ANALYSIS OF IRRS MISSIONS TO MEMBER STATES OF THE EUROPEAN UNION

2015 – 2019
Analysis of the Integrated Regulatory Review Service (IRRS) missions conducted from 2015 to 2019 to member states of the European Union

Vienna, August 2020
Executive summary

This report provides an analysis of the Integrated Regulatory Review Service (IRRS) missions conducted from 2015 to 2019 to member states of the European Union. During this period, the Agency conducted 14 initial missions and 14 follow-up missions to 25 European Union member states. Member states and the IAEA Secretariat can use this report to identify trends and issues that affect regulatory bodies around the world.

The observations arising from an IRRS mission are categorized as:

- **Recommendations**: which reflect non-compliance with a requirement from the IAEA Safety Standards;
- **Suggestions**: which identify opportunities for improvement;
- **Good Practices**: which identify regulatory practices superior to those observed elsewhere.

The analysis is divided into two. First, mission Recommendations, Suggestions and Good Practices are analyzed according to the references to the IAEA Safety Standards. Then, the Recommendations, Suggestions and Good Practices are analyzed according to a set of subject groups.

Almost 40% of the references for Recommendations and Suggestions are to *GSR Part 1 (Rev. 1)* Governmental, Legal and Regulatory Framework for Safety. *GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* accounts for just over 20% of the references with *GSR Part 2 Leadership and Management for Safety, GSR Part 7 Preparedness and Response for a Nuclear or Radiological Emergency* and various Safety Guides each accounting for about 10% of the references.

The ten most frequently referenced IAEA Safety Requirements for Recommendations and Suggestions are:

- *GSR Part 1 (Rev. 1)* Requirement 18: Staffing and competence of the regulatory body;
- *GSR Part 1 (Rev. 1)* Requirement 24: Demonstration of safety for the authorization of facilities and activities;
- *GSR Part 1 (Rev. 1)* Requirement 2: Establishment of a framework for safety;
- *GSR Part 1 (Rev. 1)* Requirement 33: Review of regulations and guides;
- *GSR Part 1 (Rev. 1)* Requirement 4: Independence of the regulatory body;
- *GSR Part 7* Requirement 2: Roles and responsibilities in emergency preparedness and response.

For Good Practices, *GSR Part 1 (Rev. 1)* accounted for the most references. However, many IRRS missions identified at least one Good Practice related to *GSR Part 2, GSR Part 3* and *GSR Part 7* requirements. The following requirements are referenced more than once for a Good Practice:

- *GSR Part 1 (Rev. 1)* Requirement 2: Establishment of a framework for safety;
- *GSR Part 1 (Rev. 1)* Requirement 14: International obligations and arrangements for international cooperation and assistance;
- *GSR Part 2* Requirement 2: Demonstration of leadership for safety by managers;
- *GSR Part 2* Requirement 9: Provision of resources;
- *GSR Part 3* Requirement 37: Justification of medical exposures;

For the analysis by subject group, each IRRS Recommendation, Suggestion and Good Practice was assigned to one of 58 subject groups. The subject groups that have more Recommendations or Suggestions should receive further attention, as this may indicate that a number of member states face similar challenges.
The subject groups with the highest number of Recommendations and Suggestions were:

- Radiation safety regulations and guides;
- Emergency planning;
- Framework for safety;
- Establishment of the regulatory body management system;
- Regulatory body staffing and competence;
- Development of authorization process;
- Development of inspection programme;
- Implementation of authorization process;
- Regulations and guides for spent fuel and radioactive waste management;
- Decommissioning and management of radioactive waste and spent fuel;
- Coordination and cooperation among authorities.

Regarding the topic of processes, procedures and guidance, these observations were broken out in the various modules for authorization, review and assessment, inspection, enforcement and emergency preparedness and response. Taken together, however, they account for 25 Recommendations and 20 Suggestions, making the topic of procedures and guidance the third most frequent observation.

Not all member states have requested a follow-up mission, where peer reviewers determine if Recommendations and Suggestions can be closed or remain open. For those member states that have hosted a follow-up mission, the closure rate for Recommendations and Suggestions directed to member state governments is 85%, while the closure rate for Recommendations and Suggestions directed to the regulatory body is 86%.

New Recommendations, Suggestions and Good Practices are also normally included in follow-up missions, with almost 45% of these referencing a requirement in *GSR Part 1 (Rev. 1)*. *GSR Part 7* accounts for 18% of the references, various Safety Guides for 13%, *GSR Part 2* for 11% and *GSR Part 3* for 8% of the references.

Every IRRS mission where the topic was within the scope of the mission made a Recommendation or Suggestion related to:

- Enhancing arrangements for effective coordination and cooperation between various regulatory authorities;
- Developing, maintaining or enhancing the regulatory body long-term human resource plan to ensure the availability and competence of staff;
- Establishing, implementing or updating the regulatory body management system;
- Developing or enhancing the regulatory body inspection programme;
- Bringing regulations and guides for occupational exposures and medical exposure into line with *GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*;
- Emergency planning.

Many missions made a Recommendation or Suggestion related to:

- Establishing or updating the national policy and strategy for safety;
- Updating the legal framework to be consistent with the IAEA Safety Standards;
- Having provisions in place to ensure the effective independence of the regulatory body;
- Establishing and implementing a national policy and strategy for decommissioning and radioactive waste management;
- Strengthening the process for reporting and reviewing events and identifying lessons to be learned;
- Formally recognizing qualified experts for radiation protection and for medical physicists;
• Developing or updating regulations and guides related to the safety of radioactive waste management;
• Developing or updating regulations and guides related to emergency preparedness and response.
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1 Introduction

1.1 The Integrated Regulatory Review Service

In 2006, the Agency introduced the Integrated Regulatory Review Service (IRRS), which replaced the former IRRT\(^1\) and RaSSIA\(^2\) review services. IRRS covers also the regulatory aspects of EPREV\(^3\) and TranSAS\(^4\) services. To the end of 2019, the Agency had conducted 113 IRRS missions (including both initial and follow-up missions) to 66 Member States. From 2015 to 2019, the Agency conducted 28 missions, including 14 initial missions and 14 follow-up missions, to 25 EU member states.

1.2 Objective and scope

This report summarizes the analysis of the 28 IRRS missions conducted to member states of the European Union (EU) from 2015 to 2019. By identifying which IAEA safety requirements are most frequently referenced, member states and the Agency can focus efforts on those requirements to further enhance nuclear and radiological safety. By categorizing the IRRS observations into subjects, again member states can self-assess their programme and identify opportunities for improvement. The Agency can use the analysis to identify topics for future workshops, training sessions and technical documents.

Although all IRRS review missions cover key aspects of the regulatory programme in a Member State, the modular nature of the IRRS service allows Member States to specify the scope of the review. In many cases, the Member State requests a review of the entire regulatory programme, while in some cases, the Member State requested that the IRRS review focus on a limited number of facilities, activities and exposure situations. The result is that IRRS missions vary substantially in their scope, based both on the nuclear and radiological facilities and activities in the Member State and the decision by the Member State on what facilities and activities and exposure situations to include in the scope.

This analysis includes data from 28 IRRS missions, which is sufficient to draw meaningful conclusions on general characteristics. However, individual mission data vary substantially, due to:

- Scope and size of the mission;
- Composition, expertise and size of the team;
- Working methods of the team leader and members;
- Nuclear and radiological activities in the member state;
- Evolution of the IRRS process over time.

1.3 Structure of the report

Chapter 2 provides the background to the IRRS and the nature of the analysis. Chapter 3 is the analysis of the Recommendations and Suggestions references to the IAEA Safety Standards. Chapter 4 is the analysis of the Good Practices references to the IAEA Safety Standards. Chapter 5 is the analysis of the observations by subject group. Chapter 6 looks at those sub-modules of the IRRS where there were no Recommendations or Suggestions. Chapter 7 is the analysis of information from follow-up missions. Chapter 8 provides some details on IRRS observations regarding the regulation of operating nuclear power plants. Chapter 9 provides some details on IRRS observations regarding the regulation of radioactive sources. Chapter 10 identifies the main issues facing regulatory bodies and provides a conclusion.

\(^1\) IRRT: International Regulatory Review Team
\(^2\) RaSSIA: Radiation Safety and Security Infrastructure Appraisal
\(^3\) EPREV: Emergency Preparedness Review
\(^4\) TranSAS: Transport Safety Appraisal Service
1.4 Missions analyzed

This analysis covers 14 initial and 14 follow-up IRRS missions to 25 European Union member states. Figure 1 shows the year and location of the IRRS missions conducted. Follow-up missions are denoted by (f). A total of 264 peer reviewers were involved in these missions.

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Figure 1 IRRS Missions to member states of the European Union from 2015 to 2019

1.5 Scope of initial missions

Figure 2 shows, for the 14 initial IRRS missions, how many included the various topics in the scope of the mission. Note that all missions included occupational exposure and all but two missions included industrial and medical radioactive sources and emergency preparedness and response.

![Figure 2 Activities covered in scope of initial missions](image-url)
2 Background

2.1 Structure of the IRRS

The Agency established the IRRS to strengthen and enhance the effectiveness of national regulatory infrastructures for nuclear, radiation, radioactive waste and transport safety while recognizing the ultimate responsibility of each Member State to ensure safety. Using the IAEA Safety Standards, the IRRS considers both regulatory technical and regulatory policy issues.

As Figure 3 shows, the IRRS has a modular structure designed to be tailored to both generic and Member State specific needs and to facilitate the review of circumstances where the scope of regulatory responsibility may be changing.

Figure 3 Modular structure of the IRRS
Note that the modular structure of IRRS changed in 2018 as described in the new IRRS Guidelines, published in December 2018. Thematic Areas related to exposure situations, covered previously by Module 11, were reallocated to Modules 1 to 10 as appropriate. Module 12 became Module 11 and Tailored module for Countries Embarking in Nuclear Power Programme became Module 12. Consequently, observations from Module 11 made during missions based on the former modular structure of IRRS, have been reallocated to Modules 1-10 as appropriate.

The observations arising from an IRRS mission are categorized as:

- **Recommendations**: which reflect non-compliance with a requirement from the IAEA Safety Standards;
- **Suggestions**: which identify opportunities for improvement;
- **Good Practices**: which identify regulatory practices superior to those observed elsewhere.

To review the progress in the implementation of the Recommendations and Suggestions from the IRRS mission, the Agency recommends that a follow-up mission takes place two to four years after the initial mission. The follow-up mission will rate each Recommendation and Suggestion as either closed or open. The follow-up mission will typically also identify further observations, resulting in new Recommendations, Suggestions or Good Practices.

In September 2019, the Agency clarified that the following three criteria must all be met in order for a practice to be considered a Good Practice:

- Outstanding performance, going beyond what is required;
- Unique performance, not generally observed elsewhere;
- Replicable by other Member States, as a model in the general drive for excellence.

Based on the requirement that all three criteria be met, it is expected that future IRRS missions will identify fewer Good Practices.

## 2.2 Relationship between IRRS and the IAEA Safety Standards

The IAEA Safety Standards provide the basis for all of the Agency’s safety related services, including the IRRS. For the IRRS, the main safety standards used for the 2015 to 2019 missions are:

- **GSR Part 1 (Rev. 1)**: Governmental, Legal and Regulatory Framework for Safety;
- **GSR Part 2**: Leadership and Management for Safety;
- **GSR Part 3**: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards;
- **GSR Part 7**: Preparedness and Response for a Nuclear or Radiological Emergency.

In addition to these four main IAEA Safety Standards, IRRS missions frequently reference other IAEA Safety Standards. The Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance may complement IAEA Safety Standards as a basis for the peer review.

**GSR Part 1** comprises 36 overarching requirements on the governmental, legal and regulatory framework for safety. The 36 requirements form the basis for the IRRS as shown in Table 1.

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5 IAEA Services Series 37 - *Integrated Regulatory Review Service Guidelines*, Vienna, December 2018

6 For ease of reading, whenever GSR Part 1 is written, the (Rev. 1) is omitted, but should be inferred
### Table 1 Modules and the associated safety requirements of the IRRS

<table>
<thead>
<tr>
<th>Module No</th>
<th>Overarching Requirement</th>
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<tbody>
<tr>
<td>1</td>
<td>GSR Part 1 (Rev. 1)</td>
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<td>R1</td>
<td>National policy and strategy</td>
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<td>R2</td>
<td>Establishment of a framework for safety</td>
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<td>R3</td>
<td>Establishment of a regulatory body</td>
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<td>R4</td>
<td>Independence of the regulatory body</td>
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<td>R5</td>
<td>Prime responsibility for safety</td>
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<td>R6</td>
<td>Compliance with regulations and responsibility for safety</td>
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<td>R7</td>
<td>Coordination of different authorities with responsibilities for safety within the regulatory framework for safety</td>
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<td>R9</td>
<td>System for protective actions to reduce existing or unregulated radiation risks</td>
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<td>R10</td>
<td>Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel</td>
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<td>R11</td>
<td>Competence for safety</td>
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<td>R13</td>
<td>Provision of technical services</td>
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<td>2</td>
<td>R14: International obligations and arrangements for international cooperation</td>
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<td>R15: Sharing of operating experience and regulatory experience</td>
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<td>3</td>
<td>R16: Organizational structure of the regulatory body and allocation of resources</td>
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<td>R17: Effective independence in the performance of regulatory functions</td>
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<td>R18: Staffing and competence of the regulatory body</td>
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<td>R20: Liaison with advisory bodies and support organizations</td>
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<td></td>
<td>R21: Liaison between the regulatory body and authorized parties</td>
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<td>R22: Stability and consistency of regulatory control</td>
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<td>R35: Safety related records</td>
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<td>R36: Communication and consultation with interested parties</td>
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<td>R19: The management system of the regulatory body</td>
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<td>5</td>
<td>R23: Authorization of facilities and activities by the regulatory body</td>
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<td>R24: Demonstration of safety for the authorization of facilities and activities</td>
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<td>R25: Review and assessment of information relevant to safety</td>
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<td>R26: Graded approach to review and assessment of a facility or an activity</td>
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<td>R28: Types of inspection of facilities and activities</td>
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<td>R31: Requiring of corrective action by authorized parties</td>
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<td>R8: Emergency preparedness and response</td>
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<td>R12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material</td>
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<td>12</td>
<td>Module on issues related to countries embarking in nuclear power</td>
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### 2.3 GSR Part 2 versus GS-R-3

The IRRS missions before 2016 were based on IAEA Safety Standard GS-R-3: *The Management System for Facilities and Activities*, published in 2006. This was superseded in 2016 by GSR Part 2: *Leadership and Management for Safety*. To be able to make valid statements on the references and observations of all missions, references to GS-R-3 were converted to their equivalent in GSR Part 2.

### 2.4 GSR Part 7 versus GS-R-2

The IRRS missions before 2016 were based on IAEA Safety Standard GS-R-2: *Preparedness and Response for a Nuclear or Radiological Emergency*, published in 2002. This was superseded in 2015 by GSR Part 7: *Preparedness and Response for a Nuclear or Radiological Emergency*. Although the main principles and requirements of the two documents are the same, they differ both in structure and format. To be able to make valid statements on the references and observations of all missions, references to GS-R-2 were converted to their equivalent in GSR Part 7.
2.5 Basis for the analysis of findings to the IAEA Safety Standards

The purpose of the IRRS is to assess the host Member State national regulatory infrastructure against the relevant IAEA Safety Standards through a peer review. Thus, the Recommendations, Suggestions and Good Practices identified during a mission are based on IAEA Safety Standards that are clearly documented in the mission report. Any IAEA Safety Requirement may form the basis for a Recommendation, Suggestion or Good Practice. Figure 4 shows how the IRRS mission report identifies the basis for Recommendations, Suggestions and Good Practices.

![Examples of IAEA Safety Standard requirements as bases for observations](image)

Each time a particular requirement from an IAEA Safety Standard was used as a basis for an observation was counted as a reference to that requirement. If two separate requirements from the same IAEA Safety Standard were cited as the basis for a particular Recommendation or Suggestion, then that would count as two references to that IAEA Safety Standard.

However, if a requirement was cited more than once for the same Recommendation or Suggestion, then that would count as a single reference.

---

7 The Code of Conduct on the Safety and Security of Radioactive Sources and its supplementary Guidance may complement IAEA Safety Standards as a peer review basis.

8 The Code of Conduct on the Safety of Research Reactors may complement IAEA Safety Standards as a peer review basis.
3 Analysis of Recommendation and Suggestion references to the IAEA Safety Standards

3.1 General references to IAEA Safety Standards

Overall during the reporting period, IAEA Safety Standards were referenced 1111 times in IRRS Recommendations and Suggestions. In average, IRRS observations had less than 2 IAEA Safety Standards as references.

As Figure 5 shows, just almost 40% of the references are to GSR Part 1. GSR Part 3 accounts for just over 20% of the references, with GSR Part 2, GSR Part 7 and various IAEA Safety Guides accounting for around 10% each.

Referring again to Figure 5, for the General Safety Requirements (GSR) and Specific Safety Requirements (SSR) documents, the references are predominantly related to Recommendations, while for the Safety Guides, the references are predominantly related to Suggestions. This is as expected, since Recommendations are only issued where there is non-compliance with an IAEA Safety Requirement. Guidance documents identify approaches for achieving the Safety Requirements but do not introduce new Safety Requirements. In every case where an IAEA Safety Guide is used as a basis for a Recommendation, there is also an IAEA Safety Requirements document as a basis.

The information presented in Sections Error! Reference source not found. to Error! Reference source not found. provides useful insights to Member States on which requirements of GSR Part 1, GSR Part 2, GSR Part 3 and GSR Part 7 they should focus upon when developing or revising their national regulatory infrastructure.
3.2 References to GSR Part 1: Governmental, Legal and Regulatory Infrastructure for Safety

As Figure 6 shows, every requirement in GSR Part 1 was referenced by at least one Recommendation or Suggestion during the reporting period, with the references for Recommendations usually outnumbering the references for Suggestions for a given requirement.

Figure 6 also shows that the following requirements were referenced most frequently:

- Requirement 18: Staffing and competence of the regulatory body (30 references);
- Requirement 24: Demonstration of safety for the authorization of facilities and activities (28 references);
- Requirement 2: Establishment of a framework for safety (23 references);
- Requirement 33: Review of regulations and guides (23 references);
- Requirement 4: Independence of the regulatory body (21 references).

The following requirements were referenced only once or twice during the reporting period:

- Requirement 8: Emergency preparedness and response (one reference);
- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material (one reference);
- Requirement 5: Prime responsibility for safety (two references);
- Requirement 13: Provision of technical services (two references);
- Requirement 21: Liaison between the regulatory body and authorized parties (two references).
3.3 References to GSR Part 2: Leadership and Management for Safety

As shown in Figure 7, the four most common GSR Part 2 requirements referenced are:
- Requirement 10: Management of processes and activities (17 references);
- Requirement 6: Integration of the management system (14 references);
- Requirement 3: Responsibility of senior management for the management system (10 references);
- Requirement 13: Measurement, assessment and improvement of the management system (10 references).

Figure 7 also shows that two GSR Part 2 requirements were not referenced during the reporting period:
- Requirement 1: Achieving the fundamental safety objective;
- Requirement 11: Management of the supply chain.
3.4 References to GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

The second most frequently referenced requirements document was GSR Part 3. As Figure 8 shows, almost 80% of the references to GSR Part 3 were for Recommendations.

Figure 8 References to GSR Part 3

Figure 8 shows that the following GSR Part 3 requirements are referenced most frequently:

- Requirement 36: Responsibilities of registrants and licensees specific to medical exposure (15 references);
- Requirement 38: Optimization of protection and safety for medical exposure (13 references);
- Requirement 34: Responsibilities of the government specific to medical exposure (12 references);
- Requirement 8: Exemption and clearance (12 references);
- Requirement 32: Monitoring and reporting for public exposure (12 references).

The following GSR Part 3 requirements are not referenced in any mission:

- Requirement 1: Application of the principles of radiation protection;
- Requirement 9: Responsibilities of registrants and licensees in planned exposure situations;
- Requirement 15: Prevention and mitigation of accidents;
- Requirement 16: Investigations and feedback of information on operating experience;
- Requirement 17: Radiation generators and radioactive sources.
3.5 References to GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency

Another frequently referenced standard in IRRS mission Recommendations and Suggestions was *GSR Part 7*.

![Figure 9 References to GSR Part 7](image)

As shown in Figure 9, the most frequently referenced requirements are:

- Requirement 2: Roles and responsibilities in emergency preparedness and response (21 references);
- Requirement 25: Training, drills and exercises for emergency preparedness and response (13 references);
- Requirement 4: Hazard assessment (eight references);
- Requirement 7: Identifying and notifying a nuclear or radiological emergency and activating an emergency response (eight references);
- Requirement 9: Taking urgent protective measures and other response actions (eight references);
- Requirement 18: Terminating a nuclear or radiological emergency (eight references).

There were also a large number of Recommendation references to Requirement 26: Quality management programme for emergency preparedness and response.

Figure 9 also shows that the following requirements were not referenced in any IRRS mission:

- Requirement 1: The emergency management system;
- Requirement 3: Responsibilities of international organizations in emergency preparedness and response;
- Requirement 10: Providing instructions, warnings and relevant information to the public;
- Requirement 16: Mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response;
- Requirement 17: Requesting, providing and receiving international assistance for emergency preparedness and response.
4 Analysis of Good Practice references to the IAEA Safety Standards

4.1 Overall references to Good Practices

Another objective of the IRRS is to share Good Practices among regulatory bodies. Many IRRS initial missions identified at least one Good Practice. Figure 10 shows the references related to Good Practices.

![Graph showing references to Good Practices by IAEA Safety Standards]

Figure 10 Overall references for Good Practices

GSR Part 1 and GSR Part 7 each accounted for almost 30% of the references for Good Practices. For GSR Part 1 and GSR Part 3, the ratio of Good Practices to Recommendations and Suggestions was around 1:30, while for GSR Part 2, the ratio was around 1:20, and for GSR Part 7, the ratio was around 1:8.

It is important to note that, in September 2019, the IAEA clarified the criteria for identifying good practices during an IRRS mission, in establishing an ad hoc policy. To be considered a Good Practice, a commendable practice must meet three criteria presented in Section 2.1. The number of good practices is expected to be significantly reduced in the future.
4.2 Good Practice references to GSR Part 1

![Graph showing Good Practice references to GSR Part 1]

Figure 11 Good Practice references to GSR Part 1

Figure 11 shows that 10 of the 36 GSR Part 1 Requirements were referenced for a Good Practice during the reporting period.

The following GSR Part 1 Requirements were referenced for a Good Practice during the reporting period:

- Requirement 2: Establishment of a framework for safety;
- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material;
- Requirement 14: International obligations and arrangements for international cooperation and assistance;
- Requirement 16: Organizational structure of the regulatory body and allocation of resources;
- Requirement 18: Staffing and competence of the regulatory body;
- Requirement 19: The management system of the regulatory body;
- Requirement 23: Authorization of facilities and activities by the regulatory body;
- Requirement 24: Demonstration of safety for the authorization of facilities and activities;
- Requirement 26: Graded approach to review and assessment of a facility or an activity;
- Requirement 34: Review of regulations and guides.
Figure 12 Recommendation and Suggestion vs. Good Practice references for GSR Part 1

Figure 12 shows that, with one exception, the number of references to a requirement for Good Practices is a small fraction of those references for Recommendations and Suggestions combined.

The exception is for Requirement 14: International obligations and arrangements for international cooperation, where the number of references to Good Practices almost one half of the number of Recommendations and Suggestions combined.

4.3 Good Practice references to GSR Part 2

Figure 13 shows that the following GSR Part 2 requirements are referenced for a Good Practice:

- Requirement 2: Demonstration of leadership for safety by managers;
- Requirement 9: Provision of resources;
- Requirement 13: Measurement, assessment and improvement of the management system.
Referring to Figure 14, it is seen that for the number of references to a Good Practice is a fraction of the number of references to a Recommendation or Suggestion.

The following GSR Part 2 requirements were not referenced in any IRRS mission during the reporting period:

- Requirement 1: Achieving the fundamental safety objective;
- Requirement 11: Management of the supply chain.

### 4.4 Good Practice references to GSR Part 3

Figure 15 shows that the following GSR Part 3 requirements were referenced for a Good Practice:

- Requirement 2: Establishment of a legal and regulatory framework;
- Requirement 3: Responsibilities of the regulatory body;
- Requirement 4: Responsibilities for protection and safety;
- Requirement 31: Radioactive waste and discharges;
- Requirement 37: Justification of medical exposures;
- Requirement 47: Responsibilities of the government specific to existing exposure.

![Figure 14: Recommendation & Suggestion vs. Good Practice references to GSR Part 2](image)

![Figure 15: Good Practice references to GSR Part 3](image)
situations:

- Requirement 50: Public exposure due to radon indoors.

Figure 16 Recommendation and Suggestion vs. Good Practice references to GSR Part 3

Referring to Figure 16, it is seen that the number of references to a Good Practice is a small fraction of the number of references to a Recommendation or Suggestion.

Four GSR Part 3 requirements, namely:

- Requirement 9: Responsibilities of registrants and licensees in planned exposure situations;
- Requirement 15: Prevention and mitigation of accidents;
- Requirement 16: Investigations and feedback of information on operating experience;
- Requirement 17: Radiation generators and radioactive sources;

were not referenced in any mission during the reporting period. The essential elements of requirements 15 and 16 are covered by requirements in other IAEA Safety Standards.

4.5 Good practice references to GSR Part 7

Figure 17 Good Practice references to GSR Part 7
As Figure 17 shows, 11 GSR Part 7 requirements were referenced for a Good Practice. Only one GSR Part 7 requirement received more than one reference, namely:

- Requirement 22: Coordination of emergency preparedness and response.

![Figure 18 Recommendation & Suggestion vs. Good Practice references to GSR Part 7](image)

Referring to Figure 18, it is seen that the number of references to a Good Practice is typically a small fraction of the number of references to a Recommendation or Suggestion.

Two requirements are only referenced for a Good Practice:

- Requirement 1: The emergency management system;
- Requirement 10: Providing instructions, warnings and relevant information to the public for emergency preparedness.

Finally, two requirements:

- Requirement 16: Mitigating non-radiological consequences of a nuclear or radiological emergency and of an emergency response;
- Requirement 17: Requesting, providing and receiving international assistance for emergency preparedness and response;

were not referenced in any mission during the reporting period.

## 5 Analysis of observations by subject groups

### 5.1 Introduction

Another way of categorizing the observations from IRRS missions is to sort them according to the subject. The subjects that more frequently result in Recommendations and Suggestions should receive further consideration, as this may indicate that a number of Member States face similar challenges.

The subject groups do not have exact definitions; rather they comprise sufficient numbers of observations sharing the similar characteristics. Consequently, although a mission report may place a
Recommendation in a particular module, for the purpose of this analysis, observations may be allocated to another, more appropriate subject group in another module.

In 2018, the subject groups were redesigned to better reflect IRRS mission findings and to provide better alignment with the IAEA Safety Standards. The number of subject groups was reduced from 73 to 58. Findings for 2015 to 2017 IRRS missions have been reanalyzed and assigned a subject group from the new list. Annex A provides more information on the various subject groups.

Observations from Module 11 of 2015-2017 IRRS missions have been reallocated to Modules 1 to 10 as appropriate. Every observation from every IRRS mission is included in the analysis by subject groups.

In the following sections, the number of observations (Recommendations, Suggestions and Good Practices) for each module are tabulated, with those subject groups with the most observations highlighted.

The aim of the analyses presented in this Chapter is to provide direction to Member States seeking for compliance with the IAEA safety standards. The most frequent observations in each subject group highlight aspects to be specifically considered by Member States when reviewing their regulatory infrastructure.

5.2 Subject Groups related to responsibilities and functions of the government

There are nine subject groups related to the responsibilities and functions of the government:

a) **National policy and strategy for safety**: Stating government intent; achieving the fundamental safety objective; applying the fundamental safety principles; long-term commitment to safety; establishing scope for framework for safety.

b) **Framework for safety**: Up-to-date comprehensive national nuclear law, regulations, decrees and orders; establishment of regulatory body with sufficient legal authority and financial resources.

c) **Regulatory body independence**: Effectively independent in its decision-making; functional separation from entities that could unduly influence decision-making; access to highest levels of government; ability to liaise directly with other regulatory bodies and with international organizations; no conflicting responsibilities or conflicts of interest.

d) **Prime responsibility for safety**: Assigned to person or organization responsible for facility or activity; cannot be delegated; responsibility extends through entire life-cycle, including waste management.

e) **Coordination and cooperation among authorities**: Authorities clearly defined to avoid omissions, duplication and conflicting requirements.

f) **Protective actions for unregulated sources or contamination from past activities or events**: Consistent with justification and optimization principles; designation of organizations responsible; access to necessary resources; regulatory body inputs.

g) **Decommission and management of radioactive waste and spent fuel**: Provisions for decommissioning, management of radioactive waste and spent fuel; interim targets and end states; continuity of responsibility.

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9 Prior to 2018, Module 11 was optional and was related to areas such as: transport; control of medical exposures; occupational radiation protection; control of radioactive discharges and materials for clearance; environmental monitoring associated with authorized practices for public radiation protection purposes; control of chronic exposures and remediation. In 2018, these areas were reallocated to Modules 5 to 9. From 2018, Module 11 deals with Interfaces with Nuclear Security. The 2015-2017 observations associated with the previous Module 11 were reallocated as described in this report.
h) **Competence for safety**: Provisions for building and maintaining competence of all parties; technical training and learning; research and development; qualification and registration of experts.

i) **Provision of technical services**: Provision of technical services for safety (e.g. dosimetry, environmental monitoring, equipment calibration, etc.); authorization by regulatory body if necessary.

As Table 2 shows, a total of 125 observations were related to the responsibilities and functions of the government, the largest number for a module, including 35 observations for framework for safety.

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a National policy and strategy for safety</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1b Framework for safety</td>
<td>28</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>1c Regulatory body independence</td>
<td>7</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>1d Prime responsibility for safety</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>1e Coordination and cooperation among authorities</td>
<td>5</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>1f Protective actions for unregulated sources or contamination from past</td>
<td>7</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>1g Decommissioning and management of radioactive waste and spent fuel</td>
<td>10</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>1h Competence for safety</td>
<td>6</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>1i Provision of technical services</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td><strong>Σ Sum of observations</strong></td>
<td><strong>81</strong></td>
<td><strong>39</strong></td>
<td><strong>5</strong></td>
</tr>
</tbody>
</table>

5.2.1 Highlights of Recommendations and Suggestions

5.2.1.1 National policy and strategy for safety

Most missions made a Recommendation to establish or update the national policy and strategy for safety in line with *GSR Part 1*.

A few missions made a Recommendation or Suggestion that the policy and strategy include and apply to all nuclear and radiological facilities and activities in the member state, including decommissioning, waste management and the transport of radioactive material.

5.2.1.2 Framework for safety

Most missions made a Recommendation or Suggestion that the legal framework be updated to be consistent with the IAEA Safety Standards.

Some missions made a Recommendation or Suggestion that the control of medical exposures be updated to be consistent with *GSR Part 3*.

A few missions made a Recommendation that the legal framework establish an independent regulatory body.

5.2.1.3 Regulatory body independence

Most missions made a Recommendation or Suggestion that provisions be in place to ensure that the regulatory body is effectively separate from entities having responsibilities or interests that could unduly influence its decision-making.
5.2.1.4 Prime responsibility for safety

Some missions made a Recommendation or Suggestion that legislation explicitly assign primary responsibility for safety to the persons or organizations responsible for facilities and activities.

Some missions made a Recommendation or Suggestion that provisions be in place such that authorized parties are responsible for verifying that products and services provided by contractors and suppliers meet expectations.

5.2.1.5 Coordination and cooperation among authorities

Every mission made a Recommendation or Suggestion that arrangements be enhanced for effective coordination and cooperation between authorities having regulatory responsibilities for nuclear and radiation safety with those responsible for nuclear security, transport safety, emergency preparedness and response and the medical application of radiation.

5.2.1.6 Protective actions for unregulated sources or contamination from past activities or events

Some missions made a Recommendation or Suggestion that the member state complete studies related to radon levels and their impact on the public and, if needed, implement an action plan for controlling public exposure due to radon indoors.

A few missions made a Recommendation or Suggestion that organizations taking actions to recover and manage orphan sources have access to adequate funding and resources.

Two missions made a Recommendation or Suggestion that the member state establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources and contamination from past activities or events and develop a legal safety framework for existing exposure situations.

5.2.1.7 Decommissioning and management of radioactive waste and spent fuel

Most missions made a Recommendation or Suggestion that the member state establish and implement a national policy and strategy for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel.

A few missions made a Recommendation or Suggestion that the member state ensure adequate funding for the safe decommissioning of facilities and the safe disposal of radioactive waste.

5.2.1.8 Competence for safety

Many missions made a Recommendation or Suggestion that the member state have provisions to ensure the competence of all parties having responsibilities for the safety of facilities and activities.

5.2.1.9 Provision of technical services

A few missions made a Recommendation or Suggestion that technical services with significance for safety be qualified and authorized.

A few missions made a Recommendation or Suggestion that the member state ensure that the appropriate dosimetry services are available.
5.2.1.10 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The effectiveness of the national radon control strategy is maximized through this “top down” approach driven by Government, ensuring all stakeholders work together in a cohesive manner;
- The regulatory body’s prompt and integrated approach to establish a consistent and comprehensive regulation taking into account international standards and good practices;
- The systematic cooperation between the regulatory body and the police significantly supports the implementation of an integrated approach to safety and security of radiation sources;
- A research project on patient radiation protection and clinical audits in new diagnostic and therapeutic technologies including topics on justification and referral criteria.

5.3 Subject groups related to Global Nuclear Safety Regime

There are three subject groups related to the Global Nuclear Safety Regime:

a) *International obligations and arrangements for international assistance and cooperation:* Fulfilling international obligations; participating in international arrangements and peer reviews; promoting international cooperation and assistance.

b) *Bilateral and multilateral arrangements:* Ensuring bilateral and multilateral arrangements are in place; import/export requirements for radioactive sources.

c) *Operating and regulatory experience:* Analysis to identify lessons to be learned; dissemination of lessons learned to authorized parties, RB and other relevant authorities; use of lessons learned; means for receiving international operating and regulatory experience; making available operating and regulatory experience to international knowledge and reporting networks.

Table 3 shows that 20 observations were related to the Global Nuclear Safety Regime, with more than half related to operating and regulatory experience.

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
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</thead>
<tbody>
<tr>
<td>2a International obligations and arrangements for international assistance and cooperation</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>2b Bilateral and multilateral arrangements</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2c Operating and regulatory experience</td>
<td>8</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>10</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>

5.3.1 Highlights of Recommendations and Suggestions

5.3.1.1 *International obligations and arrangements for international assistance and cooperation*

A few missions made a Recommendation or Suggestion that the member state makes resources available to enable active participation in international safety cooperation activities.
5.3.1.2 Bilateral and multilateral arrangements

There were no Recommendations or Suggestions made regarding bilateral and multilateral arrangements.

5.3.1.3 Operating and regulatory experience

Most missions made a Recommendation or Suggestion to establish or strengthen the formal process for reporting and reviewing events and identifying lessons to be learned. The process should include events at both in the member state and internationally.

Some missions made a Recommendation or Suggestion that operating and regulatory experience feedback is disseminated to authorized parties, the regulatory body and other relevant national and international authorities.

5.3.2 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The member state is actively engaged in international cooperation; including international arrangements, peer reviews and international support programmes;
- Active participation in many international activities related to nuclear safety shows how small non-nuclear countries can contribute to enhance global safety regime.

5.4 Subject groups related to responsibilities and functions of the regulatory body

There are six subject groups related to the responsibilities and functions of the regulatory body:

a) Organization of the regulatory body and allocation of resources: Organizational structure; allocation of resources commensurate with radiation risks.

b) Regulatory body staffing and competence: Sufficient numbers of qualified and competent staff; human resources planning; training programme; knowledge management process.

c) External involvement in the regulatory process: Advisory committees; technical support organizations; policy for seeking external expert advice; retaining regulatory responsibility; arrangements with vendors, contractors and suppliers.

d) Stability and consistency of regulatory control: Formal regulatory process; prevention of subjectivity in decision-making; careful scrutiny of proposed changes in regulatory requirements.

e) Safety related records: Establishing, maintaining and retrieving adequate safety records; registers of sealed radioactive sources and radiation generators; occupational dose records; records related to facilities and activities.

f) Communication and consultation with interested parties: Informing and consulting interested parties on risks associated with facilities and activities; informing and consulting interested parties on regulatory processes, judgements and decisions; provisions for effective communications.

As seen in Table 4, there were 78 observations related to the responsibilities and functions of the regulatory body. The subject groups most frequently identified were:

- Regulatory body staffing and competence;
- Communication and consultation with interested parties.
Table 4 Number of observations by subject group for regulatory body responsibilities and functions

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a Organization of the regulatory body and allocation of resources</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>19</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>3c External involvement in the regulatory process</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3d Stability and consistency of regulatory control</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3e Safety related records</td>
<td>6</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>3f Communication and consultation with interested parties</td>
<td>8</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>44</td>
<td>27</td>
<td>7</td>
</tr>
</tbody>
</table>

5.4.1 Highlights of Recommendations and Suggestions

5.4.1.1 Organization of regulatory body and allocation of resources

Some missions made a Recommendation or Suggestion that the regulatory body have the authority to organize as it sees fit and allocate its resources accordingly.

A few missions made a Recommendation or Suggestion that the regulatory body prioritize its tasks and allocate and manage resources using a graded approach.

5.4.1.2 Regulatory body staffing and competence

Every mission made a Recommendation or Suggestion that the regulatory body develop, maintain or enhance a long-term human resource plan to ensure the availability and competence of staff.

Some missions made a Recommendation or Suggestion that the regulatory body create or implement comprehensive trainings plans for its staff.

5.4.1.3 External involvement in the regulatory process

Two missions made a Recommendation or Suggestion that the regulatory body consult and communicate with interested parties, including the public, on regulatory judgements and decisions.

5.4.1.4 Stability and consistency of regulatory control

A few missions made a Recommendation or Suggestion that the regulatory body implement processes that follow specified procedures to ensure the stability and consistency of regulatory control and to prevent subjectivity in decision-making.

5.4.1.5 Safety related records

A few missions made a Recommendation or Suggestion that the regulatory body enhance its record-keeping system.

A few missions made a Recommendation or Suggestion that the member state establish or enhance a national register of sealed sources and radiation generators.

5.4.1.6 Communication and consultation with interested parties

Some missions made a Recommendation or Suggestion that the regulatory body define a strategy for communication and consultation with the public, the media and other interested parties on radiation risks associated with facilities and activities, and on the implementation of its regulatory functions.
A few missions made a Recommendation or Suggestion that the public be informed of doses from nuclear and radiological facilities and activities.

### 5.4.2 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The regulatory body has developed its matrix management structure that effectively allocates resources to need. It has also improved its hiring, training and strategic planning practices so as to develop new hires and to effectively anticipate and fill future needs;
- All regulatory body employees are included in systematic planning and follow up of training. The dissemination of information of the lessons learned in international courses and seminars, and the self-assessment of the usefulness of received training is an integral part of the management of training;
- The regulatory body has a system, implemented annually, for establishing and addressing the competence and training needs among its staff aimed at improving their contribution to achievement of organizational goals;
- The development, maintenance and use of a comprehensive web-based database goes beyond the collection of standard transport data by providing additional safety related data and corresponding analysis tools necessary to perform dose assessments due to transport, to identify non-compliances and to support the provincial emergency preparedness and planning;
- The regulatory body’s transport database goes beyond the normal scope of databases used in transport by linking together information applicable to different areas of the compliance assurance programme like inspection results, approval certificates, fabricated and used packaging, non-compliances, events during transport which are available for all consignors and carriers in the member state. It provides an excellent tool for the competent authority to improve and facilitate the implementation of its compliance assurance programme.

### 5.5 Module 4: Regulatory body management system

There are four subject groups related to the management system of the regulatory body:

a) **Establishment of the regulatory body management system**: Alignment with safety goals; open and transparent processes; coherence.

b) **Implementation of the regulatory body management system**: Implemented as designed; contributes to achieving safety goals; maintains efficiency and effectiveness.

c) **Assessment and review of the regulatory body management system**: Continuous assessment; self-assessments; independent assessments; audits; review methodology.

d) **Safety culture of the regulatory body**: Fostering and supporting safety culture; developing and reinforcing leadership; developing and reinforcing good safety attitudes.

Table 5 shows that there were 57 observations associated with the management system of the regulatory body, with the most common subject group being the establishment of the regulatory body management system.
Table 5 Number of observations by subject group for regulatory body management system

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a Establishment of the regulatory body management system</td>
<td>26</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>4b Implementation of the regulatory body management system</td>
<td>2</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>4c Assessment and review of the regulatory body management system</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>4d Safety culture of the regulatory body</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>34</td>
<td>17</td>
<td>6</td>
</tr>
</tbody>
</table>

5.5.1 Highlights of Recommendations and Suggestions

5.5.1.1 Establishment of the regulatory body management system

Every mission made a Recommendation or Suggestion that the regulatory body establish, implement and/or update its integrated management system, based on GSR Part 2. The management system should integrate health, safety, security, quality, environmental, human and organizational factors, societal and economic elements.

Most missions made a Recommendation or Suggestion that the regulatory body identify, develop and document all key processes contributing to safety.

A few missions made a Recommendation or Suggestion that the regulatory body develop a safety policy.

5.5.1.2 Implementation of the regulatory body management system

A few missions made a Recommendation or Suggestion that the regulatory body have up-to-date documentation for the management system and that staff have ready access to management system documentation.

5.5.1.3 Assessment and review of the regulatory body management system

A few missions made a Recommendation or Suggestion that the regulatory body put provisions in place for both self-assessment and independent assessment of the management system.

5.5.1.4 Safety culture of the regulatory body

A few missions made a Recommendation or Suggestion that the regulatory body further develop its safety culture.

5.5.2 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The regulatory body has developed an effective database to preserve and keep up to date the knowledge gained during the use of atomic energy in the member state;
- There is a documented system providing a link between the legislation mandating the organization and individual contribution to delivery of goals, including corporate values and behavioural expectations;
- Each year the senior executive management visits all the functional units of the regulatory body and discusses the goals and topical issues of the organization directly with the employees;
• The regulatory body’s radiation safety inspection activities are formally accredited to an ISO standard, which provides for openness and transparency, as well as continuous assessment and improvement;
• The regulatory body conducts self-assessment of safety culture.

5.6 Subject Groups related to authorization

There are five subject groups related to authorization:

a) Development of authorization process: Authorization as a prerequisite except where explicitly exempted; different types for different stages in lifetime or duration; ability to modify authorizations; inclusion of limits, conditions and controls; appeal process; submission of safety assessment; format and content; hold points; amendment, renewal, suspension and revocation process; formal record.

b) Implementation of authorization process: Findings related to how the regulatory body is actually implementing its authorization process.

c) Graded approach to authorization: Authorization is commensurate with associated risks.

d) Authorization procedures and guidance: Specification of necessary planned and systematic actions.

e) Competence of authorized party staff: Direct evidence of qualifications; positions to be included; qualification requirements; consistent and graded approaches; adequate training.

The authorization module had 73 observations, with significant numbers in each subject group. Table 6 shows that development of the authorization process had the most observations in the module.

Table 6 Number of observations by subject group for authorization

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a Development of authorization process</td>
<td>20</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>5b Implementation of authorization process</td>
<td>6</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>5c Graded approach to authorization</td>
<td>1</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>5d Authorization procedures and guidance</td>
<td>7</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5e Competence of authorized party staff</td>
<td>7</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>41</td>
<td>29</td>
<td>3</td>
</tr>
</tbody>
</table>

5.6.1 Highlights of Recommendations and Suggestions

5.6.1.1 Development of authorization process

Some missions made a Recommendation or Suggestion that the regulatory body establish or update the process for the authorization of facilities and activities as required by *GSR Part 1* and *GSR Part 3*, in accordance with a graded approach.

Some missions made a Recommendation or Suggestion that the regulatory body establish objective and clear criteria for the amendment, renewal, suspension or revocation of an authorization.

A few missions made a Recommendation or Suggestion that the regulatory body establish requirements for the authorization of transport of radioactive material activities in accordance with *SSR-6*.

A few missions made a Recommendation or Suggestion that the regulatory body include notification as part of its authorization process.
5.6.1.2 Implementation of authorization process

Some missions made a Recommendation or Suggestion that the regulatory body require the submission of an adequate demonstration of safety in support of an application for authorization.

Some missions made a Recommendation or Suggestion that authorizations include facility or activity specific limits, conditions and controls.

5.6.1.3 Graded approach to authorization

Some missions made a Recommendation or Suggestion that the regulatory body establish and implement a graded approach to authorization, particularly with respect to radioactive sources.

5.6.1.4 Authorization procedures and guidance

Some missions made a Recommendation or Suggestion that the regulatory body have objective and clear criteria and procedures for issuing, amending, renewing, suspending and revoking an authorization.

5.6.1.5 Competence of authorized party staff

Many missions made a Recommendation or Suggestion that the member state have a process to formally recognize qualified experts for radiation protection and for medical physicists.

5.6.2 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The regulatory body has established a web-based system that allows applications for a new radiological license to be made and for existing licenses to be renewed or amended by following clear step by step instructions on the information to be provided and documents to be uploaded in support of the application;

- The required completion of periodic safety assessment for Category I, II, and III sources contributes significantly to continuous safety improvement.

5.7 Subject Groups related to review and assessment

There are five subject groups related to review and assessment:

- Development of review and assessment process: Review and assessment of relevant information from applicant, authorized party, vendor, regulatory body or elsewhere; prior to authorization and again as appropriate; routine evaluation of operating experience; comprehensive safety review; recording of results.

- Implementation of review and assessment process: Findings related to how the regulatory body is actually implementing its review and assessment process.

- Graded approach to review and assessment: Review and assessment are commensurate with associated risks.

- Review and assessment procedures and guidance: Specification of necessary planned and systematic actions.

- Authorized party safety culture: Review and assessment of authorized party safety culture.

Table 7 shows that 41 observations were related to review and assessment. Procedures and guidance were the subject most frequently identified in review and assessment.
Table 7 Number of observations for review and assessment

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>6a Development of review and assessment process</td>
<td>7</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>6b Implementation of review and assessment process</td>
<td>8</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>6c Graded approach to review and assessment</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>6d Review and assessment procedures and guidance</td>
<td>8</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>6e Authorized party safety culture</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>28</td>
<td>9</td>
<td>4</td>
</tr>
</tbody>
</table>

5.7.1 Highlights of Recommendations and Suggestions

5.7.1.1 Development of review and assessment process
Two missions made a Recommendation or Suggestion that the regulatory body develop a process for integrated safety assessment for all facilities and activities.

5.7.1.2 Implementation of review and assessment process
Some missions made a Recommendation or Suggestion that the regulatory body implement the procedures included in its review and assessment process.

5.7.1.3 Graded approach to review and assessment
Two missions made a Recommendation or Suggestion that the regulatory body establish practice-specific procedures to ensure consistency and the application of a graded approach in the review and assessment process.

5.7.1.4 Review and assessment procedures and guidance
Some missions made a Recommendation or Suggestion that the regulatory body develop or update procedures for the review and assessment of submissions made by applicants and authorized parties.

5.7.1.5 Authorized party safety culture
One mission made a Recommendation that the regulatory body develop a programme for the promotion of leadership and management for safety culture.

5.7.2 Good Practices
Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The regulatory body has established performance indicators to monitor research reactor and interim spent fuel storage installation safety performance;
- The regulatory body has developed a scoring table for nuclear power plants to aide in the determination of appropriate post event investigations and oversight of corrective actions;
- The regulatory body has developed a comprehensive and well-defined set of criteria for assessing the risks involved in different types of uses of radiation sources;
- The regulatory body has developed and implemented an effective tool, with well-defined criteria applying a graded approach, for reviewing safety related modifications, termed “non-important modifications”.

28
5.8 **Subject Groups related to inspection**

There are four subject groups related to inspection:

a) **Development of inspection programme**: Inspections to verify compliance; do not diminish authorized party responsibility; programmed and reactive inspections; announced and unannounced; frequency and areas and programmes to be inspected; inspection records, cover all areas of RB responsibility; feedback to regulatory process; results given to authorized party.

b) **Implementation of inspection programme**: Findings related to how the regulatory body is actually implementing its inspection programme.

c) **Graded approach to inspection**: Inspections are commensurate with the associated radiation risks.

d) **Inspection procedures and guidance**: Specification of necessary planned and systematic actions.

There were 43 observations related to inspections by the regulatory body. Table 8 shows that more than half of the observations were related to the development of the inspection programme. There was also a high number of Suggestions related to inspection procedures and guidance.

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>7a Development of inspection programme</td>
<td>15</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>7b Implementation of inspection programme</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>7c Graded approach to inspection</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>7d Inspection procedures and guidance</td>
<td>3</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>22</td>
<td>21</td>
<td>0</td>
</tr>
</tbody>
</table>

5.8.1 **Highlights of Recommendations and Suggestions**

5.8.1.1 **Development of inspection process**

Every mission made a Recommendation or Suggestion that the regulatory body develop or modify its inspection programme and planning process so all regulated facilities and activities are inspected, and that the inspection programme use a graded approach.

Some missions made a Recommendation or Suggestion that the regulatory body included unannounced inspections in its inspection programme.

5.8.1.2 **Implementation of inspection process**

Some missions made a Recommendation or Suggestion that the regulatory body implement its inspection programme as designed.

5.8.1.3 **Graded approach to inspection**

Two missions made a Recommendation or Suggestion that the regulatory body apply the graded approach when planning and conducting inspections.

5.8.1.4 **Inspection procedures and guidance**

Some missions made a Recommendation or Suggestion that the regulatory body develop, approve and/or implement inspection procedures.
5.8.2 Good practice

No Good Practice related to inspection was identified during the reporting period.

5.9 Subject Groups related to enforcement

There are four subject groups related to enforcement:

a) Development of enforcement policy: Legal basis for enforcement; criteria/factors in determining enforcement actions; authority to take enforcement actions; power to take corrective actions for unforeseen radiation risks; accountability of authorized party for remediing non-compliances.

b) Implementation of enforcement policy: Findings related to how the regulatory body is actually implementing its enforcement policy.

c) Graded approach to enforcement: Enforcement and requiring of corrective actions are commensurate with the associated risks.

d) Enforcement procedures and guidance: Specification of necessary planned and systematic actions.

As Table 9 shows, there were 16 observations related to enforcement, with no Good Practices identified. Table 9 shows that most of the observations in Module 8 relate to the development of the enforcement policy.

Table 9 Number of observations by subject group for enforcement

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of enforcement policy</td>
<td>5</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Implementation of enforcement policy</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Graded approach to enforcement</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Enforcement procedures and guidance</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Σ  Sum of observations</td>
<td>8</td>
<td>8</td>
<td>0</td>
</tr>
</tbody>
</table>

5.9.1 Highlights of Recommendations and Suggestions

5.9.1.1 Development of enforcement policy

Some missions made a Recommendation or Suggestion that the regulatory body establish an enforcement policy that covers all regulated facilities and activities.

5.9.1.2 Implementation of enforcement policy

A few missions made a Recommendation or Suggestion that the regulatory body have provisions to ensure that authorized parties implement necessary corrective actions.

5.9.1.3 Graded approach to enforcement

One mission made a Suggestion that the government give the regulatory body further enforcement powers to enable a response to non-compliances, in accordance with a graded approach.

5.9.1.4 Enforcement procedures and guidance

A few missions made a Recommendation or Suggestion that the regulatory body issue procedures to implement the enforcement policy.
5.9.2 Good practice

No Good Practice related to enforcement was identified during the reporting period.

5.10 Subject Groups related to regulations and guides

There are 12 subject groups related to regulations and guides:

a) **Development of regulations and guides:** Establishing or adopting regulations and guides; specification of principles, requirements and associated criteria; consultation with interested parties; accounting for international standards, operating and regulatory experience and research and development; use for conditions of authorization and assessing compliance.

b) **Review of regulations and guides:** Reviewed and revised as necessary; consultations with interested parties; use of technological advances, research and development and institutional knowledge.

c) **Promotion of regulations and guides:** Notification of interested parties and public; availability of regulations and guides.

d) **Graded approach to regulations and guides:** coverage of regulations and guides is commensurate with associated radiation risks.

e) **Nuclear power plant regulations and guides:** Findings related to regulations and guides specific to nuclear power plants.

f) **Research reactor regulations and guides:** Findings related to regulations and guides specific to research reactors.

g) **Fuel cycle facility regulations and guides:** Findings related to regulations and guides specific to fuel cycle facilities.

h) **Decommissioning of nuclear facilities regulations and guides:** Findings related to regulations and guides specific to decommissioning of nuclear facilities.

i) **Spent fuel and radioactive waste management regulations and guides:** Findings related to regulations and guides specific to management of spent fuel and radioactive waste.

j) **Radiation safety regulations and guides:** Findings related to regulations and guides specific to radiation safety other than those related to non-conformance to GSR Part 3.

k) **Transport safety regulations and guides:** Findings related to regulations and guides specific to safety of transport of radioactive material.

l) **Environmental protection regulations and guides:** Findings related to regulations and guides specific to protection of the environment.

There were 145 observations related to regulations and guides, and as Table 10 shows, more than half of these were related to radiation safety regulations and guides. There were also a number of observations related to regulations and guides for the safety of spent fuel and radioactive waste.

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10 Note that the subject group “Implementation of International Basic Safety Standards” is no longer in use. Findings formerly associated with this subject group have been redistributed to subject groups 9j and 9m.
Table 10 Number of observations by subject group for regulations and guides

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>9a Development of regulations and guides</td>
<td>6</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>9b Review of regulations and guides</td>
<td>2</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>9c Promotion of regulations and guides</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9d Graded approach to regulations and guides</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>9e Implementation of International Basic Safety Standards (not in use)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9f Nuclear power plant regulations and guides</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9g Research reactor regulations and guides</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>9h Fuel cycle facility regulations and guides</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9i Decommissioning of nuclear facilities regulations and guides</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>9j Spent fuel and radioactive waste management regulations and guides</td>
<td>10</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>9k Radiation safety regulations and guides</td>
<td>63</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>9l Transport safety regulations and guides</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>9m Environmental protection regulations and guides</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>98</td>
<td>44</td>
<td>3</td>
</tr>
</tbody>
</table>

5.10.1 Highlights of Recommendations and Suggestions

5.10.1.1 Development of regulations and guides

A few missions made a Recommendation or Suggestion that regulations and guides that take into account internationally agreed standards be in place for all regulated facilities and activities.

5.10.1.2 Review of regulations and guides

Some missions made a Recommendation or Suggestion that the regulatory body develop and implement a process to periodically review and revise its regulations and guides, taking into account international standards, latest developments of science and technology, and lessons learned.

5.10.1.3 Promotion of regulations and guides

There were no Recommendations or Suggestions related to the promotion of regulations and guides.

5.10.1.4 Graded approach to regulations and guides

One mission made a Suggestion that the regulatory body ensure its regulations or guides provide adequate coverage of facilities and activities commensurate with the radiation risks.

5.10.1.5 Nuclear power plant regulations and guides

There were no Recommendations or Suggestions related to nuclear power plant regulations and guides.

5.10.1.6 Research reactor regulations and guides

A few missions made a Recommendation or Suggestion that the regulatory body establish requirements and guidance on conducting periodic safety reviews of research reactors.

5.10.1.7 Fuel cycle facility regulations and guides

There were no Recommendations or Suggestions related to fuel cycle facility regulations and guides.
5.10.1.8 Decommissioning of nuclear facilities regulations and guides

Some missions made a Recommendation or Suggestion that the member state establish regulations and guides that cover all aspects of decommissioning in line with GSR Part 6: Decommissioning of Facilities.

5.10.1.9 Spent fuel and radioactive waste management regulations and guides

Most missions made a Recommendation or Suggestion that the member state develop, review and update regulations and guides related to the safety of radioactive waste management and spent fuel management in line with GSR Part 5: Predisposal Management of Radioactive Waste and SSR-5: Disposal of Radioactive Waste.

5.10.1.10 Radiation safety regulations and guides

Every mission made a Recommendation or Suggestion to bring occupational exposures in line with GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.

Every mission where medical exposure was included in the scope of the mission made a Recommendation or Suggestion to bring medical exposures in line with GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.

Some missions where public exposure was included in the scope of the mission made a Recommendation or Suggestion to bring public exposure and discharge limits from facilities in line with GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.

Some missions made a Recommendation or Suggestion that the member state explicitly address the concept of clearance and establishing clearance criteria as specified in GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.

A few missions made a Recommendation or Suggestion that the member state ensure that the conditions of service of radiation workers are independent of whether they are or could be professionally exposed.

5.10.1.11 Transport safety regulations and guides

Some missions made a Recommendation or Suggestion that the regulatory body ensure that their regulations for the safe transport of radioactive material are in line with SSR-6: Regulations for the Safe Transport of Radioactive Material.

5.10.1.12 Environmental protection regulations and guides

A few missions made a Recommendation or Suggestion that the regulatory body put in place requirements and guidance for the verification of compliance with discharge limits for all regulated facilities.

5.10.2 Good Practices

Among the Good Practices identified in the IRRS missions during the reporting period, the following are highlighted:

- The regulatory framework web-portal with links between different levels of requirements and guides;
- The use of up-to-date, state-of-the-art safety standards from foreign regulatory bodies by the regulatory body in the field of decommissioning and waste management, in order to
cover gaps in the member state framework, pending further regulatory updates, requires a superior performance to what is commonly observed in decommissioning and in the on-site design, construction and operation of waste treatment facilities;

- The regulatory body took the initiative to evaluate at the national level the need to install iodine holding tanks in both existing and future iodine ablation facilities. The evaluation reviewed existing practices in the member state in relation to iodine-131 ablation discharges to the sewers, (discharges leading to the highest potential dose) and made recommendations for a regulatory policy, based on international best practice and forecasts of future activity.

### 5.11 Subject Groups related to emergency preparedness and response (regulatory aspects)

There are four subject groups related to the regulatory aspects of emergency preparedness and response (EPR):

a) **Emergency planning**: Provisions for timely and effective response to emergencies; authorized party responsibilities; national response system; designation of response organizations.

b) **EPR procedures and guidance**: Assignment of clear responsibilities; timely and effective decision-making; managing emergency response operations; role of regulatory body to provide expert advice and services; managing, controlling and recording doses of emergency workers.

c) **EPR communication and cooperation**: Effective coordination and communication between authorized parties and response organizations; arrangements to inform public about EPR.

d) **EPR training and exercises**: regulator conduct of training, drills and exercises; coverage of full range of postulated emergencies.

There were 81 observations related to the regulatory aspects of emergency preparedness and response. Table 11 shows that most observations in Module 10 were related to emergency planning and procedures and guidance. Emergency planning received the second highest number of Recommendations and Suggestions of all subject groups.

**Table 11**: Number of observations by subject group for emergency preparedness and response

<table>
<thead>
<tr>
<th>Subject groups in Module 10</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>10a Emergency planning</td>
<td>23</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>10b EPR procedures and guidance</td>
<td>8</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>10c EPR communication and cooperation</td>
<td>2</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>10d EPR training and exercises</td>
<td>5</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of Observations in the module</td>
<td>38</td>
<td>36</td>
<td>7</td>
</tr>
</tbody>
</table>

### 5.11.1 Highlights of Recommendations and Suggestions

#### 5.11.1.1 Emergency planning

Every mission where emergency preparedness and response was included in the scope of the mission made a Recommendation or Suggestion that the member state have in place, and regularly review and test, emergency plans in line with *GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency.*
Some missions that included emergency preparedness and response in the scope of the mission made a Recommendation or Suggestion that the regulatory body verify that authorized parties have adequate emergency arrangements in place.

Some missions that included emergency preparedness and response in the scope of the mission made a Recommendation or Suggestion that the member state adopt a system and develop criteria for emergency classification in line with GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency.

5.11.1.2 Emergency preparedness and response procedures and guidance

Many missions made a Recommendation or Suggestion that the regulatory body develop or update and issue regulations and guidance regarding emergency preparedness and response that is consistent with GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency.

A few missions made a Recommendation or Suggestion that the regulatory body establish criteria for designating emergency workers and make arrangements for their protection.

5.11.1.3 Emergency preparedness and response communication and cooperation

Some missions made a Recommendation or Suggestion to enhance coordination between operating organizations, response organization and government authorities.

A few missions made a Recommendation or Suggestion that the member state enhance its emergency communication system to use diverse means and be continuously available.

5.11.1.4 Emergency preparedness and response training and exercises

Some missions made a Recommendation or Suggestion that persons responsible for critical response functions participate in regular training, drills and exercises.

Some missions made a Recommendation or Suggestion that both the regulator body evaluate drills and exercises.

5.11.2 Good Practices

Among the good practices identified in the IRRS missions during the reporting period, the following are highlighted:

- Nuclear and radiological emergencies are well integrated on national and regional levels in a framework for major emergency management system and a national emergency coordination system following the all-hazards approach. The regulatory body has a key role if a radiation emergency occurs;
- When making protective action decisions during a nuclear emergency in another member State, the government default action is to implement the same protective actions as that member state prescribed for its residents. Coordinating response actions with another member state in this manner is efficient and prevents unnecessary delays in implementing protective actions and enhances public confidence by avoiding confusion or justification of differences in protective actions;
- The Integrated Measurement and Information System (IMIS), in combination with the unique Radiological Situation Report, forms a robust basis for a coordinated emergency response;
The regulatory body has developed, implemented and is systematically maintaining and improving, an information management system which is significantly contributing to efficient management and response of the regulatory body’s emergency organization for potential nuclear accidents.

5.12 Subject Group related to the interface between safety and security (regulatory aspects)

This subject group deals with findings associated with the interface of safety with nuclear security.

Table 12 shows that there were two observations related to the regulatory aspects of the interface between safety and nuclear security.

<table>
<thead>
<tr>
<th>Module 11</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Interface between safety and nuclear security</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

5.12.1 Highlights of Recommendations and Suggestions

One mission made a Recommendation or Suggestion that the member state ensure that nuclear security measures do not compromise safety and that safety measures do not compromise nuclear security.

5.12.2 Good practice

- The government has implemented effective interface between safety and security for category 1 to 4 radioactive sources through the requirement for security experts to advise and inspect security requirements with the regulatory body.

5.13 Subject Groups related to activities for embarking on a nuclear power programme

This subject group deals with findings associated with a member state’s regulatory activities related to embarking on a nuclear power programme.

Only one mission included the module on activities for embarking on a nuclear power programme. Table 13 shows that there were four observations related to regulatory activities related to embarking on a nuclear power programme. As this subject group is related to the IAEA Specific Safety Guide No. SSG-16: Establishing the Safety Infrastructure for a Nuclear Power Programme, the observations made in the IRRS missions are expected to be either Suggestions or Good Practices.

<table>
<thead>
<tr>
<th>Module 12</th>
<th>R</th>
<th>S</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Activities for embarking on a nuclear power programme</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

5.13.1 Highlights of Recommendations and Suggestions

5.13.2 Good practice

No Good Practice related to inspection was identified during the reporting period.

5.14 Overall analysis of subject groups

Figure 19 shows the subject groups with the highest number of Recommendations and Suggestions.

![Graph showing subject groups with highest number of recommendations and suggestions](image)

**Figure 19 Subject groups with highest number of Recommendations and Suggestions**

The largest number of Recommendations and Suggestions relate to radiation safety regulations and guides.

Regarding the topic of processes, procedures and guidance, these observations were broken out in the various modules for authorization, review and assessment, inspection, enforcement and emergency preparedness and response. Taken together, however, they account for 25 Recommendations and 20 Suggestions, making the topic of procedures and guidance the third most frequent observation.

Figure 20 shows the subject groups with more than one Good Practice.
Subject groups with more than one Good Practice reference

The following subject groups appear in both Figure 19 and Figure 20:

- Implementation of the authorization process;
- Emergency planning.

### 6 Sections of initial missions with no findings

While reviewing Recommendations and Suggestions provides insight to areas where better alignment with the IAEA Safety Standards may be needed, one of the main reasons for those areas where no Recommendations or Suggestions were made is that Member States’ practices are already aligned with the IAEA Safety Standards.

The sections where the majority of reports did not have any findings were:

- Liaison between the regulatory body and authorized parties;
- Provision of technical services;
- Responsibility for safety and compliance with regulations;
- Effective independence in the performance of regulatory functions;
- Liaison with advisory bodies and support organizations.

### 7 Follow-up missions

#### 7.1 General

To review the progress in the implementation of the Recommendations and Suggestions from the IRRS mission, the Agency recommends that a follow-up mission takes place two to four years after the initial mission. Two years allow significant progress to be made with the implementation of the Recommendations and Suggestions of the initial IRRS mission. Beyond four years, the effectiveness of the follow-up process may be limited, and it may be more appropriate for a Member State to request a new initial mission instead.
The follow-up mission will rate each Recommendation and Suggestion as either closed or open. The follow-up mission may also identify further observations, resulting in new Recommendations, Suggestions or Good Practices.

For the 14 European Union member states that hosted an initial mission from 2015 to 2019, three have already hosted a follow-up mission and another four have already requested a follow-up mission.

For the European Union member states that did host a follow-up mission between 2015 and 2019, Figure 21 shows the number of months between the initial and follow-up mission. The shortest time interval was just over 30 months, while the longest was almost 81 months.

Figure 21 also shows that half of the follow-up missions did not meet the IAEA recommendation that they should take place two to four years after the initial mission.

![Figure 21 Time between initial and follow-up missions](image)

7.2 Closure rates for Recommendations and Suggestions

For the European Union member states that did host a follow-up mission during the reporting period, there were 601 Recommendations and Suggestions made during the initial missions. Of these, 515 were closed during the follow-up mission, while 86 remained open. The overall closure rate for Recommendations and Suggestions was almost 86%. The closure rate for individual member states varied from 57% to 100%. Five European Union member states had a closure rate of less than 90%, while one had a closure rate of 100%.

During the initial missions, the Recommendations and Suggestions are directed to either the member state government, or to the regulatory body, or to both. For the cases where follow-up missions have taken place, during the initial missions, 19 Recommendations and Suggestions were directed to both the government and the regulatory body, 138 Recommendations and Suggestions were directed to the government alone and 444 Recommendations and Suggestions were directed to the regulatory body alone.

Of the 157 Recommendations and Suggestions directed to member state governments, 133 were closed during the follow-up mission, while 24 remained open. Overall, the closure rate for European Union member state governments is 85%. Of the 463 Recommendations and Suggestions directed to regulatory bodies, 397 were closed during the follow-up mission, while 66 remained open. Overall, the closure rate for regulatory bodies is 86%.
7.3 **Analysis of findings remaining open**

The findings that peer reviewers do not close during follow-up missions tend to fall in the following topics listed in order from most frequent to least:

- Promulgation of national nuclear laws and regulations and their alignment with the IAEA Safety Standards;
- Implementation of an integrated management system by the regulatory body;
- Building and maintaining competence for nuclear and radiological safety;
- Inspection programme enhancements;
- Providing regulatory bodies with sufficient financial and human resources;
- Developing the national policy and strategy for safety;
- Coordination amongst organizations with responsibilities for nuclear and radiological safety, particularly where various levels of government are involved, to ensure there are no gaps or conflicting requirements.

7.4 **New observations resulting in Recommendations and Suggestions in follow-up missions**

In addition to reviewing the progress made dealing with the Recommendations and Suggestions from the initial mission, the follow-up mission may also include new review areas or may expand the review of areas covered in the initial mission. In these cases, the follow-up mission will include new observations, with the resulting Recommendations, Suggestions and Good Practices. All follow-up missions except one to European Union member states from 2015 to 2019 included new observations.

![Figure 22 New references in follow-up missions](image-url)
As Figure 22, almost 45% of these new observations reference a requirement in *GSR Part 1*. *GSR Part 7* accounts for 18% of the references, various Safety Guides for 13%, *GSR Part 2* for 11% and *GSR Part 3* for 8% of the references.

![Figure 23 New references to GSR Part 1 in follow-up missions](image)

Figure 23 shows that the *GSR Part 1* Requirement 18 (Staffing and competence of the regulatory body) was referenced five times in follow-up missions.

Other *GSR Part 1* requirements referenced more than once in follow-up missions are:
- Requirement 1: National policy and strategy for safety;
- Requirement 3: Establishment of a regulatory body;
- Requirement 11: Competence for safety;
- Requirement 22: Stability and consistency of regulatory control;
- Requirement 28: Types of inspection of facilities and activities.

For *GSR Part 2*, the following requirements were referenced more than once in follow-up missions:
- Requirement 6: Integration of the management system;
- Requirement 12: Fostering a culture for safety.

For *GSR Part 3*, the following requirement received more than one reference in a follow-up mission:
- Requirement 8: Exemption and clearance.

For *GSR Part 7*, the following requirements received more than one reference in a follow-up mission:
- Requirement 2: Roles and responsibilities in emergency preparedness and response;
- Requirement 22: Coordination of emergency preparedness and response.

### 8 Analysis of IRRS missions related to the regulation of operating nuclear power plants (NPPs)

#### 8.1 Introduction

Some IRRS missions reviewed the regulation of operating NPPs. In total, 65 Recommendations, 70 Suggestions and 11 Good Practices identified during missions relate to the regulation of operating NPPs.
in European Union member states. Note that many of these Recommendations and Suggestions are not exclusively associated with the regulation of operating NPPs.

**8.2 Reference to IAEA Safety Standards**

**8.2.1 Overall references to IAEA Safety Standards**

![Figure 24 References to IAEA Safety Standards for observations related to operating NPPs](image)

As Figure 24 shows, references to *GSR Part 1 (Rev. 1)* account for just over 40% of the findings related to the regulation of operating NPPs. Various Safety Guides accounted for 20% of the findings, with *GSR Part 7* and *GSR Part 2* each accounting for around 13% of the references. Other Safety Requirements, *GSR Part 3* and *GSR Part 6* each accounted for around 5% of the references.

**8.2.2 References to GSR Part 1**

![Figure 25 References to GSR Part 1 for observations related to operating NPPs](image)

As Figure 25 shows, the most frequently referenced *GSR Part 1* requirements are:
- Requirement 18: Staffing and competence of the regulatory body (10 references);
- Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety (nine references);
- Requirement 4: Independence of the regulatory body (eight references);
- Requirement 33: Review of regulations and guides (seven references).

Figure 25 also shows that the following GSR Part I requirements are not referenced for any IRRS observation related to an operating NPP:
- Requirement 5: Prime responsibility for safety;
- Requirement 6: Compliance with regulations and responsibility for safety;
- Requirement 8: Emergency preparedness and response;
- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material;
- Requirement 13: Provision of technical services;
- Requirement 17: Effective independence in the performance of regulatory functions;
- Requirement 21: Liaison between the regulatory body and authorized parties.

8.2.3 Good Practice references

The following requirements were referenced for Good Practices related to operating NPPs:
- GSR Part I Requirement 2: Establishment of a framework for safety;
- GSR Part I Requirement 16: Organizational structure of the regulatory body and allocation of resources;
- GSR Part I Requirement 23: Authorization of facilities and activities by the regulatory body;
- GSR Part I Requirement 34: Promotion of regulations and guides to interested parties
- GSR Part 2 Requirement 9: Provision of resources;
- GSR Part 7 Requirement 4: Hazard assessment;
- GSR Part 7 Requirement 22: Coordination of emergency preparedness and response;
- GSR Part 7 Requirement 24: Logistical support and facilities for emergency response;

8.3 Analysis by subject group

Table 14 shows the subject groups with the highest number of Recommendations and Suggestions related to operating NPPs.

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>10a Emergency planning</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>9k Radiation safety regulations and guides</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>1b Framework for safety</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>5b Implementation of authorization process</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>7d Inspection procedures and guidance</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>1e Coordination and cooperation among authorities</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>1c Regulatory independence</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3a Organization of the regulatory body and allocation of resources</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7a Development of inspection process</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
9 Analysis of IRRS missions related to the regulation of radioactive sources

9.1 Introduction

All IRRS missions to European Union member states included a review of the regulatory control of radioactive sources. In total, these missions identified 357 Recommendations, 193 Suggestions and 30 Good Practices related to the regulatory control of radioactive sources. Note that many of these Recommendations and Suggestions are not exclusively associated with the regulation of radioactive sources.

9.2 Reference to IAEA Safety Standards

9.2.1 Overall references to IAEA Safety Standards

As Figure 26 shows, 37% of the findings related to the regulation of radioactive sources reference GSR Part 1 and 23% of the findings reference GSR Part 3. Around 10% of the findings reference GSR Part 7, various Safety Guides and GSR Part 2.

For all of the Requirements documents, more references were for Recommendations than Suggestions, while for the Safety Guides, the majority of the references were for Suggestions. In every case where an IAEA Safety Guide is used as a basis for a Recommendation, there is also an IAEA Safety Requirements document as a basis.
9.2.2 References to GSR Part 1

As Figure 27 shows, the following GSR Part 1 requirements were most frequently referenced with respect to radioactive sources:

- Requirement 18: Staffing and competence of the regulatory body (28 references);
- Requirement 24: Demonstration of safety for the authorization of facilities and activities (22 references);
- Requirement 33: Review of regulations and guides (22 references);

The following GSR Part 1 requirements were referenced only once or twice with respect to radioactive sources:

- Requirement 8: Emergency preparedness and response (one reference);
- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material (one reference);
- Requirement 5: Prime responsibility for safety (two references);
- Requirement 13: Provision of technical services (two references);
- Requirement 21: Liaison between the regulatory body and authorized parties (two references).

Figure 27 References to GSR Part 1 for findings related to radioactive sources

Figure 28 Good Practice references to GSR Part 1 for findings related to radioactive sources
As Figure 28 shows, nine GSR Part 1 requirements were referenced for Good Practices associated with radioactive sources. The following GSR Part 1 requirements were referenced more than once for Good Practices associated with radioactive sources:

- Requirement 14: International obligations and arrangements for international cooperation and assistance;

### 9.2.3 References to GSR Part 3

Figure 29 shows that the following GSR Part 3 requirements are referenced most frequently for Recommendations and Suggestions associated with radioactive sources:

- Requirement 36: Responsibilities of registrants and licensees specific to medical exposures (15 references);
- Requirement 38: Optimization of protection and safety for medical exposure (13 references);
- Requirement 32: Monitoring and reporting for public exposure (12 references);
- Requirement 34: Responsibilities of the government specific to medical exposure (12 references);
- Requirement 8: Exemption and clearance (ten references);
- Requirement 41: Unintended and accidental medical exposures (ten references).

The following GSR Part 3 requirements were not referenced for Recommendations and Suggestions associated with radioactive sources:

- Requirement 9: Responsibilities of registrants and licensees in planned exposure situations;
- Requirement 15: Prevention and mitigation of accidents;
- Requirement 16: Investigations and feedback of information on operating experience;
- Requirement 17: Radiation generators and radioactive sources.

### 9.2.4 Good practice references

The following requirements were referenced more than once for Good Practices related to radioactive sources:

- GSR Part 1 Requirement 2: Establishment of a framework for safety;
• GSR Part 1 Requirement 14: International obligations and arrangements for international cooperation and assistance;
• GSR Part 2 Requirement 2: Demonstration of leadership for safety by managers;
• GSR Part 3 Requirement 37: Justification of medical exposures;
• GSR Part 7 Requirement 22: Coordination of emergency preparedness and response.

9.3 Analysis by subject group

Table 15 shows the subject groups that had more than 20 Recommendations and Suggestions related to regulation of radioactive sources. There are areas where member states may consider for better alignment with IAEA Safety Standards.

Table 15 Subject Groups with the greatest number of observations related to radioactive sources

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>9k Radiation safety regulations and guides</td>
<td>63</td>
<td>17</td>
</tr>
<tr>
<td>10a Emergency planning</td>
<td>23</td>
<td>20</td>
</tr>
<tr>
<td>1b Framework for safety</td>
<td>27</td>
<td>6</td>
</tr>
<tr>
<td>4a Establishment of the regulatory body management system</td>
<td>23</td>
<td>8</td>
</tr>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td>5a Development of authorization process</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td>7a Development of inspection programme</td>
<td>13</td>
<td>7</td>
</tr>
</tbody>
</table>

10 Conclusion

Every IRRS mission to a European Union member state where the topic was within the scope of the mission made a Recommendation or Suggestion to:

• Enhance arrangements for effective coordination and cooperation between authorities having regulatory responsibilities for nuclear and radiation safety with those responsible for nuclear security, transport safety, emergency preparedness and response and the medical application of radiation;
• Develop, maintain or enhance a regulatory body long-term human resource plan to ensure the availability and competence of staff;
• Establish, implement or enhance the regulatory body integrated management system, based on GSR Part 2;
• Develop or modify the regulatory body inspection programme and planning process so all regulated facilities and activities are inspected in accordance with a graded approach;
• Bring member state regulations and guides for occupational exposures into line with GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards;
• Bring member state regulations and guides for medical exposure into line with GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards;
• Have in place, and regularly review and test, emergency plans in line with GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency.

Most missions to a European Union member state made a Recommendation or Suggestion to:

• Establish or update the national policy and strategy for safety in line with GSR Part 1;
• Update the legal framework to be consistent with the IAEA Safety Standards;
- Have provisions in place to ensure that the regulatory body is effectively separate from entities having responsibilities or interests that could unduly influence its decision-making;
- Establish and implement a national policy and strategy for the safe decommissioning of facilities, the safe management and disposal of radioactive waste, and the safe management of spent fuel;
- Establish or strengthen the formal process for reporting and reviewing events and identifying lessons to be learned. The process should include events at both in the member state and internationally;
- Identify, develop and document all key regulatory body processes contributing to safety;
- Implement a process to formally recognize qualified experts in radiation protection and for medical physicists;
- Develop, review and update regulations and guides related to the safety of radioactive waste management and spent fuel management in line with GSR Part 5 and SSR-5;
- Develop or update and issue regulations and guides related to emergency preparedness and response consistent with GSR Part 7.

The Recommendations and Suggestions presented above summarize the most frequent observations identified in IRRS missions. Member States are therefore encouraged to pay special attention to the issues raised by those observations in relation to their governmental, legal and regulatory framework for safety.

In September 2019, the IAEA clarified the criteria for identifying Good Practices during an IRRS mission. This clarification provides that, to be considered as a Good Practice, a commendable practice should be reviewed in light of all following three criteria:

- Outstanding performance, going beyond what is required;
- Unique performance, not generally observed elsewhere;
- Replicable by other Member States, as a model in the general drive for excellence.

Based on the requirement that all three criteria be met, it is expected that future IRRS missions will identify fewer Good Practices. The aim is to share useful information with the other Member States providing them with effective and useful opportunities to learn from Good Practices observed elsewhere.

It is important to highlight that half of the follow-up missions held between 2015 and 2019 did not meet the IAEA recommendation that they should take place two to four years after the initial mission. Beyond four years, the effectiveness of the follow-up process may be limited and, therefore it may be more appropriate for a Member State to request a new initial IRRS mission instead.

Overall, the analysis of results of IRRS missions indicates that regulatory bodies are continuously working to enhance the effectiveness of their regulatory systems. The missions have identified strengths (Good Practices) and opportunities for improvement (Recommendations and Suggestions) in the host Member States.
### Annex A: Subject group definitions

**Subject Group 1: Responsibilities and functions of the government**

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 1a  | National policy and strategy for safety | - Establishing the policy and strategy  
- Using a graded approach  
- Accounting for national circumstances  
- Achieving the fundamental safety objective  
- Applying the fundamental safety principles  
- Having a long-term commitment to safety  
- Stating the government intent  
- Setting out mechanisms for implementation  
- Accounting for international legal instruments  
- Establishing the scope for governmental, legal and regulatory framework  
- Providing for human and financial resources  
- Providing for research and development  
- Accounting for social and economic developments  
- Promoting leadership for safety  
- Principles of radiation protection applied  
- Management of existing exposure situations |
| 1b  | Framework for safety | - Up-to-date comprehensive national nuclear law, regulations, decrees and orders as necessary  
- RB established  
- Sufficient legal authority for the regulatory body (RB)  
- Sufficient financial resources for RB  
- Framework for protection and safety |
| 1c  | RB Independence | - Effectively independent in its decision-making  
- Functional separation from entities that could unduly influence decision-making  
- Able to perform functions without undue pressure or constraint  
- Able to give independent advice and provide reports to highest levels of government  
- Able to liaise directly with other RBs and with international organizations  
- No conflicting responsibilities  
- No conflicts of interests, including authorized parties that are government organizations  
- Able to exercise authority irrespective of possible costs |
| 1d  | Prime responsibility for safety | - Assigning prime responsibility for safety to the person or organization responsible for facility or activity  
- Cannot be delegated  
- Responsibility can extend to other entities, but does not relieve authorized party  
- Authorized party responsible for verifying that goods and services comply  
- Conferring authority on RB to compel authorized parties  
- Responsibility extends through entire life-cycle, and for waste management  
- Authorized party actively evaluates progress in safety technology  
- Consigner responsible for appropriate packaging and mode of transport  
- Complying with regulatory requirements does not relieve person or organization from its prime responsibility |
<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 1e  | Coordination and cooperation among authorities | • Authorities clearly defined to avoid omissions  
• Authorities clearly defined to avoid duplication  
• Authorities clearly defined to avoid conflicting requirements  
   |
|     | • Note: Findings related to liaison are allocated to subject group 3d  
| 1f  | Protective actions for unregulated sources or contamination from past activities or events | • System for protective actions  
• Consistent with justification and optimization principles  
• Designation of organizations responsible  
• Access to necessary resources  
• RB inputs  
|     | • Note: Findings related to liaison are allocated to subject group 3d  
| 1g  | Decommissioning and management of radioactive waste and spent fuel | • Provisions for decommissioning  
• Provisions for management of radioactive waste  
• Provisions for management of spent fuel  
• Interim targets and end states  
• Continuity of responsibility  
| 1h  | Competence for safety | • Provisions for building and maintaining competence of all parties  
• Technical training, learning, R&D  
• Qualification and registration of experts  
| 1i  | Provision of technical services | • Provision of technical services for safety (e.g. dosimetry, environmental monitoring, equipment calibration)  
• Authorization by RB if necessary  

**Subject Group 2: Global Nuclear Safety Regime**

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 2a  | International obligations and arrangements for international cooperation and assistance | • Fulfilling international obligations  
• Participating in international arrangements  
• Participating in international peer reviews  
• Promoting international cooperation and assistance  
| 2b  | Bilateral and multilateral arrangements | • Ensuring bilateral and multilateral arrangements are in place  
• Import/export of radioactive sources  
| 2c  | Operating and regulatory experience | • Analysis to identify lessons to be learned from operating and regulatory experience  
• Dissemination of lessons learned to authorized parties, RB and other relevant authorities  
• Use of lessons learned by RB and other relevant authorities  
• Means for receiving international operating and regulatory experience  
• Making available operating and regulatory experience to international knowledge and reporting networks  
• Requirement to carry out corrective actions to prevent recurrence  
• Feedback on measures taken in response to information received  

**Subject Group 3: Responsibilities and functions of the regulatory body**

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 3a  | Organization of regulatory body and allocation of resources | • Organizational structure  
• Allocation of resources commensurate with radiation risks  
• Graded approach  
• Establish or adopt regulations and guides for protection and safety and a system to ensure implementation  
| 3b  | Regulatory body staffing and competence | • Sufficient number of qualified and competent RB staff  
• Commensurate with nature and number of regulated facilities and activities  
• Human resources planning  

50
<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 3c  | External involvement in the regulatory process | • External involvement in the regulatory process: Advisory committees; involvement of other organizations in nuclear safety matters; technical support organizations; policy for seeking external expert advice; relationship with licensees.  
• Arrangements with vendors, contractors and suppliers  
• Obtaining independent technical and other expert advice  
• Retaining regulatory responsibility  
• Clear limits on degree of control and direction  
• Avoiding and/or monitoring conflicts of interest  
• Retaining core competence  
• Communicating with authorized parties  
• Mutual understanding and respect  
• Justification for regulatory decisions  
• Liaison for joint inspections |
| 3d  | Stability and consistency of regulatory control | • Stability and consistency of regulatory control  
• Formal regulatory process based on policies, principles and criteria  
• Follows management system procedures and that follows specified procedures  
• Prevention of subjectivity in decision making  
• Justification of regulatory decisions  
• Informing applicants of safety objectives, principles and criteria  
• Emphasis on continuous enhancement of safety  
• Recognition of risks associated with modifications to well-established processes  
• Careful scrutiny of proposed changes in regulatory requirements  
• Informing and consulting interested parties regarding proposed changes in regulatory requirements  
• Consistency in regulatory requirements and regulatory decision-making process |
| 3e  | Safety related records | • Establishing, maintaining and retrieving adequate safety records  
• Registers of sealed radioactive sources and radiation generators  
• Occupational dose records  
• Records related to facilities and activities  
• Records necessary for shutdown, decommissioning and closure  
• Records related to incidents, including non-routine releases to environment  
• Radioactive waste and spent fuel inventories  
• Need for authorized party to maintain records  
• Need for applicant to record information  
• Use of records by RB to support regulatory activities, including enforcement |
| 3f  | Communication and consultation with interested parties | • Informing and consulting interested parties on risks associated with facilities and activities  
• Informing and consulting interested parties on regulatory body processes, judgements and decisions  
• Provisions for effective communication  
• Meetings to inform interested parties  
• Direct communication with high-level governmental authorities  
• Legal obligations of authorized parties to inform the public and other interested parties. |
### Subject Group 4: Regulatory body management system

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 4a  | Establishment of regulatory body management system | • Alignment with safety goals  
• Open and transparent processes  
• Ensures responsibilities assigned to RB are properly discharged  
• Maintaining and improving RB performance  
• Coherence  
• Specification of necessary planned and systematic actions (overall)  
• Considering regulatory requirements |
| 4b  | Implementation of the regulatory body management system | • Contributes to achieving safety goals  
• Maintains efficiency and effectiveness of RB |
| 4c  | Assessment and review of the management system | • Continuous assessment and review |
| 4d  | Safety culture of the regulatory body | • Fostering and supporting safety culture  
• Developing and reinforcing leadership  
• Developing and reinforcing good safety attitudes |

### Subject Group 5: Authorization

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 5a  | Development of authorization process | • Authorization is prerequisite except where explicitly exempted or approved by notification  
• Different types of authorization for different stages in lifetime or duration  
• RB able to modify authorizations  
• Limits, conditions and controls  
• Appeal process  
• Submission of safety assessment  
• Format and content of application  
• Hold points  
• Amendment, renewal, suspension and revocation process  
• Formal record of decision and reasons |
| 5b  | Implementation of authorization process | • Findings related to how the RB is actually implementing its authorization process |
| 5c  | Graded approach to authorization | • Authorization is commensurate with the associated risks |
| 5d  | Authorization procedures and guidance for regulatory body staff | • Specification of necessary planned and systematic actions (specific to authorization process) |
| 5e  | Competence of authorized party staff | • Verification of competence of individuals responsible for safety |

### Subject Group 6: Review and assessment

<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 6a  | Development of review and assessment process | • Review and assessment of relevant information  
• From applicant, authorized party, vendor, assembled by RB or elsewhere  
• Prior to authorization and a gain as appropriate  
• Routine evaluation of operating experience  
• Comprehensive safety reviews  
• According to stage in regulatory process  
• Understanding of design  
• Assessment of radiation and non-radiation risks  
• Assessment of modifications  
• Identification of trends and conclusions  
• Feedback to authorized party  
• Recording of results and taking appropriate action |
<table>
<thead>
<tr>
<th>No.</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6b</td>
<td>Implementation of review and assessment process</td>
<td>Findings related to how the RB is actually implementing its review and assessment process</td>
</tr>
<tr>
<td>6c</td>
<td>Graded approach to review and assessment</td>
<td>Review and assessment are commensurate with the associated risks</td>
</tr>
<tr>
<td>6d</td>
<td>Review and assessment procedures and guidance</td>
<td>Specification of necessary planned and systematic actions (specific to review and assessment process)</td>
</tr>
<tr>
<td>6e</td>
<td>Authorized party safety culture</td>
<td>Review and assessment of authorized party safety culture</td>
</tr>
</tbody>
</table>

**Subject Group 7: Inspection**

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<tr>
<th>No.</th>
<th>Definition</th>
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</table>
| 7a  | Development of inspection process | - Inspections carried out to verify compliance  
- Do not diminish or substitute for authorized party responsibility  
- Inspections shall include programmed inspections and reactive inspections, both announced and unannounced  
- Programme shall stipulate frequency and areas and programmes to be inspection  
- Inspection results recorded and an appropriate action taken  
- Results feedback to regulatory process  
- Results provided to authorized party  
- Cover all areas of RB responsibility  
- RB authority to carry out independent inspections |
| 7b  | Implementation of inspection process | Findings related to how the RB is actually implementing inspection process |
| 7c  | Graded approach to inspection | Inspections commensurate with the associated radiation risks |
| 7d  | Inspection procedures and guidance | Specification of necessary planned and systematic actions (specific to inspection process) |

**Subject Group 8: Enforcement**

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<th>No.</th>
<th>Definition</th>
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</table>
| 8a  | Development of enforcement policy | - Legal basis for enforcement  
- Enforcement of regulatory requirements  
- Enforcement of conditions specified in authorization  
- Criteria/factors in determining enforcement/corrective actions  
- Authority to take enforcement actions  
- Power to take corrective actions for unforeseen radiation risks  
- Accountability of authorized party for remedying non-compliances  
- Accounting for international standards, OPEX and R&D  
- Used for conditions of authorization and assessing compliance |
| 8b  | Implementation of enforcement policy | Findings related to how the RB is actually implementing enforcement process |
| 8c  | Graded approach to enforcement | Enforcement and requiring of corrective actions are commensurate with the associated risks |
| 8d  | Procedures and guidance for enforcement | Specification of necessary planned and systematic actions (specific to enforcement process) |

**Subject Group 9: Regulations and guides**

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<th>No.</th>
<th>Definition</th>
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</table>
| 9a  | Development of regulations and guides | - Establishing or adopting regulations and guides  
- Part of legal framework  
- Specify principles, requirements and associated criteria  
- Regulatory judgement, decisions and actions based on regulations and guides  
- Consultation with interested parties  
- Accounting for international standards, OPEX and R&D  
- Used for conditions of authorization and assessing compliance |
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<th>No.</th>
<th>Definition</th>
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</table>
| 9b  | Review of regulations and guides                                         | • Reviewed and revised as necessary  
• Accounting for international safety standards, technical standards, OPEX  
• Consultations with interested parties  
• Use technological advances, R&D, institutional knowledge |
| 9c  | Promotion of regulations and guides                                      | • Notification of interested parties and public  
• Availability of regulations and guides |
| 9d  | Graded approach to regulations and guides                                | • Coverage commensurate with associated radiation risks |
| 9f  | NPP regulations and guides                                               | • Observations related to regulations and guides specific to nuclear power plants |
| 9g  | RR regulations and guides                                                | • Observations related to regulations and guides specific to research reactors |
| 9h  | FCF regulations and guides                                               | • Observations related to regulations and guides specific to fuel cycle facilities |
| 9i  | Decommissioning of nuclear facilities regulations and guides             | • Observations related to regulations and guides specific to decommissioning of nuclear facilities |
| 9j  | Spent fuel and radioactive waste management regulations and guides       | • Observations related to regulations and guides specific to management of spent fuel and radioactive waste |
| 9k  | Radiation safety regulations and guides                                  | • Observations related to regulations and guides specific to radiation safety (including observations related to conformance of regulations and guides to GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards) |
| 9l  | Transport safety regulations and guides                                   | • Observations related to regulations and guides specific to safety of transport of radioactive material |
| 9m  | Environmental protection regulations and guides                          | • Observations related to regulations and guides specific to protection of the environment |

**Subject Group 10: Emergency preparedness and response (regulatory aspects)**

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</table>
| 10a | Emergency planning                                                       | • Provisions for timely and effective response to emergencies  
• Authorized party responsibilities  
• Notification  
• Regulatory body response  
• National response system  
• Designation of response organizations |
| 10b | Emergency preparedness and response procedures and guidance             | • Assignment of clear responsibilities  
• Timely and effective decision making  
• Managing emergency response operations  
• Role of regulatory body to provide expert advice and services  
• Managing, controlling and recording doses of emergency workers |
| 10c | Emergency preparedness and response communication and cooperation       | • Effective coordination of and communication between authorized parties and response organizations  
• Arrangements to inform public about emergency preparedness and response, both generally and specifically |
| 10d | Emergency preparedness and response training and exercises              | • Regular conduct of training, drills and exercises  
• Cover full range of postulated emergencies |
**Subject Group 11: interface between safety and security (regulatory aspects)**

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<tr>
<th>No.</th>
<th>Definition</th>
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<tbody>
<tr>
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<td>Interface between safety and security</td>
<td>• Interface between safety and security</td>
</tr>
</tbody>
</table>

**Subject Group 12: Activities for embarking on a nuclear power programme**

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<tr>
<th>No.</th>
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<th>Includes findings related to:</th>
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<tbody>
<tr>
<td>12</td>
<td>Activities for embarking on a nuclear power programme</td>
<td>• Activities identified in IAEA Safety Standard Series No. SSG-16.</td>
</tr>
</tbody>
</table>