ANALYSIS OF IRRS MISSIONS TO MEMBER STATES OF THE EUROPEAN UNION

2018 – 2022
Analysis of the Integrated Regulatory Review Service (IRRS) missions conducted from 2018 to 2022 to member states of the European Union
Executive summary

This report provides an analysis of the Integrated Regulatory Review Service (IRRS) missions conducted from 2018 to 2022 to member states of the European Union (EU). During this period, the Agency conducted 11 initial missions and six follow-up missions to 17 EU member states. The Agency and EU member states can use this report to identify trends and issues that affect regulatory bodies around the world. Where appropriate, comparisons are also made with the results of the previous reporting period (2015 to 2019).

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

Just over 36% of the references are to GSR Part 1 (Rev. 1) Governmental, Legal and Regulatory Framework for Safety. Various IAEA Safety Guides and GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards each account for almost 20% of the references. GSR Part 2 Leadership and Management for Safety accounts for just over 10% of the references and GSR Part 7 Preparedness and Response for a Nuclear or Radiological Emergency accounts for just over 7%.

The following IAEA Safety Requirements were referenced at least ten times for Recommendations and Suggestions:

- 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 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety;
- GSR Part 1 (Rev. 1) Requirement 4: Independence of the regulatory body;
- GSR Part 1 (Rev. 1) Requirement 22: Stability and consistency of regulatory control;
- GSR Part 1 (Rev. 1) Requirement 2: Establishment of a framework for safety;
- GSR Part 1 (Rev. 1) Requirement 32: Regulations and guides;
- GSR Part 2 Requirement 6: Integration of the management system;
- GSR Part 1 (Rev. 1) Requirement 33: Review of regulations and guides;
- GSR Part 1 (Rev. 1) Requirement 27: Inspection of facilities and activities;
- GSR Part 2 Requirement 10: Management of processes and activities;
- GSR Part 2 Requirement 13: Measurement, assessment and improvement of the management system.

During the current reporting period, IRRS missions identified 11 Good Practices. GSR Part 7 accounted for 45% of the references for Good Practices, while GSR Part 1 (Rev. 1) accounted for 30%.

For the analysis by subject group, each Recommendation, Suggestion and Good Practice was assigned to one of 59 subject groups. The subject groups that have more Recommendations or Suggestions should receive further attention, as this may indicate that a number of EU Member States face similar challenges.

The subject groups with at least ten Recommendations and Suggestions were:

- Radiation safety regulations and guides;
- Implementation of authorization process;
- Emergency planning;
- Regulatory body staffing and competence;
• Development of regulations and guides;
• Establishment of the regulatory body management system;
• Framework for safety;
• Inspection procedures and guidance;
• Development of authorization process;
• Development of inspection programme;
• Emergency preparedness and response procedures and guidance;
• Authorization procedures and guidance;
• 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 21 Recommendations and 19 Suggestions, making the topic of procedures and guidance the most frequent observation.

Every IRRS mission where the topic was within the scope of the mission made a Recommendation or Suggestion related to:
• Bringing regulations and guides for occupational exposures and medical exposures into line with GSR Part 3;
• Emergency planning.

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 the follow-up missions conducted during the reporting period, the closure rate for Recommendations and Suggestions directed to EU member state governments is 72%, while the closure rate for Recommendations and Suggestions directed to the regulatory body is 80%. Both are lower than in the previous reporting period. New Recommendations, Suggestions and Good Practices are also normally included in follow-up missions. GSR Part 1 (Rev. 1) and GSR Part 3 each account for about 25% of the references for new Recommendations and Suggestions. Various Safety Guides references account for another 25% of the references.
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1 Introduction

The Integrated Regulatory Review Service

In 2006, the Agency introduced the Integrated Regulatory Review Service (IRRS) to assist Member States to enhance the effectiveness of their national governmental, legal and regulatory framework for safety and to strengthen the capacity of regulatory bodies to discharge their responsibilities and functions in an effective manner, whilst recognizing the ultimate responsibility of each State to ensure safety. The service aims at assisting Member States by facilitating experience sharing among the regulatory bodies and by supporting the application of the IAEA safety standards. IRRS replaced the former IRRT\(^1\) and RaSSIA\(^2\) review services. IRRS also covers the regulatory aspects of EPREV\(^3\) and TranSAS\(^4\) services.

From 2018 to 2022, the Agency conducted 11 initial missions and six follow-up missions to 17 EU member states, compared with 14 initial missions and 14 follow-up missions to 25 Member States during the previous reporting period (2015-2019).

Objective and scope

This report summarizes the analysis of the 17 IRRS missions conducted from 2018 to 2022.

By identifying which IAEA safety requirements are most frequently referenced, EU 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 EU 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 an EU member state, the modular nature of the IRRS service allows EU member states to specify the scope of the review. In many cases, the EU member state requests a review of the entire regulatory programme, while in some cases, the EU 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 EU member state and the decision by the EU member state on what facilities and activities and exposure situations to include in the scope.

This analysis includes data from 17 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 EU member state;
- Evolution of the IRRS process over time.

Where appropriate, comparisons are made with the results of the previous reporting period (2015-2019).

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\(^1\)IRRT: International Regulatory Review Team  
\(^2\)RaSSIA: Radiation Safety and Security Infrastructure Appraisal  
\(^3\)EPREV: Emergency Preparedness Review  
\(^4\)TranSAS: Transport Safety Appraisal Service
**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 is a new addition to the report and shows the most frequently made Recommendations and Suggestions. Chapter 6 is the analysis of information from follow-up missions. Chapter 7 provides some details on IRRS observations regarding the regulation of operating nuclear power plants. Chapter 8 provides some details on IRRS observations regarding the regulation of radioactive sources. Chapter 9 identifies the main issues facing regulatory bodies and provides a conclusion.

**Missions analyzed**

This analysis covers 11 initial and six follow-up IRRS missions to 17 EU member states. Figure 1 shows the year and location of the IRRS missions conducted. Follow-up missions are denoted by (f). A total of 143 peer reviewers were involved in these missions.

<table>
<thead>
<tr>
<th>Austria</th>
<th>Finland</th>
<th>Portugal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary (f)</td>
<td>Croatia (f)</td>
<td>Slovakia</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>Estonia (f)</td>
<td>Slovenia</td>
</tr>
<tr>
<td>Netherlands (f)</td>
<td>Germany</td>
<td>Lithuania (f)</td>
</tr>
<tr>
<td>Spain</td>
<td>Latvia</td>
<td>Malta (f)</td>
</tr>
</tbody>
</table>

**Figure 1 IRRS Missions to EU member states from 2018 to 2022**

**Scope of initial missions**

Figure 2 shows, for the 11 initial IRRS missions, how many included the various topics in the scope of the mission. All initial IRRS missions included occupational exposure and all, but two missions included industrial and medical radioactive sources. No mission included naturally-occurring radioactive material in its scope.

**Figure 2 Activities covered in scope of EU member state initial missions from 2018-2022**
For 2015-2019, the order is different for several review areas.

Figure 3 Activities covered in scope of EU member state initial missions from 2015-2019

2 Background

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 EU member state to ensure safety. Using the IAEA safety standards, the IRRS considers both regulatory technical and regulatory policy issues.

As Figure 4 shows, the IRRS has a modular structure designed to be tailored to both generic and EU member state specific needs and to facilitate the review of circumstances where the scope of regulatory responsibility may be changing.
The modular structure of IRRS changed in 2018 as described in the new IRRS Guidelines, published in December 2018\(^5\). Thematic Areas related to exposure situations, covered previously by Module 11, were reallocated to Modules 5 to 9 as appropriate. Module 12 became Module 11 and a 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 other Modules 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 an outstanding organization, arrangement, programme or performance superior to those generally observed elsewhere.

\(^5\) IAEA Services Series 37 - *Integrated Regulatory Review Service Guidelines*, Vienna, December 2018
In September 2019, the Agency clarified that the following three criteria must all be met for a practice to be considered a Good Practice:

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

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

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.

**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 2018 to 2022 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 of Research Reactors and 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. Except for Module 12, the 36 requirements form the basis for the IRRS as shown in Table 1.

**Table 1 Modules and the associated safety requirements of the IRRS**

<table>
<thead>
<tr>
<th>Module No</th>
<th>GSR Part 1 (Rev. 1) Overarching Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R1: National policy and strategy</td>
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<tr>
<td></td>
<td>R2: Establishment of a framework for safety</td>
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<tr>
<td></td>
<td>R3: Establishment of a regulatory body</td>
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<td></td>
<td>R4: Independence of the regulatory body</td>
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<td></td>
<td>R5: Prime responsibility for safety</td>
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<td></td>
<td>R6: Compliance with regulations and responsbility for safety</td>
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<td></td>
<td>R7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety</td>
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<tr>
<td></td>
<td>R9: System for protective actions to reduce existing or unregulated radiation risks</td>
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<td></td>
<td>R10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel</td>
</tr>
<tr>
<td></td>
<td>R11: Competence for safety</td>
</tr>
<tr>
<td></td>
<td>R13: Provision of technical services</td>
</tr>
<tr>
<td>2</td>
<td>R14: International obligations and arrangements for international cooperation</td>
</tr>
<tr>
<td></td>
<td>R15: Sharing of operating experience and regulatory experience</td>
</tr>
<tr>
<td>3</td>
<td>R16: Organizational structure of the regulatory body and allocation of resources</td>
</tr>
<tr>
<td></td>
<td>R17: Effective independence in the performance of regulatory functions</td>
</tr>
<tr>
<td></td>
<td>R18: Staffing and competence of the regulatory body</td>
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<tr>
<td></td>
<td>R20: Liaison with advisory bodies and support organizations</td>
</tr>
</tbody>
</table>

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6 For ease of reading, whenever *GSR Part 1* is written, the *(Rev. 1)* is omitted, but should be inferred
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.

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

Figure 5 shows how the IRRS mission report identifies the basis for Recommendations, Suggestions and Good Practices.

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Number of Recommendations and Suggestions compared to the previous reporting period

During the current reporting period, peer reviewers made 218 Recommendations and 157 Suggestions in 11 initial missions. During the previous reporting period (2015-2019), peer reviewers made 349 Recommendations and 199 Suggestions in 14 initial missions.

When normalized for the number of missions conducted, the number of Recommendations decreased by 20%, while the number of Suggestions was unchanged.

When normalized for the number of missions conducted, the number of Good Practices decreased by 63% during the current reporting period. Section 4.1 of the report explains this dramatic decrease.

3 Analysis of initial mission Recommendation and Suggestion references to the IAEA safety standards

General references to IAEA safety standards

During the reporting period, IAEA safety standards were referenced 656 times in IRRS Recommendations and Suggestions in 11 initial missions. For comparison, during the previous reporting period, IAEA safety standards were referenced 1111 times in 14 initial missions.

As Figure 6 shows, just over 36% of the references are to GSR Part 1. Various IAEA Safety Guides and GSR Part 3 each account for almost 20% of the references. GSR Part 2 accounts for just over 10% of the references and GSR Part 7 accounts for just over 7%. For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

Referring again to Figure 6, 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.

Figure 6 References to IAEA safety standards

The information presented in Sections 0 to 0 provides useful insights to EU member states on which requirements of GSR Part 1, GSR Part 2, GSR Part 3 and GSR Part 7 they should focus on when developing or revising their national regulatory infrastructure in accordance with the IAEA safety standards.

References to GSR Part 1: Governmental, Legal and Regulatory Infrastructure for Safety

Figure 7 References to GSR Part 1
As Figure 7 shows, every requirement in *GSR Part 1* was referenced by at least one Recommendation and one Suggestion during the reporting period, with the references for Recommendations usually outnumbering the references for Suggestions for a given requirement. For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

The following requirements were referenced more than ten times:

- Requirement 18: Staffing and competence of the regulatory body (20 references);
- Requirement 24: Demonstration of safety for the authorization of facilities and activities (17 references);
- Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety (14 references);
- Requirement 4: Independence of the regulatory body (13 references);
- Requirement 22: Stability and consistency of regulatory control (12 references);
- Requirement 2: Establishment of a framework for safety (11 references);
- Requirement 32: Regulations and guides (11 references);
- Requirement 33: Review of regulations and guides (11 references).

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

- Requirement 5: Prime responsibility for safety;
- Requirement 9: System for protective actions to reduce existing or unregulated risks;
- Requirement 13: Provision of technical services;
- Requirement 21: Liaison between the regulatory body and authorized parties.

Recommendations account for 66% of the references to *GSR Part 1*. This is lower than for *GSR Parts 2 to 7*, where Recommendations tend to account for at least 75% of the references. There are two main reasons for this. The first is that compliance with *GSR Part 1* (primarily enacting a nuclear law and establishing a regulatory body) is necessary for a Member State to begin addressing *GSR Parts 2-7* requirements. This means that in many cases, the Member State does have some provision in place for complying with *GSR Part 1* requirements, so a Recommendation would not be appropriate. However, these provisions may need fine-tuning, making a Suggestion more appropriate. The second reason is that most of the *GSR Part 1* requirements describe an end-state, allowing each Member State to decide how best to achieve compliance. Again, Suggestions may be more appropriate since some provision is likely already in place for compliance. *GSR Parts 2-7* focus on more specific topics, and it is therefore more likely that a Member State has not yet made any provision for compliance, making a Recommendation appropriate.

Finally, Figure 7 shows a similar pattern of distribution of the references as during the previous reporting period.

### References to GSR Part 2: Leadership and Management for Safety

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

The four most common *GSR Part 2* requirements referenced are:

- Requirement 6: Integration of the management system (11 references);
- Requirement 10: Management of processes and activities (10 references);
- Requirement 13: Measurement, assessment and improvement of the management system (10 references);
- Requirement 3: Responsibility of senior management for the management system (9
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.

Finally, except for Requirement 9 (Provision of resources), which is trending up, Figure 8 shows a similar pattern of distribution of the references as during the previous reporting period.

### References to GSR Part 3: *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*

The second most frequently referenced Safety Requirements document was *GSR Part 3*.

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019). The following *GSR Part 3* requirements are referenced five times or more:

- Requirement 38: Optimization of protection and safety for medical exposure (8 references);
- Requirement 36: Responsibilities of registrants and licensees specific to medical exposure (7 references);
- Requirement 2: Establishment of a legal and regulatory framework (6 references);
- Requirement 50: Public exposure due to radon indoors (6 references);
- Requirement 34: Responsibilities of the government specific to medical exposure (5 references);
- Requirement 4: Responsibilities for protection and safety (5 references);
- Requirement 41: Unintended and accidental medical exposures (5 references).
The following *GSR Part 3* requirements are not referenced in any mission:

- Requirement 1: Application of the principles of radiation protection;
- Requirement 10: Justification of practices;
- Requirement 14: Monitoring for verification of compliance;
- Requirement 15: Prevention and mitigation of accidents;
- Requirement 16: Investigations and feedback of information on operating experience;
- Requirement 23: Cooperation between employers and registrants and licensees;
- Requirement 27: Conditions of service (occupational exposure);
- Requirement 39: Pregnant or breast-feeding patients;
- Requirement 43: Emergency management system;
- Requirement 44: Preparedness and response for an emergency;
- Requirement 46: Arrangements for the transition from an emergency exposure situation to an existing exposure situation;
- Requirement 48: Justification for protective actions and optimization of protection and safety (existing exposure situations);
- Requirement 49: Responsibilities for remediation of areas with residual radioactive material.

Finally, Figure 9 shows a similar pattern of distribution of the references as during the previous reporting period.

**References to GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency**

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

The most frequently referenced *GSR Part 7* requirements are:

- Requirement 2: Roles and responsibilities in emergency preparedness and response (9 references);
- Requirement 4: Hazard assessment (7 references);
- Requirement 25: Training, drills and exercises for emergency preparedness and response (7 references);
• Requirement 23: Plans and procedures for emergency preparedness and response (5 references).

Figure 10 References to GSR Part 7

The following requirements were not referenced in any IRRS mission:
• Requirement 1: The emergency management system;
• Requirement 6: Managing operations in emergency response;
• Requirement 7: Identifying and notifying a nuclear or radiological emergency and activating an emergency response;
• Requirement 8: Taking mitigatory actions;
• 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;
• Requirement 24: Logistical support and facilities for emergency response.

Finally, Figure 10 shows that a similar pattern of distribution of the references as during the previous reporting period. The exceptions are Requirements 6 and 7. During the previous reporting period, Requirement 6 (Managing operations in emergency response) was referenced four times. During the previous reporting period, Requirement 7 (Identifying and notifying a nuclear or radiological emergency and activating an emergency response) was one of the most referenced GSR Part 7 requirements.

4 Analysis of initial mission Good Practice references to the IAEA safety standards

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 11 shows the references related to Good Practices.
During the current reporting period, IRRS missions identified 11 Good Practices. *GSR Part 7* accounted for 45% of the references for Good Practices, while *GSR Part 1* accounted for 30%. For *GSR Part 1*, the ratio of Good Practices to Recommendations and Suggestions was 1:40; for *GSR Part 3*, the ratio was around 1:55; for *GSR Part 7*, the ratio was around 1:5. For reference, the light green line shows the number of Good Practices identified during the previous reporting period (2015-2019).

As already mentioned, in September 2019 the Agency clarified the criteria for identifying Good Practices during an IRRS mission. As expected, the number of Good Practices identified is substantially lower than in the previous reporting period, where 29 Good Practices were identified.

**Good Practice references to GSR Part 1**

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

- 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 25: Review and assessment of information relevant to safety;
- Requirement 26: Graded approach to review and assessment of a facility or an activity;
- Requirement 34: Review of regulations and guides;
- Requirement 36: Communication and consultation with interested parties.
Good Practice references to GSR Part 3

The following GSR Part 3 requirements were referenced for a Good Practice:
- Requirement 30: Responsibilities of relevant parties specific to public exposure;
- Requirement 38: Optimization of protection and safety (medical exposure).

Good practice references to GSR Part 7

The following GSR Part 7 requirement was referenced for 3 Good Practices:
- Requirement 22: Coordination of emergency preparedness and response.

The following GSR Part 7 requirements were each referenced once for a Good Practice:
- Requirement 1: The emergency management system;
- Requirement 2: Roles and responsibilities in emergency preparedness and response;
- Requirement 6: Managing operations in an emergency response;
- Requirement 7: Identifying and notifying a nuclear or radiological emergency and activating an emergency response;
- Requirement 9: Taking urgent protective actions and other response actions;
- Requirement 10: Providing instructions, warnings and relevant information to the public for emergency preparedness and response.

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 were not referenced in any mission during the reporting period:
- 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.
5 Analysis of initial mission observations by subject groups

Introduction

Another way of categorizing the observations from IRRS missions is to sort them according to subject. Subjects that more frequently result in Recommendations and Suggestions should receive further consideration, as this may indicate that a number of EU 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 59. Annex A provides more information on the various 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 EU 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 EU member states when reviewing their regulatory infrastructure.

A new feature of the report is the “R&S Trend” in the Tables. This compares the results from the current reporting period from those in the previous reporting period (2015-2019). An up arrow (↑)

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8 The trends are normalized to account for the different number of missions conducted during the reporting periods.
indicates that the number of Recommendations and Suggestions has increased from the previous period; a down arrow (↓) indicates that the number of Recommendations and Suggestions has decreased from the previous period; A dash (-) indicates that the number of Recommendations and Suggestions is similar to that of the previous period.

**Subject Groups related to responsibilities and functions of the government**

There are 9 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) **Decommissioning 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.

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 (dosimetry, environmental monitoring, equipment calibration, etc.); authorization by regulatory body if necessary.

**Table 1 Number of observations for responsibilities and functions of the government**

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a National policy and strategy for safety</td>
<td>6</td>
<td>2</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>1b Framework for safety</td>
<td>12</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>1c Regulatory body independence</td>
<td>5</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>1d Prime responsibility for safety</td>
<td>5</td>
<td>1</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>1e Coordination and cooperation among authorities</td>
<td>2</td>
<td>8</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>1f Protective actions for unregulated sources or contamination from past</td>
<td>2</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>1g Decommissioning and management of radioactive waste and spent fuel</td>
<td>4</td>
<td>1</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>1h Competence for safety</td>
<td>4</td>
<td>2</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>1i Provision of technical services</td>
<td>0</td>
<td>0</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>40</td>
<td>21</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
5.1.1 Highlights of Recommendations and Suggestions

5.1.1.1 National policy and strategy for safety

Many missions recommended or suggested to establish or update a national policy and strategy for safety that is consistent with the IAEA safety standards.

Some missions recommended or suggested to establish 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; and should make provisions, including the funding, for the safe decommissioning of facilities and the safe disposal of radioactive waste.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.1.2 Framework for safety

Many missions recommended or suggested that the legal framework be consistent with the IAEA safety standards.

A few missions recommended or suggested that the legal framework clearly delineate the roles, responsibilities and authorities of the various entities in the EU member state.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.1.3 Regulatory body independence

Many missions recommended or suggested 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.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.1.4 Prime responsibility for safety

A few missions recommended or suggested that legislation explicitly assign primary responsibility for safety to the persons or organizations responsible for facilities and activities.

Two missions recommended or suggested that provisions be in place such that authorized parties are responsible for verifying that products and services provided by contractors and suppliers meet expectations.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.1.5 Coordination and cooperation among authorities

Most missions recommended or suggested that arrangements be in place 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.

The relative number of Recommendations and Suggestions is consistent with those in the previous
reporting period and focus on similar issues.

5.1.1.6 **Protective actions for unregulated sources or contamination from past activities or events**

Two missions recommended or suggested that the EU 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.

Two missions recommended or suggested that the EU 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.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.1.7 **Decommissioning and management of radioactive waste and spent fuel**

A few missions recommended or suggested that the EU 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 recommended or suggested that the EU member state ensure adequate funding for the safe decommissioning of facilities and the safe disposal of radioactive waste.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.1.8 **Competence for safety**

Some missions recommended or suggested that the EU member state have provisions to ensure the competence of all parties having responsibilities for the safety of facilities and activities.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.1.9 **Provision of technical services**

No mission to an EU member state made any observations related to the provision of technical services.

During the previous reporting period, recommendations or suggestions were made to qualify or authorize technical services and to ensure that appropriate dosimetry services are available. These issues did not arise in the current reporting period.

**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:** Fulfiling 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 9 observations were related to the Global Nuclear Safety Regime, the second fewest of any module. Most observations were related to operating and regulatory experience.

**Table 2 Number of observations for Global Nuclear Safety Regime**

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a International obligations and arrangements for international assistance and cooperation</td>
<td>1</td>
<td>2</td>
<td>↓</td>
<td>1</td>
</tr>
<tr>
<td>2b Bilateral and multilateral arrangements</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>2c Operating and regulatory experience</td>
<td>1</td>
<td>4</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>2</td>
<td>6</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

5.1.2 Highlights of Recommendations and Suggestions

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

Two missions recommended or suggested that the EU member state makes resources available to enable active participation in international safety cooperation activities.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.2.2 **Bilateral and multilateral arrangements**

There were no Recommendations or Suggestions made regarding bilateral and multilateral arrangements in either the current reporting period or the previous reporting period.

5.1.2.3 **Operating and regulatory experience**

Some missions recommended or suggested 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 EU member state and internationally.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.3 Good Practice

Active participation in many international activities related to nuclear safety shows how small non-nuclear countries can contribute to enhance global safety regime.

**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 40 observations related to the responsibilities and functions of the regulatory body. The most frequently identified subject group was regulatory body staffing and competence.

### Table 3: Number of observations for regulatory body responsibilities and functions

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a Organization of the regulatory body and allocation of resources</td>
<td>1</td>
<td>5</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>10</td>
<td>7</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>3c External involvement in the regulatory process</td>
<td>2</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>3d Stability and consistency of regulatory control</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>3e Safety related records</td>
<td>1</td>
<td>3</td>
<td>↓</td>
<td>2</td>
</tr>
<tr>
<td>3f Communication and consultation with interested parties</td>
<td>1</td>
<td>5</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>15</td>
<td>23</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

### 5.1.4 Highlights of Recommendations and Suggestions

#### 5.1.4.1 Organization of regulatory body and allocation of resources

Some missions recommended or suggested that the regulatory body prioritizes its tasks and allocate and manage resources using a graded approach.

In the previous reporting period, some missions recommended or suggested that the regulatory body has the authority to organize as it sees fit and allocate its resources accordingly, but that issue only arose in one mission during the current reporting period.

#### 5.1.4.2 Regulatory body staffing and competence

Most missions recommended or suggested that the regulatory body develops, maintains or enhances a long-term human resource plan to ensure the availability and competence of staff.
Some missions recommended or suggested that the regulatory body creates or implements comprehensive training plans for its staff.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on similar issues.

5.1.4.3 External involvement in the regulatory process

Two missions recommended or suggested that the regulatory body establishes external advisory bodies to obtain technical or other expert professional advice in support of its regulatory functions.

Although the relative number of Recommendations and Suggestions is trending down, they focus on similar issues.

5.1.4.4 Stability and consistency of regulatory control

One mission suggested that the regulatory body finalizes the update of its environmental programme.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.4.5 Safety related records

A few missions recommended or suggested that the regulatory body enhances safety-related record-keeping.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.4.6 Communication and consultation with interested parties

Many missions recommended or suggested that the regulatory body defines 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.

The relative number of Recommendations and Suggestions is trending down. During the previous reporting period, a few missions recommended or suggested that the regulatory body inform the public regarding doses from nuclear and radiological facilities and activities. This issue did not arise during the current reporting period.

5.1.5 Good Practices

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 Spain. It provides an excellent tool for the competent authority to improve and facilitate the implementation of its compliance assurance programme.

The active integration of relevant information from other national registers into the regulatory body’s Central Record Management provides an early warning on authorized parties capabilities that enables intervention prior to potential loss of control of radiation sources.
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) Leadership and culture for safety for the regulatory body: Fostering and supporting safety culture; developing and reinforcing leadership; developing and reinforcing good safety attitudes.

Table 5 shows that there were 37 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 4 Number of observations for regulatory body management system

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a Establishment of the regulatory body management system</td>
<td>13</td>
<td>1</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>4b Implementation of the regulatory body management system</td>
<td>2</td>
<td>6</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>4c Assessment and review of the regulatory body management system</td>
<td>7</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>4d Leadership and culture for safety for the regulatory body</td>
<td>5</td>
<td>1</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>27</td>
<td>10</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

5.1.6 Highlights of Recommendations and Suggestions

5.1.6.1 Establishment of the regulatory body management system

Most missions recommended or suggested 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.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.6.2 Implementation of the regulatory body management system

Some missions recommended or suggested that the regulatory body better document its management system.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.6.3 Assessment and review of the regulatory body management system

Some missions recommended or suggested that the regulatory body put provisions in place for both self-assessment and independent assessment of the management system.
Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.6.4 Leadership and culture for safety for the regulatory body

Some missions recommended or suggested that the regulatory body further develop its safety culture.

Although the relative number of Recommendations and Suggestions is trending up, the same issues continue to result in observations and no new issues are emerging.

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 48 observations, the third highest for a module. Table 6 shows that development of the authorization process, implementation of the authorization process and authorization procedures and guidance had high number of observations.

Table 5 Number of observations for authorization

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a  Development of authorization process</td>
<td>9</td>
<td>4</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>5b  Implementation of authorization process</td>
<td>10</td>
<td>10</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>5c  Graded approach to authorization</td>
<td>0</td>
<td>1</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>5d  Authorization procedures and guidance</td>
<td>6</td>
<td>4</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>5e  Competence of authorized party staff</td>
<td>2</td>
<td>2</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>27</td>
<td>21</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

5.1.7 Highlights of Recommendations and Suggestions

5.1.7.1 Development of authorization process

Many missions recommended or suggested 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 recommended or suggested that the regulatory body establish objective and clear criteria for the amendment, renewal, suspension or revocation of an authorization.
Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.7.2 Implementation of authorization process

Some missions recommended or suggested that authorizations include facility or activity specific limits, conditions and controls.

Some missions recommended or suggested that the regulatory body require the submission of an adequate demonstration of safety in support of an application for authorization.

Although the relative number of Recommendations and Suggestions is trending up, the same issues continue to result in observations and no new issues are emerging.

5.1.7.3 Graded approach to authorization

One mission suggested that the regulatory body enhance its graded approach to authorization.

Although the relative number of Recommendations and Suggestions is trending down, the same issue continues to result in observations and no new issues are emerging.

5.1.7.4 Authorization procedures and guidance

Some missions recommended or suggested that the regulatory body have objective and clear criteria and procedures for issuing, amending, renewing, suspending and revoking an authorization.

Although the relative number of Recommendations and Suggestions is trending up, the same issue continues to result in observations and no new issues are emerging.

5.1.7.5 Competence of authorized party staff

A few missions recommended or suggested that the EU member state have a process to formally recognize qualified experts.

Although the relative number of Recommendations and Suggestions is trending down, the same issue continues to result in observations and no new issues are emerging.

Subject Groups related to review and assessment

There are five subject groups related to review and assessment:

a) 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.

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

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

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

e) Authorized party safety culture: Review and assessment of authorized party safety culture.

Table 7 shows that 23 observations were related to review and assessment.
Table 6 Number of observations for review and assessment

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>6a Development of review and assessment process</td>
<td>6</td>
<td>2</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>6b Implementation of review and assessment process</td>
<td>5</td>
<td>1</td>
<td>↑</td>
<td>1</td>
</tr>
<tr>
<td>6c Graded approach to review and assessment</td>
<td>2</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>6d Review and assessment procedures and guidance</td>
<td>2</td>
<td>2</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>6e Authorized party safety culture</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>16</td>
<td>5</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

5.1.8 Highlights of Recommendations and Suggestions

5.1.8.1 Development of review and assessment process

Some missions recommended or suggested that the regulatory body develop or update its integrated review and assessment process.

Although the relative number of Recommendations and Suggestions is trending up, this is the same issue as in the previous reporting period.

5.1.8.2 Implementation of review and assessment process

Some missions recommended or suggested that the regulatory body implement the procedures included in its review and assessment process.

Although the relative number of Recommendations and Suggestions is trending up, this is the same issue as in the previous reporting period.

5.1.8.3 Graded approach to review and assessment

A few missions recommended or suggested that the regulatory body establish practice-specific procedures to ensure consistency and the application of a graded approach in the review and assessment process.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.8.4 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.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.8.5 Authorized party safety culture

There were no Recommendations or Suggestions related to authorized party safety culture during the reporting period. In the previous reporting period, two missions recommended or suggested that the regulatory body establish and implement systematic oversight of authorized party safety culture.
5.1.9 Good Practices

The regulatory body has implemented a systematic model for continuous overall safety assessment of nuclear facilities which allows it to regularly monitor the licensees’ overall safety and take adequate measures based on the results.

The DosReg portal is a very comprehensive tool for supervision and optimisation of patient dosimetry, both for licensees and for the regulatory body. Additionally, the data on hospitals, equipment and typical doses for procedures, including clinical indication, being open access, allows any interested party to find relevant benchmarks for patient dosimetry.

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 34 observations related to inspections by the regulatory body.

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>7a Development of inspection programme</td>
<td>8</td>
<td>4</td>
<td>↑</td>
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</tr>
<tr>
<td>7b Implementation of inspection programme</td>
<td>2</td>
<td>4</td>
<td>-</td>
<td>0</td>
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<tr>
<td>7c Graded approach to inspection</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>7d Inspection procedures and guidance</td>
<td>7</td>
<td>7</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>Σ Sum of observations</td>
<td>18</td>
<td>16</td>
<td></td>
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</tr>
</tbody>
</table>

5.1.10 Highlights of Recommendations and Suggestions

5.1.10.1 Development of inspection process

Most missions recommended or suggested that the regulatory body develop or modify its inspection programme and planning process so that all regulated facilities and activities are inspected, and that the inspection programme use a graded approach.

Some missions recommended or suggested that the regulatory body included unannounced inspections in its inspection programme.

Although the relative number of Recommendations and Suggestions is trending up, the same issues continue to result in observations and no new issues are emerging.
5.1.10.2 Implementation of inspection process

Some missions recommended or suggested that the regulatory body implement its inspection programme as designed.

The relative number of Recommendations and Suggestions is consistent with the previous reporting period and focus on similar issues.

5.1.10.3 Graded approach to inspection

Two missions recommended or suggested that the regulatory body apply the graded approach when planning and conducting inspections.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.10.4 Inspection procedures and guidance

Many missions recommended or suggested that the regulatory body develop, approve and/or implement inspection procedures.

Although the relative number of Recommendations and Suggestions is trending up, the same issues continue to result in observations and no new issues are emerging.

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 remedying 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 13 observations related to enforcement. Table 9 shows that most of the observations in Module 8 relate to the development of the enforcement policy.

Table 8 Number of observations for enforcement

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>8a Development of enforcement policy</td>
<td>5</td>
<td>3</td>
<td>-</td>
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<tr>
<td>8b Implementation of enforcement policy</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>8c Graded approach to enforcement</td>
<td>0</td>
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<tr>
<td>8d Enforcement procedures and guidance</td>
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<tr>
<td>Σ Sum of observations</td>
<td>6</td>
<td>7</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
5.1.11 Highlights of Recommendations and Suggestions

5.1.11.1 Development of enforcement policy

Many missions recommended or suggested that the regulatory body establish an enforcement policy that covers all regulated facilities and activities.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.11.2 Implementation of enforcement policy

A few missions recommended or suggested that the regulatory body have provisions to ensure that authorized parties implement necessary corrective actions.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.11.3 Graded approach to enforcement

There were no Recommendations or Suggestions related to the graded approach to enforcement during either the previous or the current reporting period.

During the previous reporting period, there was one Suggestions regarding the graded approach to enforcement.

5.1.11.4 Enforcement procedures and guidance

Two missions suggested that the regulatory body issue procedures or improve its guidance regarding its enforcement policy.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

Subject Groups related to regulations and guides

There are 13 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) Not in use

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

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

h) Fuel cycle facility regulations and guides: Findings related to regulations and guides specific to fuel cycle facilities.
i) **Decommissioning of nuclear facilities regulations and guides**: Findings related to regulations and guides specific to decommissioning of nuclear facilities.

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

k) **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.

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

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

There were 78 observations related to regulations and guides, the most of any module. As Table 10 shows, more than 40% of these observations were related to radiation safety regulations and guides. There were also many observations related to the development of regulations and guides.

Table 9 Number of observations for regulations and guides

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>9a Development of regulations and guides</td>
<td>11</td>
<td>4</td>
<td>↑</td>
<td>0</td>
</tr>
<tr>
<td>9b Review of regulations and guides</td>
<td>3</td>
<td>6</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9c Promotion of regulations and guides</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9d Graded approach to regulations and guides</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9e Implementation of International Basic Safety Standards (not in use)</td>
<td>1</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9f Nuclear power plant regulations and guides</td>
<td>1</td>
<td>1</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>9g Research reactor regulations and guides</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9h Fuel cycle facility regulations and guides</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9i Decommissioning of nuclear facilities regulations and guides</td>
<td>0</td>
<td>3</td>
<td>↓</td>
<td>0</td>
</tr>
<tr>
<td>9j Spent fuel and radioactive waste management regulations and guides</td>
<td>4</td>
<td>5</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>9k Radiation safety regulations and guides</td>
<td>21</td>
<td>13</td>
<td>↓</td>
<td>0</td>
</tr>
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<td>9l Transport safety regulations and guides</td>
<td>3</td>
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<td>9m Environmental protection regulations and guides</td>
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<tr>
<td>Σ Sum of observations</td>
<td>44</td>
<td>34</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

5.1.12  Highlights of Recommendations and Suggestions

5.1.12.1 Development of regulations and guides

Most missions recommended or suggested that regulations and guides that take into account internationally agreed standards be in place for all regulated facilities and activities.

Although the relative number of Recommendations and Suggestions is trending up, the same issues continue to result in observations and no new issues are emerging.

5.1.12.2 Review of regulations and guides

Many missions recommended or suggested that the regulatory body develop and implement a process to periodically review and revise its regulations and guides, considering international standards, latest developments of science and technology, and lessons learned.

The relative number of Recommendations and Suggestions is consistent with those in the previous
reporting period and focus on the same issue.

5.1.12.3 Promotion of regulations and guides

There were no Recommendations or Suggestions regarding the promotion of regulations or guides. There were no Recommendations or Suggestions during the previous reporting period.

5.1.12.4 Graded approach to regulations and guides

There were no Recommendations or Suggestions regarding a graded approach to regulations or guides. During the previous reporting period, there was one Suggestion.

5.1.12.5 Nuclear power plant regulations and guides

One mission recommended that the regulatory body update its nuclear power plant regulations and guides to reflect international guidance. During the previous reporting period, there were no Recommendations or Suggestions regarding nuclear power plant regulations or guides.

5.1.12.6 Research reactor regulations and guides

Two missions recommended or suggested that the regulatory body update research reactor regulations and guides in line with the IAEA safety standards.

During the previous reporting period, a few missions recommended that the regulatory body establish requirements and guidance on conducting periodic safety reviews of research reactors. This did not arise in the current reporting period.

5.1.12.7 Fuel cycle facility regulations and guides

There were no Recommendations or Suggestions regarding fuel cycle facility of regulations or guides during either the current reporting period or the previous reporting period.

5.1.12.8 Decommissioning of nuclear facilities regulations and guides

One mission suggested that regulations and guides cover all aspects of decommissioning in line with GSR Part 6: Decommissioning of Facilities.

Although the relative number of Recommendations and Suggestions is trending down, the same issue continues to result in observations.

5.1.12.9 Spent fuel and radioactive waste management regulations and guides

Many missions recommended or suggested that the EU 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.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issues.

5.1.12.10 Radiation safety regulations and guides

Every mission where occupational exposure was included in the scope of the mission recommended or suggested that regulations related to occupational exposures be brought in line with GSR Part 3.
Most missions where medical exposure was included in the scope of the mission recommended or suggested that regulations related to medical exposures be brought in line with *GSR Part 3*.

Many missions where public exposure was included in the scope of the mission recommended or suggested that regulations related to public exposure and discharge limits from facilities be brought in line with *GSR Part 3*.

Some missions recommended or suggested that regulations related to commodities and consumer products be brought in line with *GSR Part 3*. This was not an issue in the previous reporting period.

Some missions recommended or suggested that the EU member state explicitly address the concept of clearance and establishing clearance criteria as specified in *GSR Part 3*.

During the previous reporting period, a few missions recommended or suggested that EU member states ensure that the conditions of service of radiation workers are independent of whether they are or could be professionally exposed. This was not an issue during the current reporting period.

### 5.1.12.11 Transport safety regulations and guides

Three missions recommended or suggested 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*.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

### 5.1.12.12 Environmental protection regulations and guides

Two missions recommended that requirements and guidance be in place with respect to discharge limits for all regulated facilities.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

### 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 36 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.
<table>
<thead>
<tr>
<th>Subject groups in Module 10</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>10a Emergency planning</td>
<td>11</td>
<td>6</td>
<td>↓</td>
<td>3</td>
</tr>
<tr>
<td>10b EPR procedures and guidance</td>
<td>6</td>
<td>4</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>10c EPR communication and cooperation</td>
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<td>10d EPR training and exercises</td>
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<td>0</td>
</tr>
<tr>
<td>Σ Sum of Observations</td>
<td>20</td>
<td>13</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

5.1.13 Highlights of Recommendations and Suggestions

5.1.13.1 Emergency planning

Every mission where emergency preparedness and response were included in the scope of the mission recommended or suggested that the EU member state have in place, and regularly review and test, emergency plans in line with GSR Part 7.

Some missions made a Recommendation or Suggestion related to the protection and training of emergency response personnel, including medical personnel who may be called upon to treat radiation exposure.

Although the relative number of Recommendations and Suggestions is trending down, the same issues continue to result in observations and no new issues are emerging.

5.1.13.2 Emergency preparedness and response procedures and guidance

Many missions recommended or suggested that the regulatory body develop or update its regulations and guidance regarding emergency preparedness and response consistent with GSR Part 7.

During the previous reporting period, a few missions recommended or suggested that the regulatory body establish criteria for designating emergency workers and make arrangements for their protection.

5.1.13.3 Emergency preparedness and response communication and cooperation

Some missions made recommendations or suggestions regarding the improvement of communication and cooperation among organizations involved in emergency preparedness and response.

The relative number of Recommendations and Suggestions is consistent with those in the previous reporting period and focus on the same issue.

5.1.13.4 Emergency preparedness and response training and exercises

Two missions recommended or suggested that the regulatory body periodically assess licensees’ emergency response drills and exercises.

Although the relative number of Recommendations and Suggestions is trending down, the same issue continues to result in observations and no new issues are emerging.
5.1.14 Good Practices

- The strong integration of the radiological and nuclear emergency response arrangements into the national all-hazards emergency management system. A single all hazard response structure is used, leveraging the expertise of the regulatory body effectively for nuclear emergencies;
- When making protective action decisions during a nuclear emergency in another country, the government default action is to implement the same protective actions as that country prescribed for its residents. Coordinating response actions with another country 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.

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.

There were five observations related to the regulatory aspects of the interface between safety and nuclear security, the fewest of any module.

Table 11 Number of observations for interface between safety and security

<table>
<thead>
<tr>
<th>Module 11</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 Interface between safety and nuclear security</td>
<td>3</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

5.1.15 Highlights of Recommendations and Suggestions

Three missions suggested that the EU member state ensure that nuclear security measures do not compromise safety and that safety measures do not compromise nuclear security. Similar suggestions were made during the previous reporting period.

5.1.16 Good Practice

The regulatory body’s activities with regards to organising and conducting emergency exercises based on realistically simulated cyberattacks leading to a safety and nuclear security event were found remarkable for effective training and management of the interface between safety and nuclear security.

Overall analysis of subject groups

Figure 14 shows the subject groups with at least ten Recommendations and Suggestions during the current review period. For reference, the orange line shows the number of Recommendations and Suggestions during the previous review period (2015-2019).

The largest number of Recommendations and Suggestions relate to radiation safety regulations and guides. However, 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. When taken together, they account for 21 Recommendations and 19 Suggestions, making the topic of procedures and guidance the most frequent observation.
Figure 14 Subject groups with highest number of Recommendations and Suggestions

Figure 15 shows the subject groups with a Good Practice.

**Emerging trends**

There were no issues identified in the current reporting period that were had not been previously identified.

**Declining trends**

The following issues were present during the previous reporting period, but were not significant in the current reporting period:

- Recommendations or Suggestions to establish a process for the formal recognition of qualified experts;
• Recommendations or Suggestions that the regulatory body have the authority to organize as it sees fit and allocate its resources accordingly;
• Recommendations or Suggestions that the regulatory body inform the public regarding doses from nuclear and radiological facilities and activities;
• Recommendations or Suggestions that the regulatory body establish and implement systematic oversight of authorized party safety culture;
• Recommendations or Suggestions that the regulatory body establish requirements and guidance on conducting periodic safety reviews of research reactors;
• Recommendations or Suggestions that EU member states ensure that the conditions of service of radiation workers are independent of whether they are or could be professionally exposed;
• Recommendations or Suggestions that the regulatory body establish criteria for designating emergency workers and make arrangements for their protection.

6 Follow-up missions

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 24 to 48 months after the initial mission. Twenty-four months allow significant progress to be made with the implementation of the recommendations and suggestions of the initial IRRS mission. Beyond 48 months, the effectiveness of the follow-up process may be limited, yet still useful. Sometimes, it may be more appropriate for a member state to request a new initial mission.

Figure 16 Time between initial and follow-up missions

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 follow-up missions conducted during the reporting period, Figure 16 shows the number of months between the initial and follow-up mission. The shortest time interval was 30 months, while the longest was 61 months.

Closure rates for Recommendations and Suggestions

For the EU member states that did host a follow-up mission during the reporting period, there were
303 Recommendations and Suggestions made during the initial missions. Of these, 241 were closed during the follow-up mission, while 62 remained open. The overall closure rate for Recommendations and Suggestions was just under 80%. The closure rate for individual EU member states varied from 57% to 98%. Two EU member states had a closure rate of greater than 90%.

During the initial missions, the Recommendations and Suggestions are directed to either the EU 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, 11 Recommendations and Suggestions were directed to both the government and the regulatory body, 64 Recommendations and Suggestions were directed to the government alone and 228 Recommendations and Suggestions were directed to the regulatory body alone.

Of the 75 Recommendations and Suggestions directed to EU member state governments, 58 were closed during the follow-up mission, while 17 remained open. Overall, the closure rate for EU member state governments is 77%. Of the 239 Recommendations and Suggestions directed to regulatory bodies, 192 were closed during the follow-up mission, while 47 remained open. Overall, the closure rate for regulatory bodies is just over 80%. For comparison, during the previous reporting period (2015-2019), the overall closure rate for EU member state governments was higher at 85%, while that of the regulatory bodies was higher at 86%.

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:

- Building and maintaining competence for nuclear and radiological safety;
- 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;
- Enhancements to emergency preparedness;
- Providing regulatory bodies with sufficient financial and human resources.

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. Five of the six follow-up missions 2018 to 2022 included new observations. Two Recommendations and one Suggestion were directed to the EU member state government, while five Recommendations and six Suggestions were directed to the regulatory body. None of the follow-up missions identified a Good Practice.
As Figure 17 shows, GSR Part 1 accounts for almost 40% of the references for new observations. No individual requirement was referenced more than once in follow-up mission Recommendations or Suggestions.

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

#### Introduction

Some IRRS missions reviewed the regulation of operating NPPs. In total, 74 Recommendations, 84 Suggestions and 5 Good Practices identified during IRRS missions relate to the regulation of operating NPPs. Note that many of these Recommendations and Suggestions are not exclusively associated with the regulation of operating NPPs.

#### Reference to IAEA safety standards

##### 7.1.1 Overall references to IAEA safety standards

As Figure 18 shows, GSR Part 1 (Rev. 1) accounts for almost 40% of the references for observations related to the regulation of operating NPPs. Various Safety Guides accounted for just over 25% of the findings, with GSR Part 2, GSR Part 3 and GSR Part 7 each accounting for around 10% of the references. For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).
7.1.2 References to GSR Part 1

As Figure 19 shows, GSR Part 1 requirements referenced more than five times are:

- Requirement 18: Staffing and competence of the regulatory body (12 references);
- Requirement 4: Independence of the regulatory body (seven references);
- Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety (seven references);
- Requirement 2: Establishment of a framework for safety (six references);
- Requirement 19: The management system of the regulatory body (six references);
- Requirement 32: Regulations and guides (six references).

Figure 19 also shows that the following GSR Part 1 requirements are not referenced for any IRRS observation related to an operating NPP:
• Requirement 6: Compliance with regulations and responsibility for safety;  
• 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;  
• Requirement 23: Authorization of facilities and activities by the regulatory body;  
• Requirement 27: Inspection of facilities and activities.

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

### 7.1.3 Good practice references

IRRS missions identified five Good Practices related to the regulation of operating NPPs during the reporting period.

The following *GSR Part 1* requirements were each referenced once for a Good Practice during the reporting period:

- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for, and control of, nuclear material;
- Requirement 25: Review and assessment of information relevant to safety;
- Requirement 26: Graded approach to review and assessment of a facility or an activity;
- Requirement 34: Promotion of regulations and guides to interested parties;
- Requirement 36: Communication and consultation with interested parties.

Two *GSR Part 7* requirements were referenced for a Good Practice during the reporting period:

- Requirement 2: Roles and responsibilities in emergency preparedness and response;
- Requirement 22: Coordination of emergency preparedness and response (2 references).

### Analysis by subject group

Table 13 shows the subject groups with the highest number of Recommendations and Suggestions related to operating NPPs. For the four subject groups that are trending upward, the Agency and EU member states may wish to conduct further analysis on these trends.

### Table 13 Subject Groups with the highest number of observations related to operating NPPs

<table>
<thead>
<tr>
<th>Subject group</th>
<th>R</th>
<th>S</th>
<th>R&amp;S Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>4</td>
<td>6</td>
<td>↑</td>
</tr>
<tr>
<td>7d Inspection procedures and guidance</td>
<td>4</td>
<td>5</td>
<td>↑</td>
</tr>
<tr>
<td>4c Assessment and review of the management system</td>
<td>7</td>
<td>1</td>
<td>↑</td>
</tr>
<tr>
<td>9a Development of regulations and guides</td>
<td>5</td>
<td>3</td>
<td>↑</td>
</tr>
<tr>
<td>10a Emergency planning</td>
<td>4</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>5b Implementation of the authorization process</td>
<td>3</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>1c Regulatory body independence</td>
<td>4</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>9b Review of regulations and guides</td>
<td>2</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>1e Coordination and cooperation among authorities</td>
<td>1</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>7a Development of inspection process</td>
<td>2</td>
<td>3</td>
<td>-</td>
</tr>
</tbody>
</table>
8 Analysis of IRRS missions related to the regulation of radioactive sources

Introduction

All but one of the IRRS missions conducted during the review period included a review of the regulatory control of radioactive sources. In total, these missions identified 197 Recommendations, 113 Suggestions and 9 Good Practices related to the regulatory control of radioactive sources. Many of these Recommendations and Suggestions are not exclusively associated with the regulation of radioactive sources.

Reference to IAEA safety standards

8.1.1 Overall references to IAEA safety standards

As Figure 20 shows, just over one third of the Recommendations and Suggestions related to the regulation of radioactive sources reference GSR Part 1 and almost 20% of the observations reference GSR Part 3. Around 15% of the observations reference various Safety Guides, while GSR Part 7 and GSR Part 2 each account for around 10%. For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

![Figure 20](image)

Figure 20 References to IAEA safety standards for observations related to radioactive sources

8.1.2 References to GSR Part 1

As Figure 21 shows, the following GSR Part 1 requirements were most frequently referenced with respect to the regulation of radioactive sources:

- Requirement 18: Staffing and competence of the regulatory body (18 references);
- Requirement 4: Independence of the regulatory body (11 references);
- Requirement 7: Coordination of different authorities with responsibilities within the regulatory framework (11 references);
- Requirement 33: Review of regulations and guides (11 references);
- Requirement 32: Regulations and guides (10 references);
- Requirement 19: The management system of the regulatory body (9 references);
• Requirement 24: Demonstration of safety for the authorization of facilities and activities (9 references).

Figure 21 References to GSR Part 1 for observations related to radioactive sources

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

The following GSR Part 1 requirements were only referenced once with respect to the regulation of radioactive sources:

• Requirement 9: System for protective actions to reduce existing or unregulated radiation risks;
• Requirement 13: Provision of technical services;
• Requirement 21: Liaison between the regulatory body and authorized parties.

8.1.3 References to GSR Part 2

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

Figure 22 References to GSR Part 2 for observations related to radioactive sources
Figure 22 shows that the following GSR Part 2 requirements are referenced most frequently for Recommendations and Suggestions associated with the regulation of radioactive sources:

- Requirement 6: Integration of the management system (11 references);
- Requirement 13: Measurement, assessment and improvement of the management system (ten references);
- Requirement 10: Management of processes and activities (nine references);
- Requirement 3: Responsibility of senior management for the management system (eight references);
- Requirement 9: Provision of resources (eight references).

Figure 22 also shows that Requirement 1 (Achieving the fundamental safety objective) and Requirement 11 (Management of the supply chain) were not referenced.

8.1.4 References to GSR Part 3

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019). 

Figure 23 References to GSR Part 3 for observations related to radioactive sources

Figure 23 shows that the following GSR Part 3 requirements are referenced most frequently for Recommendations and Suggestions associated with the regulation of radioactive sources:

- Requirement 38: Optimization of protection and safety for medical exposure (eight references);
- Requirement 36: Responsibilities of registrants and licensees specific to medical exposure (seven references);
- Requirement 2: Establishment of a legal and regulatory framework (six references);
- Requirement 4: Responsibilities for protection and safety (five references);
- Requirement 34: Responsibilities of the government specific to medical exposure (five references);
- Requirement 41: Unintended and accidental medical exposures (five references).
8.1.5 References to GSR Part 7

For reference, the orange line shows the number of Recommendations and Suggestions made during the previous reporting period (2015-2019).

Figure 24 shows that the following GSR Part 7 requirements are referenced most frequently for Recommendations and Suggestions associated with the regulation of radioactive sources:

- Requirement 2: Roles and responsibilities in emergency preparedness and response (eight references);
- Requirement 4: Hazard assessment (seven references);
- Requirement 25: Training, drills and exercises for emergency preparedness and response (seven references).

![Figure 24 References to GSR Part 7 for observations related to radioactive sources](image)

**Analysis by subject group**

Table 14 shows the subject groups that had more than 30 Recommendations and Suggestions related to regulation of radioactive sources. Most of these are also trending up. The Agency and EU member states may wish to examine these further to determine the reason for these upward trends.

**Table 14 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>
<th>R&amp;S Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>9k Radiation safety regulations and guides</td>
<td>20</td>
<td>9</td>
<td>↓</td>
</tr>
<tr>
<td>5b Implementation of authorization process</td>
<td>9</td>
<td>8</td>
<td>↑</td>
</tr>
<tr>
<td>3b Regulatory body staffing and competence</td>
<td>10</td>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>10a Emergency planning</td>
<td>11</td>
<td>4</td>
<td>↓</td>
</tr>
<tr>
<td>4a Establishment of the regulatory body management system</td>
<td>12</td>
<td>1</td>
<td>↓</td>
</tr>
<tr>
<td>9a Regulations and guides</td>
<td>10</td>
<td>2</td>
<td>↑</td>
</tr>
<tr>
<td>1b Framework for safety</td>
<td>10</td>
<td>1</td>
<td>↓</td>
</tr>
<tr>
<td>5a Development of authorization process</td>
<td>8</td>
<td>2</td>
<td>↓</td>
</tr>
</tbody>
</table>
9 Conclusion

Every mission where the topic was in scope included a recommendation or suggestion to:

- Bring occupational exposures in line with GSR Part 3;
- Emergency planning.

The analysis did not identify any emerging issues that the Agency or EU member states need to further analyze. A number of issues that were of concern in the previous reporting period were not significant during the current reporting period.

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 EU member states.
## Annex A: Subject group definitions

(Unless noted otherwise, all references are to *GSR Part I (Rev. 1)*)

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

<table>
<thead>
<tr>
<th>Subject Group</th>
<th>Description</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 1a            | National policy and strategy for safety | – Establishing the policy and strategy (R1; GSR Part 5 R2; GSR Part 6 R9; CofCRS para 7, 13, 14)  
– Using a graded approach (R1, para 2.4)  
– Accounting for national circumstances (R1)  
– Achieving the fundamental safety objective (R1, para 2.3a)  
– Applying the fundamental safety principles (R1, para 2.3a)  
– Having a long-term commitment to safety (para 2.3)  
– Stating the government intent (para 2.3)  
– Setting out mechanisms for implementation (para 2.3)  
– Accounting for international legal instruments (para 2.3b)  
– Establishing the scope for governmental, legal and regulatory framework (para 2.3c)  
– Providing for human and financial resources (para 2.3d)  
– Providing for research and development (2.3e)  
– Accounting for social and economic developments (2.3f)  
– Promoting leadership for safety (2.3g)  
– Principles of radiation protection applied (GSR Part 3 R1)  
– Management of existing exposure situations (GSR Part 3 R47; R48, R49, R50) |
| 1b            | Framework for safety | – Up-to-date comprehensive national nuclear law, regulations, decrees and orders as necessary (R2, para 2.5, 2.6; GSR Part 5 R1; GSR Part 6 R4; CofCRS para 8, 18, 19)  
– RB established (para 2.5(7), R3, para 4.6; CofCRS para 21)  
– Sufficient legal authority for RB (R3, para 2.8a, 2.12, 2.13, CofCRS para 20, 22)  
– Sufficient financial resources for RB (para 2.8b)  
– Framework for protection and safety (GSR Part 3 R2) |
| 1c            | RB Independence | – Effectively independent in its decision-making (R4, para 2.8c)  
– Functional separation from entities that could unduly influence decision-making (R4, para 4.9)  
– Able to perform functions without undue pressure or constraint (para 2.7, 2.8d)  
– Able to give independent advice and provide reports to highest levels of government (para 2.8e)  
– Able to liaise directly with other RBs and with international organizations (para 2.8f)  
– No conflicting responsibilities (para 2.9, R17)  
– No conflicts of interests, including authorized parties that are government organizations (para 2.10, 2.11, 4.7)  
– Able to exercise authority irrespective of possible costs (para 4.10) |
| 1d            | Prime responsibility for safety | – Assigning prime responsibility for safety to the person or organization responsible for facility or activity (R5; GSR Part 3 R4, R9)  
– Cannot be delegated (para 2.14)  
– Responsibility can extend to other entities, but does not relieve authorized party (para 2.14; CofCRS para 15)  
– Authorized party responsible for verifying that goods and services comply (para 2.14)  
– Conferring authority on RB to compel authorized parties (R5)  
– Responsibility extends through entire life-cycle, and for waste management (para 2.15, 2.16)  
– Authorized party actively evaluates progress in safety technology (para 2.15, 2.16) |
Subject Group 2: Global Nuclear Safety Regime

<table>
<thead>
<tr>
<th>Subject Group</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 (R14)  
- Participating in international arrangements (R14)  
- Participating in international peer reviews (R14)  
- Promoting international cooperation and assistance (R14) |
| 2b            | Bilateral and multilateral arrangements | - Ensuring bilateral and multilateral arrangements are in place (para 3.2A)  
- Import / export of radioactive sources (CofCRS para 23, 24, 25, 26, 27, 28, 29) |
| 2c            | Operating and regulatory experience | - Analysis to identify lessons to be learned from operating and regulatory experience (R15)  
- Dissemination of lessons learned to authorized parties, RB and other relevant authorities (R15)  
- Use of lessons learned by RB and other relevant authorities (R15)  
- Means for receiving international operating and regulatory experience (para 3.4)  
- Making available operating and regulatory experience to international knowledge and reporting networks (para 3.4, 3.5A) |
### Subject Group 3: Responsibilities and functions of the regulatory body

<table>
<thead>
<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 3a            | Organization of RB and allocation of resources | - Organizational structure (R16, para 4.5)  
- Allocation of resources commensurate with radiation risks (R16, para 4.5; GSR Part 5 R3; GSR Part 6 R5)  
- Graded approach (R16)  
- Establish or adopt regulations and guides for protection and safety and a system to ensure implementation (GSR Part 3 R3) |
| 3b            | RB staffing and competence | - Sufficient number of qualified and competent RB staff (para 2.8a, R18)  
- Commensurate with nature and number of regulated facilities and activities (R18)  
- Human resources planning (para 4.11, 4.12)  
- Training programme (para 4.13)  
- Knowledge management process (para 4.13)  
- Provisions related to training of staff newly hired from authorized parties (para 4.8) |
| 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 (GSR Part 2 R11)  
- Obtaining independent technical and other expert advice (R20, para 4.18)  
- Retaining regulatory responsibility (R20, para 4.22)  
- Clear limits on degree of control and direction (para 4.19)  
- Avoiding and/or monitoring conflicts of interest (para 4.20, 4.21)  
- Retaining core competence (para 4.22)  
- Communicating with authorized parties (R21, para 4.23)  
- Mutual understanding and respect (para 4.24)  
- Justification for regulatory decisions (para 4.25)  
- Liaison for joint inspections (para 4.53-5th and 8th bullets) |
| 3d            | Stability and consistency of regulatory control | - Stability and consistency of regulatory control (R22)  
- Formal regulatory process based on policies, principles and criteria (para 4.26)  
- Follows management system procedures and that follows specified procedures (para 4.26)  
- Prevention of subjectivity in decision making (para 4.26)  
- Justification of regulatory decisions (para 4.26)  
- Informing applicants of safety objectives, principles and criteria (para 4.26)  
- Emphasis on continuous enhancement of safety (para 4.27)  
- Recognition of risks associated with modifications to well-established processes (para 4.27)  
- Careful scrutiny of proposed changes in regulatory requirements (para 4.27)  
- Informing and consulting interested parties regarding proposed changes in regulatory requirements (para 4.27)  
- Consistency in regulatory requirements and regulatory decision-making process (para 4.28) |
| 3e            | Safety related records | - Establishing, maintaining and retrieving adequate safety records (R35, para 4.63)  
- Registers of sealed radioactive sources and radiation generators (para 4.63 first point; CofCRS para 11)  
- Occupational dose records (para 4.63 second point)  
- Records related to facilities and activities (para 4.63 third point)  
- Records necessary for shutdown, decommissioning and closure (para 4.63) |
fourth point)
- Records related to incidents, including non-routine releases to environment (para 4.63 fifth point)
- Radioactive waste and spent fuel inventories (para 4.63 sixth point)
- Need for authorized party to maintain records (para 4.64)
- Need for applicant to record information (para 4.65)
- Use of records by RB to support regulatory activities, including enforcement (para 4.65)

3f Communication and consultation with interested parties
- Informing and consulting interested parties on risks associated with facilities and activities (R36, para 4.66; CoFCRS para 12, 13)
- Informing and consulting interested parties on regulatory body processes, judgements and decisions (R36, para 4.66a, 4.66c, 4.66d)
- Provisions for effective communication (para 4.66; CoFCRS para 17)
- Meetings to inform interested parties (para 4.66)
- Direct communication with high-level governmental authorities (para 4.66b)
- Legal obligations of authorized parties to inform the public and other interested parties (4.68).

**Subject Group 4: Regulatory body management system**

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<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
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</table>
| 4a            | Establishment of RB management system | - Alignment with safety goals (R19; GSR Part 2 R1; GSR Part 3 R5)
- Open and transparent processes (para 4.14; GSR Part 2 R10)
- Ensures responsibilities assigned to RB are properly discharged (4.15(1); GSR Part 2 R4)
- Maintaining and improving RB performance (4.15(2); GSR Part 2 R4, R5, R9, R11)
- Coherence (para 4.17; GSR Part 2 R6)
- Specification of necessary planned and systematic actions (overall) (para 4.17; GSR Part 2 R8)
- Considering regulatory requirements (para 4.17) |
| 4b            | Implementation of the RB management system | - Contributes to achieving safety goals (R19; GSR Part 2 R7)
- Maintains efficiency and effectiveness of RB (para 4.15(2), 4.16) |
| 4c            | Assessment and review of the management system | - Continuous assessment and review (R19; GSR Part 2 R13, R14) |
| 4d            | Leadership and culture for safety for the RB | - Fostering and supporting safety culture (para 4.15(c); GSR Part 2 R12)
- Developing and reinforcing leadership (para 4.15(c); GSR Part 2 R2, R3, R12)
- Developing and reinforcing good safety attitudes (para 4.15(c); GSR Part 2 R12) |

**Subject Group 5: Authorization**

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<tr>
<th>Subject group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
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| 5a            | Development of authorization process | - Authorization is prerequisite except where explicitly exempted or approved by notification (R23; GSR Part 3 R7, R8, R18, R19, R20, R34)
- Different types of authorization for different stages in lifetime or duration (para 4.29)
- RB able to modify authorizations (para 4.29)
- Limits, conditions and controls (para 4.31)
- Appeal process (para 4.32)
- Submission of safety assessment (R24, para 4.33; GSR Part 3 R13) |
Subject Group 6: Review and assessment

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<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
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</thead>
</table>
| 6a            | Development of review and assessment process | - Review and assessment of relevant information (R25, para 4.45)  
- From applicant, authorized party, vendor, assembled by RB or elsewhere (R25, para 4.41, 4.45)  
- Prior to authorization and again as appropriate (R25, 4.45)  
- Routine evaluation of operating experience (para 4.39A)  
- Comprehensive safety reviews (para 4.39A, 4.45)  
- According to stage in regulatory process (para 4.40, 4.45)  
- Understanding of design (para 4.42, 4.45)  
- Assessment of radiation and non-radiation risks (para 4.43, 4.45, 4.47)  
- Assessment of modifications (para 4.44, 4.45)  
- Identification of trends and conclusions (para 4.46)  
- Feedback to authorized party (para 4.46)  
- Recording of results and taking appropriate action (para 4.48) |
| 6b            | Implementation of review and assessment process | - Findings related to how the RB is actually implementing its review and assessment process (R22, para 4.26, 4.28, R25, R26) |
| 6c            | Graded approach to review and assessment | - Review and assessment are commensurate with the associated risks (R26, para 4.39A, 4.40, 4.46) |
| 6d            | Review and assessment procedures and guidance | - Specification of necessary planned and systematic actions (specific to review and assessment process) (para 4.17, 4.26) |
| 6e            | Authorized party safety culture | - Review and assessment of authorized party safety culture (para 4.53-7th bullet) |

Subject Group 7: Inspection

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<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
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| 7a            | Development of inspection process | - Inspections carried out to verify compliance (R27; GSR Part 6 R15)  
- Do not diminish or substitute for authorized party responsibility (para 4.49) |
Inspections shall include programmed inspections and reactive inspections, both announced and unannounced (R28, para 4.50, 4.52).
- Programme shall stipulate frequency and areas and programmes to be inspection (para 4.50, 4.53).
- Inspection results recorded and appropriate action taken (para 4.51).
- Results feedback to regulatory process (para 4.51).
- Results provided to authorized party (para 4.51).
- Cover all areas of RB responsibility (para 4.52, 4.53).
- RB authority to carry out independent inspections (para 4.52).

### Subject Group 8: Enforcement

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<thead>
<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
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</thead>
</table>
| 8a | Development of enforcement policy | - Legal basis for enforcement (R30)
- Enforcement of regulatory requirements (R30)
- Enforcement of conditions specified in authorization (R30)
- Criteria/factors in determining enforcement/corrective actions (R31, para 4.55, 4.58)
- Authority to take enforcement actions (R31, para 4.58)
- Power to take corrective actions for unforeseen radiation risks (R31, para 4.59)
- Accountability of authorized party for remedying non-compliances (R31, para 4.57) |
| 8b | Implementation of enforcement policy | - Findings related to how the RB is actually implementing enforcement process (para 4.26, 4.28, R30, R31, para 4.56, 4.60) |
| 8c | Graded approach to enforcement | - Enforcement and requiring of corrective actions are commensurate with the associated risks (R31, para 4.54) |
| 8d | Procedures and guidance for enforcement | - Specification of necessary planned and systematic actions (specific to enforcement process) (para 4.17, 4.26) |

### Subject Group 9: Regulations and guides

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<tr>
<th>Subject Group</th>
<th>Definition</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 9a | Development of regulations and guides | - Establishing or adopting regulations and guides (R32)
- Part of legal framework (R32, para 4.61)
- Specify principles, requirements and associated criteria (R32)
- Regulatory judgement, decisions and actions based on regulations and guides (R32, para 4.26, 4.28, 4.61)
- Consultation with interested parties (para 4.61)
- Accounting for international standards, OPEX and R&D (para 4.61)
- Used for conditions of authorization and assessing compliance (para 4.26, 4.28, 4.62) |
| 9b | Review of regulations and guides | - Reviewed and revised as necessary (R33, para 4.61)
- Accounting for international safety standards, technical standards, OPEX (R33, para 4.61)
- Consultations with interested parties (para 4.61)
- Use technological advances, R&D, institutional knowledge (para 4.61) |
<table>
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<tr>
<th>Subject Group</th>
<th>Description</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 9c            | Promotion of regulations and guides | - Notification of interested parties and public (R34)  
- Availability of regulations and guides (R34) |
| 9d            | Graded approach to regulations and guides | - Coverage commensurate with associated radiation risks (para 4.62) |
| 9e            | Not assigned | - Not assigned |
| 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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<thead>
<tr>
<th>Subject group</th>
<th>Description</th>
<th>Includes findings related to:</th>
</tr>
</thead>
</table>
| 10a           | Emergency planning | - Provisions for timely and effective response to emergencies (R8, para 2.20, 2.21, 2.22; GSR Part 3 R43, R44; GSR Part 7 R1, R4, R5, R23, R26)  
- Authorized party responsibilities (para 2.20)  
- Notification (para 2.20; GSR Part 7 R7)  
- Regulatory body response (para 2.20, para 2.24)  
- National response system (para 2.21; GSR Part 7 R8, R19)  
- Designation of response organizations (para 2.22) |
| 10b           | Emergency preparedness and response procedures and guidance | - Assignment of clear responsibilities (para 2.23; GSR Part 7 R2, R3, R20)  
- Timely and effective decision making (para 2.23; GSR Part 7 R17)  
- Managing emergency response operations (GSR Part 7 R6, R9, R12, R14, R15, R16, R18, R21, R24)  
- Role of regulatory body to provide expert advice and services (para 2.24)  
- Managing, controlling and recording doses of emergency workers (GSR Part 3 R45; GSR Part 7 R11) |
<p>| 10c           | Emergency | - Effective coordination of and communication between authorized parties |</p>
<table>
<thead>
<tr>
<th>Subject Group 11: interface between safety and security</th>
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<tbody>
<tr>
<td>Subject group</td>
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<tr>
<td>11</td>
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<tr>
<th>Subject Group 12: Activities for embarking on a nuclear power programme</th>
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<tbody>
<tr>
<td>Subject group</td>
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<tr>
<td>12</td>
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