q&A

- Question: How is human and org performance measured? Performance indicators?
- Answer: Explicit requirements. Requirements in the legislation, licences and regulatory documents. Also guidance and expectations. For inspections there are specific inspection criteria that point to requirements. It takes a lot of effort to produce the desktop review and inspection guides, also regulatory documents and discussion papers – 4 HOF-related documents currently in preparation.
- Comment from Adriana: the results of CNSC evaluation on Human Performance appear in the annual evaluation of safety control areas. They are qualitative and quantitative by nature. There is a system for rating.
- Question: Who are HOF specialists? How they become specialists?
- Answer: Range of backgrounds is large and does not necessarily include (extensive) nuclear. (examples were given).The CNSC offers strong, comprehensive training in many topics and specific HOF-related training is planned to be available to all CNSC staff.. The Human and Organizational Performance Division comprises specialists in psychology, and other human sciences backgrounds. There is a strong demand on HF specialists and there has been success in training people without practical experience

of HOF issues, but who possess systems thinking abilities and enthusiasm for the domain.

- Question: More details about training and certification?
- Answer: Personnel Certification Division used to take care of the certification test for NPPs, but exams are now conducted by the Licensees, with CNSC oversight of the process.
- Comment: IAEA is working on a new Workshop (and document) on certification and training of NPP personnel.
- Question: Are there specialists in CNSC focused on planning and decision-making during outages?
- Answer: Management Systems Division and technical divisions look at that. Not specifically for HOF.
- Question: Romania produced a regulatory guide for regulatory review of FSAR on US NRC model. An additional chapter (18) for HOF were introduced in this regard. Where such information can be found – other aspects than the ergonomics ones should be covered?
- Answer: There is an IAEA format. For each safety factor, specific guides were written by the CNSC to guide vendor design reviews. Internal guidance for staff on considering HOF in PSR /ISR is being prepared at the moment. Much information exists on HOF at the CNSC, but it needs to be collated and presented in the appropriate format for these reviews, with specific guidance on how to carry out the reviews.

Mr Christopher Kopish presented the regulatory oversight of HOF in Germany. He described the legal and regulatory framework (most are available in English) including: the Atomic Energy Act; the Requirements for Nuclear Power Plants and the Nuclear Safety Standard for Integrated Management System. The oversight of safety is done at two levels in Germany: at federal and lander (state) level. The oversight strategy of HOF of the regulatory body of one particular state was presented, because of its comprehensive level.

The regulatory body strategy to oversee HOF is based on the following aspects:

- Interaction between Human, Organization and Technology;
- Personnel and organization are vital for safety;
- Systemic analysis and oversight;
- External factors;
- Focus on integrated management system (IMS) and Safety Culture (SC);
- Influence of regulatory oversight on SC of licensee;
- Interaction focus on senior management.

The regulatory body uses the following mechanisms to oversee HOF: Integrated Inspections for Safety Culture, control of the self-assessment of Licensee's IMS; annual evaluation of inspection results; annual meeting with the senior management of the licensee to discuss improvements, findings and strategies. For the integrated inspections for Safety Culture they use the KOMFORT tool which is based on the Schein Safety culture Model. This tool is very well known by the inspectors and integrated in regular inspections. KOMFORT allows collecting Safety Culture information about workload, quality... and contains SC indicators (at artefact level according to the Schein model). KOMFORT tool has been used since 2005. The HTO group comprises members of 4 sections.

Q&A

- Question: Do inspectors have to use this tool in regular inspections? Are they trained on it?
- Answer: Yes. The tool is not seen as intensive on resources, plus it gives more insights –it is seen as helpful by inspectors.
- Question: Do inspectors include these assessments on the agenda? Do they choose to have a special focus on something?
- Answer: They may concentrate on a single or multiple indicators. They do it alone.
- Question: Is the RB comparing of results with self-assessments done by licensee? Are different problematic areas identified that raise additional questions from inspectors?
- Answer: RB performs only evaluation of the MS report by licensee. SC self-assessments are not communicated to the RB (no requirements), but annual meetings are held on specific issues. If the SC issues are prompted, they are discussed.
- Comment: As the regulator, we are reviewing the activities of the licensee, but we must be able to compare results in order to see if there are any gaps in the review.

Regulatory oversight of HOF in Finland was presented by Ms Nykanen. She described the legal framework. HOF is captured under 5 articles of the Government Decree 717/2013: 6/ Management of human factors; 24/ Operational experience feedback and safety research; 28/ Safety Culture; 29/ Safety and Quality Management; and 30/ Lines of management, responsibilities and expertise. Fukushima accident was taken into account when STUK (The Finnish Regulatory Body) revised the complete set of YVL guides. The process finalized in June 2014 allowed reducing the number of guides from 80 guides to 45 guides. Two of these guides were specifically pointed out:

- A.1 Regulatory oversight of safety in the use of nuclear energy
- A.3 on Management system for a nuclear facility: *Management of human and organisational factors*

The Organization and Management Systems section (6 people - 4 technical and 2 non-technical) oversees HOF process and practices. The HOF findings are identified when conducting oversight activities: Inspections; Observations and surveillance of licensee performance at site; Review and assessment; Operating experiences, Event reporting; Oversight of implementation of projects, modifications, outages; and Interactions with licensee (meetings, audits, training). Resident inspectors are posted at Site. Findings are collected and recorded in the HAKE database. The objective is to integrate all of this information in a systemic way.

Q&A

- Question: Is HAKE appropriate for STUK activities? What pilot period suggests?
- Answer: STUK finds the database appropriate for integration into activities. Feedback from IT is positive also.
- Question: How were the topics chosen for HAKE?
- Answer: We had a discussion about what are the topics that would describe safety culture and management system. Most of these topics are included in YVL Guide A.3.

3.2. Breakout session 1: Concept and areas for oversight on HOF

The breakout session was introduced by the Scientific Secretary. The objective of the first breakout session was to further develop a common understanding on HOF. 4 Groups were formed. Each of them was requested to discuss several issues and to get prepared for presenting their conclusions, including possible recommendations during a plenary session in day 3.

4. DAY 3 – 16 December 2015

Main conclusions of Day 2 were presented by Scientific Secretary before the Chairman introduced the day 3.

4.1. Breakout session 1: Results

The conclusions of all groups as presented and discussed in plenum are provided below.

Group 1

- **Definition of human and organizational factor:** human and organizational factors are factors that positively or adversely influence human performance as it relates to nuclear safety (and security)
- **What are the key aspects of HOF? Why is it important or not?** All are important because they can impact nuclear safety
 - Inherent human characteristics: capabilities and limitations, cognitive capabilities (e.g. memory, drive to completion), perception, anthropometry;
 - Other human characteristics (knowledge, skills, reasoning, fitness for duty);
 - Environmental factors: heat, cold, radiation, noise, PPE, vibration, lighting, air quality
 - Technological factors: usability of equipment, process in which the equipment is used, complexity, procedures, workplace ergonomics, user expectations and habits, user fooling and transparency
 - Organizational factors:
 - Management system, processes, procedures,
 - Shift working,
 - Use operational experience feedback; training and qualification
 - SCWE (Safety culture working environment) – safety conscious work environment; blame-free, reporting culture
 - Safety culture,
 - Human performance tools (e.g. three-way communication, STAR, peer checks, self-checks, phonetic alphabet, stop when unsure; procedure compliance, questioning attitude, etc.),
 - Observation and coaching, quality of supervision,
 - External factors:
 - Social, economic, political aspects,
 - Regulatory framework and regime,
 - National culture.
- **What does a systemic and integrated view means? ITO – Individuals, Technology, Organization**
 - Complex system with lots of elements which are all somehow connected;

- Different system boundaries have to be considered (e.g. work groups, departments, organizations, external influences);
- Communication and interaction;
- E.g. changes to systems based on some requirements disregarding others (e.g. improvements to security that may impact on safety; improvements for severe accident management which may affect normal operation).

Q&A

- Question: Is HOF restricted to nuclear safety?
- Answer: HOF needs to be applied to all areas of nuclear safety. HOF also helps the efficiency and productivity of the organization as a whole. Due to the fact that Group 1 looked at regulations, the group only focused on nuclear safety. Overall organizational performance is based on HOF.
- Question: Does HOF consider individuals or the group as a whole?
- Answer: HOF refers to the people working for an organization.
- Comments: The main goal of HOF refers to human performance which wants to achieve the safety goals of the organization. But this does not refer to the overall objective of the organization. Agreed definition of HOF: use the IAEA's definition found in GS-G-3.1

Group 2

- **What could be the definition of HOF? What are the key aspects of it? Why is it important or not? Organizational factors vs Human Factors**
- Capability of licensee to ensure the safety though:
 - Reliability of qualified, competent staff regularly trained for normal and abnormal condition in sufficient number, fitness for duty,
 - Efficiency of organization structure (clear responsibilities, no overlaps, no gaps);
 - Efficient communication (direct, open, trustful, feedbacks, common understanding, proactive attitude, sharing of proper information at all level);
 - Process orientated management system (integrated management system, clear procedures, clear priorities, clear decision making, change management, improving continuously, management of change, quality management, self-assessment, Knowledge Management, recruitment process);
 - Ability of employees to perform the work on safe/proper way
 - Ergonomics , Man-Machine Interface, optimizing human action , preventing human errors,
 - Error preventing tools (3 way communication, STOP methods, Self-reflection, etc.),
 - Human performance improvements programme,
 - Work environment, working conditions, etc.
- **HOF and external interactions/relations of licensees**
 - Open and frank communication and information with regulator;
 - Graded approach of frank and open information of public;
 - Effectiveness of the regulatory body has influence on safety performance of licensees;

- Open and frank communication and information with contractors, subcontractors.

Q&A

- Comment: IAEA safety standards on the management system cover most items that were mentioned in this presentation.
- Answer: Group 2 had a long discussion about the difference between change management and management of change. The Group decided that good change management covers all changes realized in a short period of time. Organization structure needs clear responsibilities. Gaps are dangerous.
- Comment (Scientific Secretary): A clear organizational structure is important but so is flexibility. Some organizations have difficulties in that. Cross-cutting structure of an organization is also important.
- Comment (Slovenia): The management level should be taken into account when talking about staff.
- Question: Shouldn't HOF be a key element for promoting a healthy safety culture instead of outlining it as part of the safety culture?
- Answer: Yes, it should.

Group 3

- **Should HOF permeate all activities?**
 - HOF permeates all activities during the lifetime of nuclear installations as:
 - Design,
 - Construction,
 - Commission,
 - Operation (Maintenance, Human Resource Management, Engineering and Technical support, Waste Management, Change Management)
 - Decommissioning
- **Should not be too cumbersome?** Yes, because regulatory bodies need to find the right way between too descriptive or too general. RB uses graded approach for assessment and evaluation of requirements. HOF are intangible.
- **How to manage HOF? Role of the management system:** RB doesn't manage HOF as separate objectives, but earlier is identifying in all objectives of regulatory activities as follows:
 - Authorization, Inspection or Assessment;
 - LH should focus attention in documentation of integrated management systems for all aspects of HOF.
- **What are the difficulties to oversee HOF?**
 - Deficiencies and gaps in regulations and guidelines where HOF issues should be addressed (proactive requirements);
 - It is not so easy to ensure validity of input data to support the oversight of HOF issues;
 - Different analytical tools and methods (i.e. set of safety indicators with defined thresholds and respective actions; different RCA methods for the events'

analysis) should be used to oversee HOF properly. Respective amount of resources and expertise should be allocated at RB for that purposes.

Q&A

- Question: How to address deficiencies and gaps? Important to choose the adequate method.
- Answer: Can only be done from lessons learned and experience. Indicators can also support this.
- Question: Is HOF intangible?
- Answer: Requirements cannot cover and consider all future mistakes whether human or technological.
- Comment (Scientific Secretary): Maybe it would be better to state: Not all HOF are tangible. If there is no explicit focus on humans in a technical organization, then HOF tends not to be considered at all. Siting needs to be included as it is important for nuclear safety.

Group 4

- **How HOF can be considered to contribute positively to safety?** It should provide the best possible conditions and circumstances for using, developing and fostering personnel competencies and motivation to perform individually or collectively their tasks reliability and adequately:
 - o It provides adequate support to task performance: motivation, physiological and psychological health, skill, knowledge, learning, social skills, feeling free of reporting incident, interpersonal respect, personal development.
- **What should be addressed to prevent organization failures? What are the key attributes for managing organizational changes? How to manage HOF? Role of the management system**
 - o Organization failure:
 - if the act or event can be attributed to failure of organizational characteristics of a structure or processes of the organization
 - Organizational factors related to failures
 - o The term “failure” should be defined (to guaranty failure report)
 - o Tasks assigned to the workers have to avoid inadequate workload/ they have to stimulate motivation proper incentives
 - o Well defined structures, responsibilities, authority;
 - o Strong learning organization (monitoring and improvement of the process);
 - o Clear and transparent reporting system;
 - o Many observations collected by inspectors. The observations are considered to be symptoms of degradation of safety culture;
 - o Good relationship between licensee and the regulatory body.
- **What are the difficulties to oversee HOF?**
 - o Various and interaction of factors (everything in the working situation and organization that has an influence on the activity);
 - o Knowledge evolving (advance human-machine interfaces)-> one have to keep up to date;

- Some of this factors are not observable easily (psychological factors, motivation, fears, fatigue);
 - Variations in individual behaviour/cultural differences;
 - Variations in working environment (e.g., inadequate tool, inadequate time allocated to a task);
 - Time and resources, knowledge of regulatory inspectors, expertise of the regulatory body;
 - Availability of the data (extended working hours...).
- **What are the difficulties to oversee HOF?**
- Difficulties to make assessment on the contribution of these factors to performance and safety;
 - Risk of oversimplification view of human behaviour;
 - Involving of regulatory body in the licensee's organization (prime responsibility for safety – too prescriptive);
 - Licensee transparency/ access to information (interviews);
 - Regulatory body self-censorship; when a person is too technical and disregard other more soft aspects
 - Incomplete/inadequate rules and regulations;
 - Independence of the regulatory body.

Q&A

- Question: Can good methodologies easily identify psychological factors?
- Answer: Motivation is inherently personal and not as clearly detectable as for example procedures.
- Question: What is meant by regulatory body self-censorship?
- Answer: Self-censorship refers to biases of an individual in terms of what to look at.
- Comments (Scientific Secretary): Other factors that could influence performance were not mentioned such as the working environment and physical resources. In interaction, the combination of factors should be also looked at.

4.2. Presentations

Ms Haage (IAEA/OSS) presented *The Human and Organization Part of Nuclear Safety*, focusing on the licensee side in relation to the HOF. Ms Haage outlined that the discussion on safety mainly focuses on technical aspects and not on human factors. HOF is still not as strongly recognized as technical aspects. Chapter 2 of the IAEA Fukushima report outlines why the Fukushima Daiichi accident happened and highlights that one lesson learned is the necessity to proactively deal with the complexity of nuclear operations. In her presentation, Ms Haage further outlined that the systemic approach to safety refers to the interaction between the human, organizational and technical aspects. The IAEA Safety Fundamentals refer to this in the Safety Fundamental Principle 3 as well as the IAEA Safety Guide GS-G-3.5. Ms Haage described Licensees HOF/SC Areas. She concluded in highlighting the complexity and Systemic Challenges in relation to Safety and the need for Personal and behavioural competences (analytical thinking, problem solving, personal effectiveness and self-management, communication, team work, management and leadership, safety culture).

Ms Haage invited participants to attend the Conference on Human and Organizational Aspects of Assuring Nuclear Safety which is taking place in February 2016 in Vienna.

Q&A

- Question: Is IAEA training on human and organizational factors available?
- Answer: Yes, when IAEA Member States request such training, the IAEA will facilitate it.

Ms Tronea presented the regulatory framework and practices for the oversight of HOF in nuclear installations in Romania. She stated that general requirements exist on HOF and that up to date they have proved sufficient to support the regulatory oversight purposes. Romania is currently considering producing new regulatory guidance documents on human factors in design and operation of nuclear installations based on requests received from licensee. CNCAN, the Romanian Regulatory Body, covers the following areas on regulatory oversight of HOF:

- o Design,
- o Safety analysis,
- o Procedures,
- o Operational performance,
- o Emergency planning and preparedness,
- o Organizational structure and staffing,
- o Management system and its processes,
- o Safety conscious work environment,
- o Implementation of the nuclear safety policy,
- o Implementation of the internal independent nuclear safety oversight,
- o Nuclear safety culture.

The establishment of the Safety Culture Oversight Process (SCOP) started in 2010 following the recommendation from the 4th Review meeting of the Contracting Parties to the Convention on Nuclear Safety. The SCOP procedure was reviewed and revised in 2015. SCOP includes the collection of data, regulatory team analysis, presentation to the licensee and reporting. General criteria for safety culture include issues related to safety culture attributes; findings that constitute deliberate non-compliance with the license conditions; as well as issues that indicate a mismatch between the declared policies and organization values. A data base is currently being developed for safety culture oversight.

Q&A

- Question: Whether regulatory oversight is provided for siting stage also? What is the lead time for license applications?
- Answer: Siting phase, 12months before the start of the work; construction phase, at least 18 months before the start of the work; commissioning phase, at least 12 months before the start of the process, etc. The time varies.

Ms Godinez-Sanchez presented the Mexican nuclear regulatory framework on HOF. At the beginning of her presentation, she reminded the importance of HOF but the difficulty to oversee some of them. She stated also that the organizational structure guides the behavior of the human factor, giving formalism and complexity to the process. She provided a detailed description of technical requirements for selection, qualification and training in

focussing on organization structure,. She explained that Qualification is a combination of education, experience and training and the licensee training programmes are reviewed by the regulatory body. Then she provided details on Human and Organizational Factors requirements which cover Education, knowledge and ability to communicate. The fitness for duty programme was presented. It aims at maintaining capabilities and skills needed to perform tasks safely and efficiently. She concluded that the human factor is the most important of all the elements that make up an organization and at the same time, it is the most difficult to control, due to the thought and perspective of each who is very different.

Q&A

- Question: Is it common practice to test the alcohol level before staff enters the site of a license?
- Answer: It is a new practice that is being implemented.
- Question: Are there other parameters?
- Answer: illness and fatigue.

Mr Kudryavtsev presented the Practice of HOF regulatory oversight in the Russian Federation. He mentioned that human and organizational factors are taken into account:

- according to national legislation and safety requirements;
- during both licensing and inspections activities.

Then he provided an overview of the legal and regulatory requirements mainly about training, competence and qualifications of licensee staff. The Russian Regulatory Body carried out different types of inspections: planned and unplanned; complex inspection; dedicated inspections for licensing. The inspection programme addressed HOF. He indicated that the regulatory body issues permits for key individuals (DG, DDG, Directors...) to ensure an efficient nuclear management. Mr Kudryavtsev concluded that: Regulatory oversight of human factor, including quality and training of personnel is a key factor for safety culture; and oversight of organizational factors should be of importance for regulatory body during organizational changes in nuclear industry.

Q&A

- Question: Are the psychological tests realized periodically? In Hungary, this is a requirement.
- Answer: No, a general medical document showing that the applicant is of good health is sufficient for the staff to be working for five years. The important part is the signature by a psychologist.
- Question: Do you have unannounced inspections?
- Answer: No, the Russian Federation does not perform unannounced inspections. Planned inspections are announced to the utility or the licensee at the beginning of the year. It is open information. One month before the inspection, the programme of inspection is shown to the licensee.
- Question: What does independence of the licensee manager from Headquarters mean and how is this being enforced?
- Answer: The independence from the governing body is important because it should not seriously influence safety issues. This is being implemented.

- Question: Licensing of the managers. Romania's license is based on an interview. What about the exam in the Russian Federation?
- Answer: It is a real oral exam with 10 questions connected to safety requirements. For a Director General interview, questions include the physical protection system or material accounting system. For chief engineers, more technical questions and requirements are needed. Questions also refer to nuclear legislation. To pass the exam, the applicant needs to provide good answers for at least 7-8 questions. 15% do not get permissions.
- Question: In the Russian Federation, only qualifications are related to HOF?
- Answer: Yes, qualification and training. The Russian Federation needs to pay more attention to other HOF factors.

4.3. Breakout session 2: Content of a HOF regulatory oversight programme

The breakout session was introduced by the Scientific Secretary. The objective of the second breakout session was to develop the content of an effective HOF regulatory oversight programme. 4 Groups formed were the same as for the breakout session 1. Each of them was requested to discuss several issues and to get prepared for presenting their conclusions, including recommendations during a plenary session in day 4.

5. DAY 4 – 17 December 2015

Main conclusions of Day 3 were presented by Scientific Secretary before the Chairman introduced the day 4.

5.1. Presentations

Mr Pecherytsia's presentation focused on "Supporting the regulatory activities in the area of HOF in Ukraine".

- TSO uses a two-tiered approach to identify and assess of HOF-related issues:
 - o assessment of reports on operational events;
 - o analysis of NPP operational experience;
- Application of safety indicators developed and used to supervise HOF:
 - o Development of the Integrated NPP Safety Oversight System;
 - o 3 areas of development: Organization, Operational safety and Radiation safety, and Radioactive Waste.

The regulatory body has different approaches and methods to oversee HOF, which are based on TSO support, and have planned for the use of multiple tools to ensure validity of data to support review on HOF. It also envisages to revise and develop new regulations and guides to address HOF as well as to organize training courses, specifically designed for senior management.

Q&A

- Question: How many low level event and analysis take place per year and how?
- Answer: RB obtains data upon request. This is part of the regulations.
- Question: What is the methodology to investigate the root cause of the operational events?
- Answer: Staff obtains skills and tools after participating in relevant events and workshops and training courses. Recently, the European Commission has provided training courses on root cause analysis methods.
- Question: What does the regulatory oversight in Ukraine cover?
- Answer: The presentation was devoted to describe activities of TSO for supporting overall regulatory oversight process. Ukrainian oversight, however, is much broader.
- Question: Does a comparison between results of the licensee and results of the RB take place?
- Answer: Yes, this is periodically done.
- Question: How do oversight HOF and connecting indicators detect safety culture deficiencies?
- Answer: This indicator is based on event investigation results. For root causes there is a special code for safety culture deficiencies.

Mr Raukach presented Current practices in the area of HOF regulatory oversight on the Belarusian NPP in Belarus. He described the legal and regulatory system in Belarus as well as the regulatory body and its functions. He highlighted the importance of quality assurance for safety. The regulatory is facing the challenge to manage the staff growth and know-how in a short period of time. The education programme is supported by IAEA, Russian Federation, and EU through Training courses, on-job training and expert missions aims at:

- Transferring Methodology and knowledge;
- Enhancing Competence;
- Supporting Belarusian Regulatory Body growth.

No questions and answers

Mr RP Gupta gave a presentation on the *Regulatory oversight of HOF during different stages in Indian NPPs*. Salient aspects addressed in his presentation include the following:

- Review areas pertaining to HOF during all stages of Nuclear and Radiation Facilities include:
 - Training programmes, qualifications and licensing policies,
 - Prescription of the syllabi for training of personnel ins safety aspects at all levels
 - Operational experience in light of radiological and other safety criteriaThese aspects are part of consenting process.
- Strategy to oversee HOF
 - Organization structure, responsibilities and authorities
 - Managing the organisational changes
 - Competence
 - Safety culture
- Lessons learned of regulatory oversight of HOF
 - Introduced regulatory requirement for submission of reports on significant events/change in a timely manner based on criteria specified by AERB;
 - Introduced regulatory requirement of submission of “Basis of Acceptance” document for safety critical equipment;
 - Inclusion of requirement related to issuance of RO’s Policy on outsourcing of services;
 - Planning to carryout inspections to check implementation of QA program at design, procurement and off-site manufacturing stages;
- Organization support in accident management:
 - Regulatory oversight on EOPs, whose success depends on human performance
 - In deterministic safety analysis, aspects related to credit of operator actions are also checked;
 - Review of analysis of Human Error Probability and its contribution to CDF as part of PSA
- Safety Assessment after major Nuclear Accidents
- IRRS feedback: to develop action plan to further enhance the staff with specialized competence, knowledge, skills and abilities in the area of HOF.

Q&A

- Question: What kind of methodology is used for the time for human actions?
- Answer: The methodology is based on the accident analysis. Simulators are used for training the operators to handle different situations viz. Normal operations, Anticipated Operational Occurrences and accident conditions. This is part of licensing of the NPP operators.
- Question: Do you perform the review of PSA level 2?
- Answer: PSA Level-2 is not a mandatory requirement at present. Utility has performed the PSA level 2 for one of NPPs. AERB has undertaken review of this PSA report. This is in line with the suggestion from the IRRS mission. Based on the experience regulatory requirements may be reviewed/ revised, if required.
- Question: Do use a cognitive model to compose the human actions?
- Answer: Not directly but there are interviews and assessment of performance on simulators.
- Question: HOF-related requirements are important in siting. What do you look at in siting?
- Answer: During the siting stage, we require multi-disciplinary inputs (such as data obtained from geotechnical investigations, meteorological data, site seismicity, hydrological studies, epidemiological studies and feasibility of off-site emergency response plan) from various organizations (of Central Government, State Governments and others). If there is not proper arrangement for effective interfaces and activities not performed by a competent person then the data may not be of required quality/ representative of what is needed for siting consent.

Mr Szabo presented the *Slovak regulatory oversight of HOF*. He described legal and regulatory infrastructure for safety and existing regulatory requirements related to HOF: quality management system: Quality policy, documentation; Job position identification: work positions, competences; Training and fitness and mentally competent; Modification changes important to safety are under RB approval; etc. He also shared information on inspection guides and procedures. The current challenge of UJD SR, the Slovak Nuclear Safety Regulatory Body, is the preparation of new Atomic Act and associated regulations.

Q&A

- -Question: Please elaborate on the re-training of staff which resulted in new jobs. Does this mean that they are now doing a different job in a different department?
- -Answer: There are different phases of training; changing jobs means going from low level to high level or changes of daily activities or facilities.

5.2. Breakout session 2: Results

The conclusions of all groups as presented and discussed in plenum are provided below.

Group 1

HOF regulatory oversight program Strategy

- Basic inspection plan - have to cover different technical systems areas to include various HOF topics - initiating events, safety systems, defence in depth, radiation

protection, emergency planning, physical protection (security), operational events analysis;

- You have to put HOF oversight into all strategic areas - management system, procedures, training, work organization, matching with HRA (human reliability analysis as part of PSA), minimum staff compliment, fitness for duty, etc.
- We have to mix with stand-alone inspections on human factors topics;
- Standalone inspections - training program, simulator using, staff qualification, human performance monitoring, procedures, management system etc.
- Prioritize human actions that are risk significant;
- May consider normal operations and AOO (anticipated operational occurrences) plant states;
- May need to update regulatory framework;
- Support from high level regulatory management;
- Knowledge and competence of human and organizational factors in regulatory body.

HOF regulatory oversight program Key requirements

- Group responsible for the HOF program – for both regulatory body and licensee.
- Promotion, education and awareness of HOF to the licensees.
- Criteria for assessment of human factors.
- List of human factors elements HTO.
- Continuity and learning, professional development in HOF topics.
- Educating other regulatory body divisions.
- Monitoring and evaluation of regulatory body HOF program.

HOF regulatory oversight program Content

- Training,
- Procedures,
- Human factors in design (HFE),
- Fitness for duty,
- Methods and methodology.

Q&A

- Comment: Before talking about training, the organizational structure needs to be outlined. Also, processes can be divided into three groups:
 - Management function,
 - Planning in relation to performance,
 - Measures in relation to assessment.

Group 2

Regulatory strategy

- Common principles, priorities
 - Influence of the regulator on licensees strategy and action of HOF
 - Common understanding of HOF(regulator, licensees)
 - HOF influence on safety
 - Appropriate Interaction with licensees at all levels
 - Continuously improving
 - Legal right to oversight the HOF issues

Strategy process:

- Definition of HOF(regulator, licensees)
 - Identifying and prioritizing the key elements of HOF
 - How the key elements can positively and negatively be influence on safety
 - Ideal characteristic of key elements
 - Depending on the nature of the elements of HOF(Measurable ⇔Intangible) approach of regulator (direct ⇔qualitative interaction) always systemic
- Formulating and communicating the requirements, guidance, and specifications. Formulating and communicating of HOF oversight strategy and policy.
- Choosing of method for assessments, conducting them (e.g.: Inspections, collecting the dates, evaluation)
- Choosing of method of feedback, Feedback for licensees (e.g. identifying the good practices, enforcement of improvements (corrective actions, recommendations, obligations)
- Assessment of the follow up actions of licensees, monitoring of improvements
- Self-assessment, improvement of regulators approach by the regulator itself

Key regulatory requirements of HOF

- Quality assurance program
- Integrated management system and continuously improving it
- Maintaining high safety culture
- Requirements for staff (number, qualification, training, etc)
- Justifying of upgrading of designs of plants, interfaces, work environments
- Sufficient communication channels (internal, external)
- Clear organizational structure (including subcontractors interface)

Regulatory Oversight Programme

- Regular meeting and interview with top management
- Topical, focused, integral and general inspections
- Collecting inspection findings in systematic way (e.g.: databases)
- Systemic analyse of inspections findings
- Sharing the findings, lessons learned inside regulatory body
- Checking the documentations

Q&A

- Comment: Regulatory strategy should include the legal aspects first.
- Comment: It is understood that some factors are missing because it is not possible to include everything in the presentation. Also, the oversight programme mentioned the systemic analysis of inspections findings. Should this only include findings from inspections or also other regulatory function findings?
- Answer: Yes, more function assessments should be included. Time was short.

Group 3

Regulatory strategy

- RB can oversight HOF only based on exist requirements in own regulatory framework.
- RB need create these requirements for all documentation important for follow licensing processes (Sitting, Construction, Commissioning, Operation and Decommissioning).

- Main requirements need to add to documentation of integrated management system, as policy for elimination of negative aspects of HOF.
- Policy should include:
 - a written pledge by top management to preferentially achieve, maintain and constantly develop a high attention for identification and elimination of HOF with negative impact for nuclear safety, nuclear security , emergency preparedness and radiation protection,
 - a policy including requirements for meeting and monitoring of HOF,
 - a written pledge by all levels of management to identify and create the database of HOF,
 - assess and continuously evaluate the HOF during the defined time period,
 - system for using of corrective action for elimination of repetition of identified HOFs,

Regulatory oversight of organizational changes

- Changes are the qualitative or quantitative changing of equipment or documentation with impact for nuclear safety, nuclear security or emergency planning.
- Changes must be justified in advance, carefully planned, and assessed following implementation.
- Changes shall be performed in accordance with principles and requirements applicable for the original facility or documentation.
- Changes to original design requirements or implementation of new requirements must be justified and relevant analyses must be performed to document their acceptability.
- The licensee applicant or a LH shall submit:
 - An analysis of the causes of the proposed change, with justification of the goal of the change,
 - Assessment of the impact of the change on nuclear safety, etc.
 - proposed measures to eliminate possible negative effects of a new facility on existing facilities during its installation, inspection, tests, maintenance and operation,
 - Proposed measures to eliminate possible negative effects of the change, including its inclusion in quality management system documentation or employee vocational training,
 - A record of the quality management system documentation that the change shall affect, and changed quality management system documentation if it is subject to RB approval, or if the RB requests it for examination,
 - A safety assessment for the proposed change performed by an independent subject through risk analysis,
 - An evaluation of the proposed change by the author of the original project, or another qualified individual.

Regulatory oversight program:

- Assess the licensee policy including requirements for meeting and monitoring of HOF,
- Provide an inspection mechanism which has allow:
 - to supervise how adequate those requirements are fulfilled by LH,
 - to assess and continuously evaluate the HOF during the defined time period,

- Evaluate system of LH for using of corrective action for elimination of repetition of identified HOFs.
- Allocate adequate resources (human, knowledge, etc..) for effective implementation of mentioned activities.

Q&A

- Question: What do you mean by negative aspects of HOF?
- Answer: As an example, negative aspects include no training activities provided to staff, or old training material used. These aspects can have negative effects on staff capabilities.
- Comment: First step to regulate should to strongly encourage or, if necessary, require the licensee to develop and implement an improvement programme on HOF.

Group 4

Regulatory strategy

- Goal: HOF should be considered in such a way that safety is enhanced using state-of-the-art knowledge and properly interfaced with technology, during the entire lifecycle of the facility
- Strategy
 - To have a legal basis
 - To have the proper resources
 - Proper interactions between RB and licensee (including follow-up)
 - Proper interactions between the licensee and RB
 - The RB must be a learning organization by internal and external resources
 - Encompassing perspectives of HOF
 - Application of graded/differentiated approach during the lifecycle
 - Resources
 - Provision on HOF in the legislative framework
 - Regulations and guidelines on HOF
 - Adequate resources to perform HOF oversight (including human resources)
 - Objectives
 - Failure prevention and mitigation
 - Best possible support

Key regulatory requirements

- Expectations
 - Submission on HOF program
- Assessment of the program and implementation
- Monitoring & control and improvement

Regulatory oversight program: to be defined, implemented, continually improved

- Content, criteria, and scheduling
- It should include inspections on site. It should include valid information which can be evaluated (interviews, observation of working activities, documents assessments...)
- It should be performed by inspectors who have a minimal knowledge of HOF
- Behaviour of the inspectors should be fair, appropriate, objective
- Open and dissemination of information among inspectors and licensees

Q&A

- Question: Is it a fact when saying that inspectors have minimum knowledge of HOF?
- Answer: No, it is beneficial to have inspectors with a minimum knowledge of HOF.

5.3. Panel discussion: Opportunities and Challenges to Change

The panellists were: Mr Alvarenga from Brazil, Ms Salway from Canada, Ms Retflavi from Hungary, Mr Gupta from India and Ms Tronea from Romania

INTRODUCTION

Ms Tronea

- We have all learned by now how important HOF is for nuclear safety; it is equally if not more important than technical factors.
- Major lessons learned from major accidents in the past.
- Lessons learned are important to improve regulatory practices to prevent such accidents in the future.
- RB has an important role as it sets standards about what is acceptable in relation with the licensee.
- Once the RB gives more attention to HOF, so would the licensee.

Mr Alvarenga

- Each country has HOF split into four characteristics:
 - 1. laws and regulations that include items related HOF,
 - 2. Special inspection planning on nuclear safety,
 - 3. inspections for operational events (safety culture),
 - 4. Performance indicators used to identify HOF
- This subjects need more discussion: 1/ Criteria of identification of HOF elements in the findings of inspections plan; 2/ treatment of human actions significant to risk in order to propose design modications.

Mr Gupta

- We have seen the importance of the HOF
- Countries have different practices
- Countries have different practices
- Regulatory oversight of HOF is generally emphasized and requirements are specified for operation stage. These aspects are required to be addressed for all the stages of Nuclear and radiation Facilities.
- Most of the HOF aspects are addressed in different documents. These are required to be integrated and gaps, if any, to be removed.
- We should try and agree on a common set of conclusions as well as on mechanisms to assess and improve regulatory oversight

Ms Salway

- Difficulties and challenges: you can't bring your programme forward faster than the understanding of the staff of RB and the licensee. Therefore, education and training is important.

- Opportunities: Nuclear licensees seem more receptive to HOF considerations when you talk about supporting desirable human performance rather than a focus purely on human errors.

Ms Retflavi

- More HOF data and observation is needed.
- We need a common definition in the RB.
- We need good tools to collect data. That is why Hungary has started developing IT tools but for this to really work, we need a common understanding/common categories. We need better communication inside of the RB.
- Result: best way is strong commitment of the top management.

DISCUSSION

Scientific Secretary Question: What would be the first step you will take after this meeting to start working on HOF?

- Ms Retflavi answer: First step is to receive the commitment of the top management.
- Ms Tronea answer: First step is to involve the supervisor and colleagues to provide support to develop a more systematic approach of HOF. Although Romania has requirements that have been sufficient so far, these are scattered among several documents. In Romania, we will improve the listing of strategies of HOF and create an inventory of all requirements currently available. We need a standard to benchmark ourselves. Training is necessary as there are no HOF specialists.
- Mr Alvarenga answer: As a first step, implement oversight inspection planning based on risks as well as special safety procedures in safety culture. Process of HOF must be unified among all people involved in an organization. Promote a common language.
- Mr Gupta answer: It is a practice in our country that participants of Technical Meetings prepare a deputation report highlighting the various aspects covered during the discussion. Management of the AERB will be briefed about the main conclusion of the Technical meeting. As first action, an approach paper/ action plan is prepared for internal review by AERB. After approval, the prepared action plans are communicated to the Utilities in a Theme Meeting/ Technical Discussion. Or comments utilities comments are obtained on the same. Outcome of the technical discussions/ utilities comments are disposed by the experts identified by AERB. Actions for developing regulatory documents/ implementation of the identified requirements are initiated by AERB accordingly.

GERMANY question: How would you start to develop a common understanding between the RB and the licensee?

- Ms Tronea answer: Implement a similar strategy as for the safety culture oversight in Romania. It was successful through the attendance of common (IAEA) training. The training involved people from the industry and staff from RB.
- Mr Alvarenga answer: In Brazil, people from different fields are brought together and their work is integrated.
- Mr Gupta: In India, most of the HOF aspects are addressed in present regulatory documents and regulatory oversight covers the same. However, certain new concepts, as discussed in the Technical meeting would be considered for inclusion appropriately. As indicated earlier, common understanding can be achieved through

organizing Theme meetings and training programs. During regulatory inspections also, the plant management is latest developments/ new information about regulation and other safety aspects. Similar approach would be adopted for this case also.

- Ms Salway answer: Working with the RB and the licensee at the level of HOF specialists usually works really well. Individual one-on-one discussion on the staff level is very useful. CNSC uses discussion papers prior to producing its regulatory documents.
- Ms Retflavi answer: Personal discussion most useful.

PAKISTAN question: What tasks would be new for the RB in relation to HOF if the licensee already implements HOF?

- Ms Tronea answer: It gives an opportunity to look at the same areas with more competencies/expertise in HOF.
- Mr Gupta answer: India covers HOF in various activities, however, there are certain missing links (generally those of intangible nature, difficult to quantify/ specify). Better is to have a more systematic self-assessment of these aspects by the utility to improve the safety of the nuclear power plant. Regulatory body may review the results of such self-assessment for its adequacy.
- Ms Salway answer: It would enable a more practical approach. We are trying to tie in with the licensees in their human performance programmes, also with focus on what is going well rather than on safety as an absence of negative events. More sustainable HOF is needed which is tied up with considering resilience and the systemic approach. HOF doesn't happen in isolation.
- Ms Retflavi answer: Activities and factors of HOF should be assessed.

SLOVENIA question: How to teach the licensee to realize modifications?

- Mr Alvarenga answer: You need to have a methodology to prioritize issues (maybe PSA)
- Mr Gupta answer: After accident at Fukushima, safety assessment of the NPPs was carried out by an Apex Committee consisting of experts. Utilities also performed the self-assessments regarding capabilities for handling the severe accidents. Required modifications were enlisted in these assessment reports. Modifications/ areas of improvements (action plans for short term, intermediate term and long term measures) were identified by the safety committees, in which Utilities also participated in the discussions, considering the outcome of these assessments. Thus adequate clarity is available to the licensee regarding understanding of required modifications and their implementation.
- Ms Tronea answer: It is true that the RB put a lot of pressure on the utility to perform upgrades after Fukushima. It may have happened that modifications were done too quickly and some modifications had to be re-done.
- Mr Salway answer: In Canada, an independent committee was formed after Fukushima. This committee highlighted that HOF consideration are extremely important. The licensees existing human factors and design processes are carried out for post-Fukushima modifications. Desktop reviews have been carried out by the CNSC and HOF will be considered in inspection of the design implementations.

MEXICO question: How does the RB analyse whether a utility has a good organizational structure and function? Do we have to develop HOF also inside of the RB?

- Ms Tronea answer: In Romania, there is an understanding that the organization and staffing of the licensee should support nuclear safety. The licensee needs to demonstrate the effective organization and staffing to the RB. No real standards exist. The RB can ask why the licensee chose a specific structure. Why does the licensee think that it is the correct structure?
- Ms Salway answer: RB in Canada as a departmental structure by functions. But the matrix organization is adopted for specific project using multi-disciplinary project teams.

INDONESIA question: Could HOF be integrated in the management system?

- Ms Salway answer: HOF is already considered in the management system in the CSA N286 standard. But we need to highlight HOF as the management system does not provide detailed guidance on specific HOF topics.

INDONESIA question: what is meant by systemic approach for HOF?

- Ms Salway answer: When talking about a systemic approach we refer to a holistic approach. This is also known as “Systems thinking”. In this regard education is important.

SOUTH KOREA question: Does the RB have the authority to impose HOF actions on the licensee?

- Mr Alvarenga answer: Enforcement by the RB is not the correct way. Requirements and recommendations can happen before achievement of highest level of enforcement actions.
- Comment by ARMENIA: RB cannot give advice on how to operate.
- Mr Alvarenga answer: RB has to issue standards and can recommend the right concepts. Enforcement has many steps with different level of actions.
- Ms Salway answer: It is possible to enforce that the licensee incorporates processes that meet the RB’s requirements and follows them. HOF is included in this as well.
- Ms Tronea answer: RBs have different opportunities than licensees, for example, most licensee staff cannot attend IAEA conferences. RBs around the world exchange experience through such events and can then advise the licensees. RB cannot enforce attitudes but RB can enforce the artefacts.
- Ms Retflavi answer: In Hungary, there are soft enforcement policies, “consider”.

GERMANY question: Why has it taken so long to focus on HOF despite the fact that the Three Mile Island accident happened over thirty years ago?

- Ms Tronea answer: Complex issue. People are not prepared to fully understand the lessons learned of accidents so far. Utilities are interested in human performance tools but not so much in human factors design aspects.
- Ms Salway answer: Qualification methods for HOF do exist, for example the European qualification on HOF (Registered European Ergonomist certification through the CREE (Centre for Registration of European Ergonomists). North America also does this through the BCPE (Board of Certification in Professional Ergonomics). The birth of human factor engineering came about in WWII so has been around for a

long time. Nuclear industry, however, is very conservative and HOF have been adopted slowly.

GERMANY question: How has our mind set changed in terms of HOF?

- SCIENTIFIC SECRETARY answer: The area is not tackled the way it should be. For example, the most popular solution to counter staff problems is still training and a new safety policy.
- Ms Tronea answer: Not even Directors and managers get training in HOF.
- SLOVENIA comment: Licensee staff receives more training in HOF than the RB.
- Ms Salway answer: CNSC is working on providing HOF training throughout the regulatory body.

PAKISTAN question: How to assess HOF?

- Ms Tronea answer: There are various disciplines. Get a human factors expert or to train someone.

PAKISTAN question: Is there a standard for assessment of HOF?

- Ms Retflavi answer: There are many different ways.
- Mr Alvarenga answer: It is a process.
- SLOVAKIA: Recently, the IAEA issued a special TECDOC No. 756 on the Root Cause Analysis Following an Event at a Nuclear Installation, which lists the different standards.
- Ms Tronea: There are several standards available.

6. DAY 5 – 18 December 2015

Main conclusions of Day 4 were presented by Scientific Secretary before the Chairman introduced the day 5. The meeting was officially closed by Ms Adriana Nicic, the NSNI/RAS Acting Section Head.

6.1. Main conclusions of the meeting

During this session, the Rapporteur of the technical meeting presented the draft report in plenum for discussion. All the participants agreed on the following conclusions.

The meeting was well organized. The way the meeting was chaired, managed and supported was also very much appreciated. The agenda timing was precisely followed. Sufficient technical and IAEA safety standards background were provided at the beginning of the meeting. All participants were actively involved in the breakout sessions and discussions. It resulted in effective conduct of this technical meeting without any problem in an excellent atmosphere. The participants concluded that objectives of the meeting were fully achieved.

According to the IAEA Safety Guide GS-G-3.1 *“Whereas the culture of an organization influences human behaviour through the values, beliefs and assumptions held by the personnel of the organization, there are also other factors that may have a positive or negative influence the human behaviour on how humans act in a given situation”*. An individual has various types of resource at their disposal to enable them to carry out a task successfully in a given situation:

- The individual, e.g., competence, motivation, cognitive abilities
- Physical resources, e.g., tools, procedures or computer aids
- Working environment, e.g., through teamwork, communication and leadership, in the management system and culture.

The proper consideration of HOF will support the individual to positively contribute to safety. In this respect, all the aforesaid resources and their combination help in preventing human error by providing barriers to error and mitigating the possible consequences.

The participants concluded that human and organizational factors (HOF) are those factors which have significant influence, in a positive or adverse manner, on human performance. Therefore, HOF have a key importance for safety, keeping in mind that safety is the result of interaction of Individuals, Organization and Technology.

HOF need to be applied to all safety-related areas for the different stages in the lifetime of a facility and the duration of an activity.

There are many HOF and they can be categorized in different ways. One example presented during the meeting comprises 5 categories:

- Individuals;
- Technology or systems;

- Working environment;
- Task-Related;
- Organizational and cultural factors.

Any taxonomy that is chosen must include human, technology and organizational considerations.

Adopting a clear HOF categorization will support a common understanding within the regulatory body and with other key organizations, including its technical support organizations and its licensees. This categorization will facilitate constructive and professional liaisons and discussions as well as oversight of HOF.

Expectations and influence of external stakeholders (Public, Market, etc.) could affect the performance of the individual and overall organization, including through the organizational culture. In this respect, it was recalled the approach to regulate safety influences the organizational culture of the licensee and the way it is considered the HOF to support good performance. The regulatory body should in this respect establish constructive and professional liaison with its licensees in order to achieve their common objectives in ensuring safety and to foster mutual understanding on HOF and how to improve their contribution to safety.

The regulatory body should develop a strategy for overseeing HOF in performing its regulatory functions and in accordance with the graded approach. A proper balance between promotion and regulatory enforcement action in the area of HOF should be sought.

One key element of this strategy should be to strongly encourage or if necessary to require the licensee to establish, implement and continuously improve a HOF programme. The regulatory body should review this programme to evaluate its relevance and inspect its actual implementation. The continuous improvement of this programme should be part of the constructive dialogue between the regulatory body and the licensee.

The regulatory body should develop regulations and guides in line with the national legislation to ensure proper HOF oversight. Special care should be taken when developing regulations and guides to ensure that gaps and inconsistencies related to HOF are addressed.

The regulatory body should ensure that its resources, including human and knowledge resources, are sufficient to implement its strategy to oversee HOF. The regulatory body should firstly develop and then strengthen its competence on HOF and should strive to acquire relevant expertise in this area. In this respect, inspection on HOF should be carried out by inspectors having the adequate level of competence. Support from the IAEA will be welcomed to contribute to train the regulatory body staff.

The regulatory body should review relevant event reports using a systemic approach to ensure HOF-related root causes have been properly identified and addressed by the licensee. The results of the event report review should be also considered when conducting periodically the integrated review as described below and required the IAEA Safety Standard GSR Part 1 under the requirements 25 and 26 (Para 4.46.).

When exercising its regulatory functions, especially Inspection and Review & Assessment, the regulatory body should have a way to collect, organize and record HOF-related results. Those data should be periodically analysed in an integrated manner to identify trends and conclusions. Feedback information from this integrated analysis should be used as part of the constructive dialogue between the regulatory body and the licensee.

It is encouraged that the Member States use experiences from other organizations, at national or international level to assess HOF (checklists, questionnaires, simulators, mock-up exercises, inspection guides, etc.).

The regulatory oversight programme for HOF should cover changes and modifications: Organization, Engineering, Processes and Procedures, etc.

The regulatory body should strive to continuously enhance its strategy to oversee HOF and improve its regulatory oversight programme and processes. This can impact the legal and regulatory framework.

A key prerequisite for HOF oversight is senior managements' understanding of HOF and their importance for safety. It is crucial that the senior management to be strongly committed, to establish, promote and implement a strategy to develop and strengthen a regulatory oversight programme of HOF. This should be a shared opinion that HOF oversight should be conducted on continuous basis.

The participants underlined the importance of developing a common understanding and knowledge within the regulatory bodies. The education and training of the key staff should be a priority. Beyond the fact that will raise the competence and expertise of the regulatory body, that will help also the regulatory staff to understand the importance of HOF and the rationale why to work on HOF.

The regulatory body should identify, whether in regulations, legislation or in other documentation, the means and provisions related to HOF. That information may be scattered in several documents and should be identified to allow a more integrated approach for HOF oversight and also to determine the missing elements to be addressed.

Tools should be prepared with the support of competent staff and involvement of the users to assist them to look at HOF area in an efficient way. For example, there could be a need to develop check-lists, template or other aids for assisting the inspectors to identify findings and collect relevant data.

As a first step to actually oversee HOF, the regulatory body should interact with the licensee to develop a common understanding on HOF and on the strategy of the regulatory body for overseeing HOF. The discussion with the licensee should be conducted at different levels in the organization. A common understanding with the licensee can also be achieved through the participation in a joint training courses, conferences, technical meetings, etc.

The participants strongly felt that the development of an IAEA publication on Regulatory oversight of HOF should be a priority and that training courses should be provided to Member States. It is recommended that review missions also cover HOF oversight strategies.