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International Atomic Energy Agency

Integrated Regulatory Review Service Guidelines

Vienna, December 2018

IAEA Services Series 37

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

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IAEA SERVICES SERIES No. 37

INTEGRATED REGULATORY REVIEW SERVICE GUIDELINES

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The IAEA's Integrated Regulatory Review Service (IRRS) was established to advise Member States on ways to strengthen and enhance the effectiveness of national regulatory frameworks for nuclear, radiation, radioactive waste and transport safety while recognizing the ultimate responsibility of each State to ensure safety in these areas. The IRRS process sets out to accomplish this purpose by enabling structured peer review of national regulatory technical and policy approaches against IAEA safety standards and the sharing of relevant good practices. These IRRS Guidelines are published to set out expectations and foster consistency in the preparation for and the conduct and follow-up of an IRRS mission.

Peer exchange on technical and policy approaches gives insight into the effectiveness and efficiency of the legal, governmental and regulatory framework for safety. Through this process, opportunities for improvement are explored and potential improvement strategies identified, which may also be shared with other States. IRRS missions thus provide an opportunity to share regulatory experiences, harmonize regulatory approaches among States and create mutual learning opportunities among regulators.

IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles, provides the basis for IAEA safety standards and safety related programmes. In support of effective regulation, the IAEA has established safety standards on the Governmental, Legal and Regulatory Framework for Safety (GSR Part 1 (Rev. 1)). Review against these safety standards is the core component of the IRRS process.

Other requirements, such as those established in GSR Part 2, Leadership and Management for Safety, and GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, are also used in conjunction with GSR Part 1 (Rev. 1) in order to conduct a thorough review of a national legal and governmental framework against the most relevant IAEA Safety Requirements and Safety Guides.

Organizational structures and regulatory processes, such as the use of prescriptive or non prescriptive approaches to regulation, vary from country to country depending on national legal and administrative systems, the size and structure of the nuclear and radiation safety programmes, the financial resources available to the regulatory body, and social customs and traditions. The IRRS process accommodates such variations within a single integrated review service. It is performance oriented in the sense that different approaches to the organization and practices of a regulatory framework and regulatory body are accommodated so long as they contribute to a strong national nuclear and radiation safety regime and are compatible with the IAEA safety standards. During an IRRS mission, recommendations and suggestions may be offered to the host country. Recommendations are related to items of direct relevance to safety as referenced in IAEA Safety Requirements; suggestions relate to items that, while not essential to ensure compatibility with IAEA Safety Requirements, may enhance the effectiveness of the national nuclear and radiation safety regime against the guidance presented in IAEA Safety Guides. Good practices may also be documented for consideration by other States.

To support the development of these guidelines, and provide an opportunity for Member State contribution and comments, a series of review meetings were held. The IAEA also initiated, during 2014–2015, consultancy meetings to analyse the effectiveness and efficiency of IRRS missions taking into account feedback of experience from previous IRRS missions. In addition, a review of the results of IRRS missions conducted from 2006 to 2010 was carried out and the findings were presented at the third Workshop on Lessons Learned from Integrated Regulatory Review Service (IRRS) Missions, held in Washington, DC, in October 2011. Furthermore, for the fourth Workshop on Lessons Learned from IRRS Missions, held in Moscow in December 2014, two reports were prepared: Lessons Learned from IRRS Missions to Countries with Operating Nuclear Power Plants, 2006–2013 and IRRS Missions 2006–2013: Analysis from a Radiation Safety Perspective. In April 2015, the IAEA organized a workshop for experienced IRRS reviewers to discuss potential improvements to the IRRS process. Finally, in February 2017, a Technical Meeting was held with the aim of providing a platform for the exchange of views on the proposed changes to the IRRS Guidelines.

The revision of the IRRS Guidelines was conducted by the IAEA with the financial assistance of the European Union. The views expressed in these guidelines do not necessarily reflect the views of the European Commission.

The IAEA would like to express its appreciation to all the experts who contributed to the development and review of these guidelines. The IAEA officers responsible for this publication were G. Macsuga of the Division of Nuclear Installation Safety and O. Makarovska of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

Each State is responsible for establishing a governmental, legal and regulatory framework for ensuring the safety of facilities, activities and practices involving radiation sources and radioactive materials on its own territory. Developing and implementing a suitable framework and capability can present a significant challenge given the diversity of facilities, activities and practices that can be involved. The need to address factors such as changes in technology and organisational models – for example, increasing use of international design and supply chain organisations – also needs to be taken into account. Thus, there is a growing need to support and strengthen national regulatory bodies and to consider the broader policy implications presented by such challenges and emerging issues.

The IAEA Fundamental Safety Principles [1] provide the basis for the IAEA safety standards including regulation of safety. In particular, the IAEA has established safety standards addressing the governmental, legal and regulatory framework for safety. These safety standards provide requirements and guidance for every national regulatory body's authority, independence and competence.

The Integrated Regulatory Review Service was developed to support the application of the IAEA Safety Fundamentals, safety requirements and guides and to enhance the effectiveness of national regulatory infrastructures for safety. It requires a Member State to conduct a self-assessment of its regulatory infrastructure against the IAEA safety standards, in accordance with the IAEA Self-Assessment Methodology. This is then followed by an IAEA-coordinated peer review conducted by a team of international reviewers, led by a senior regulator from a Member State. The review is structured to lead to the identification of areas for improvement and the formulation, by the host country, of an action plan to address identified deficiencies. IRRS missions provide an opportunity for the host country and peer review team members to share experience regarding both regulatory technical and policy matters. Discussions conducted during IRRS missions take into account issues identified during both the States' self-assessments and the IRRS Team's review of regulatory technical areas.

Within the reasonable and necessary variations among national regulatory approaches, there is no absolute measure of the adequacy and effectiveness of the various systems. Notable differences are inevitable between the regulatory infrastructures of States having one or more nuclear installations and a large number and variety of practices using radiation sources relative to those States having no nuclear installations and relatively few practices using radiation sources. The regulatory approach and requirements may differ significantly between these two extremes. The IRRS regulatory review process provides the opportunity for peer review of both regulatory technical and policy issues in any State regardless of the level of development of its facilities and activities involving ionizing radiation or nuclear programme. It enables an objective comparison of the national regulatory framework and infrastructure against IAEA safety standards. The IRRS evaluates, as objectively as possible, the State's regulatory infrastructure for safety with respect to these standards, and provides recommendations and suggestions for improvement as well as good practices. An expert peer review of the current extent of compliance with IAEA safety standards provides a good indication of the effectiveness of the regulatory oversight of nuclear, radiation, radioactive waste and transport safety.

A follow-up mission is undertaken, within 4 years, through which the host country and IRRS Team assess progress in implementing the recommendations and suggestions in the period since the initial review. The IRRS follow-up mission also provides an opportunity for the

IAEA, international reviewers and host country to identify additional technical and policy issues for review and to identify further good practices.

Experience indicates that the IRRS process ideally follows a 10-year cycle with initial IRRS missions repeating every 10 years and IRRS follow-up missions being conducted 2-4 years after the initial ones. Such a cycle provides clarity and consistency, meaning that all parties understand expectations and can plan accordingly. However, flexibility exists in defining this cycle to meet the operational needs of a host country. Although adopting a 10-year cycle is good practice, it is up to the host country to request an IRRS, like any other IAEA service.

These IRRS Guidelines provide:

— guidance to host countries, peer reviewers and IAEA Coordinators on the preparation, execution, and reporting of initial and follow-up IRRS missions;

— a consistent and systematic methodology for:
  - conducting the review of both regulatory technical and policy issues;
  - a detailed, consistent evaluation of the status of development of the national regulatory infrastructure for nuclear and radiation safety;
  - the identification of areas for improvements of the national regulatory infrastructure to meet IAEA safety standards;
  - providing recommendations and suggestions related to the identified areas for improvement;
  - providing assistance, if necessary, with the development of an action plan to achieve improvements.

This 2018 revision of the IRRS Guidelines supersedes the previous version issued in 2013. The major changes are listed below:

— The module of IRRS additional (and optional) areas was deleted. The content of this module was distributed across other modules 5 to 9, which were revised accordingly.

— Fukushima module was deleted as IAEA Safety Requirements have been modified to consider the lessons learned from the accident.

— Chapter 4.4 discusses the tailored module 12 aiming to address the needs of countries embarking on nuclear power programmes. This module comprises a review against actions set out in SSG-16. Additional details and guidance are given in Appendix III on the arrangements for IRRS in embarking countries and provide recommendations to the host country on the scope of the mission depending on the level of development of the national safety infrastructure in phases 1 to 3.

— Roles and responsibilities of key IRRS team members were systematically and coherently revised. More details were included on the IRRS team composition and size and guidance was introduced on ‘sub-teams’ and ‘module leading experts’ concepts.

— A new template was included for the terms of reference to be signed by the host country representative and the IAEA Coordinator during the IRRS preparatory meeting.

— The IRRS information meeting was included in the preparatory process. Host country input to policy discussions was included.

— The IRRS follow-up process was described in more details, methodology was improved and clarification was given that IRRS follow-up was an integral part of the IRRS process.

2. IRRS BACKGROUND

The importance of international peer review to the continuous improvement of regulatory effectiveness, and the opportunity it provides to share knowledge and experience of regulatory issues and good practices, has been acknowledged at, inter alia, Review Meetings of the contracting parties to the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The need for international peer reviews has also been recognized and further emphasised at major international nuclear safety conferences in the aftermath of the 2011 accident at the TEPCO Fukushima Dai-ichi Nuclear Power Plant.

In addition to addressing the technical safety requirements for effective regulatory control, it is important for the peer review to consider the broader policy implications for States receiving peer review of emerging issues and share relevant insights with the wider international community. Consideration of both technical and policy matters provides opportunities for improvements to regulatory infrastructure that might be shared with other Member States.

The IRRS provides a cross-cutting review, against the relevant IAEA safety standards [2-50], of the governmental, legal and regulatory framework for safety and the regulatory oversight of all facilities and activities utilising radiation in the host country.

All IAEA safety reviews provide an opportunity to exchange professional experience and to share lessons learned and good practices. They constitute a mutual learning mechanism that accommodates approaches to national regulatory body and practices that may differ but that share the common objective of ensuring effective regulation of nuclear and radiation safety and radiation protection. These reviews may also provide opportunity for identifying insights, if any, for future strengthening of the IAEA safety standards and for the establishment of a knowledge base in the context of an integrated safety approach.

3. OBJECTIVES AND BENEFITS OF THE IRRS

The IRRS offers States a means to assess, through peer review, the status of the national regulatory framework against IAEA safety standards. The team of international reviewers participating in an IRRS has direct experience applicable to all aspects of the agreed scope of the review.

The objectives of an IRRS mission are to enhance nuclear and radiation safety and regulatory effectiveness by:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (regulatory body and governmental authorities) with a review of its regulatory technical and policy issues;

c) providing the host country (regulatory body and governmental authorities) with an objective evaluation of its regulatory framework with respect to IAEA safety standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS Team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other States with information regarding good practices identified in the course of the review;

h) providing IRRS Reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden their own experience (mutual learning process);

i) contributing to the harmonization of regulatory approaches among States;

j) promoting the application of IAEA safety standards;

k) providing feedback on the use and application of IAEA safety standards.

These objectives are consistent with the development and application of self-assessment methodologies as component parts of regulatory body management systems, including the IAEA Self-Assessment Methodology and its associated tools such as the Self-Assessment of the Regulatory Infrastructure for Safety (SARIS) [53]. Some regulatory bodies have already implemented a continuous improvement strategy based on experience feedback and self-assessment, but for those countries still developing management systems, the IRRS helps to identify the strengths and weaknesses in the existing regulatory system through its combination of self-assessment and peer review.

An IRRS review fosters:

— an enhanced global nuclear safety regime through sharing of information between international reviewers and the host country, experience feedback and insights on contemporary issues of relevance;

— greater openness and transparency of the governmental, legal and regulatory framework;

— improved regulatory management systems emphasizing continuous improvement through periodic self-assessment, and consideration and application of lessons learned from international experience, thereby enhancing safety culture;

— more effective use of information and knowledge management networks to share relevant information on regulatory issues among and between States having common interests.

Critical feedback collected as part of the review of regulatory technical and policy issues helps to improve IAEA safety standards and enhance understanding of regulatory issues having a widespread impact on nuclear and radiation safety.

4. STRUCTURE AND PROCESS OF THE IRRS

4.1. GENERAL OVERVIEW

4.1.1. IRRS process

The IRRS process flowchart is provided in Fig. 1. It consists of the following phases:

— Preparatory phase, including self-assessment;

— Conduct of the review mission;

— Post-mission activities, including completion and dissemination of the mission report;

— Follow-up mission.

FIG. 1. The IRRS process.

The IRRS is performed by an international team comprising senior regulatory experts with broad knowledge of the regulation of nuclear and radiation safety and extensive related experience, often in specialized areas.

The IRRS process also provides an opportunity for identifying any insights for future strengthening of the IAEA safety standards. Thus, all IRRS participants are encouraged to consider providing feedback for potential strengthening of the IAEA safety standards.

The outcome of an IRRS mission is a report that, following the preliminary steps of collating, drafting, reviewing and finalization, is submitted through official channels to the State concerned. The IAEA will use the report to update the reviewed country's radiation and waste safety infrastructure profile and the nuclear safety profile, as appropriate.

A follow-up mission within 2 to 4 years is an integral part of the IRRS process. The purpose of an IRRS follow-up mission is to continue the work of improving regulatory effectiveness by reviewing the State's progress in response to the initial IRRS mission recommendations or suggestions.

4.1.2. IRRS scope

An IRRS, as a peer review, offers an integrated approach to the review of a state's governmental and legal framework and regulatory infrastructure for safety. Therefore, the scope of the mission includes all organisations which have relevant regulatory responsibilities and functions for the supervision of all facilities and activities involving ionising radiation above exemption levels and all exposure situations.

When a state requests an IRRS, all agencies that legally and collectively provide the full scope of the national regulatory responsibilities and functions (as defined in GSR Part 1 (Rev. 1)) are subject to the review. These agencies and their roles are identified and confirmed at the IRRS preparatory meeting.

The scope of an IRRS mission includes the core modules, i.e., Modules 1 to 10, together with policy discussions. In order to be called an IRRS mission, therefore, the mission scope always covers Modules 1-10 and policy discussions. If there is a wish to exclude specific agencies, specific facilities and activities or specific exposure situations from the review, the host country formally notifies the IAEA of its request so that a limited scope IRRS mission can be offered. With minor changes in the mission scope (e.g. to exclude specific low-risk facilities and activities or specific low-risk exposure situations) the IRRS mission is still considered as full-scope.

4.2. TECHNICAL AREAS

4.2.1 Modular structure of technical areas

The IRRS has a modular structure designed to be tailored to both generic and country-specific needs and to facilitate the review of circumstances where the scope of regulatory responsibility may be changing. Fig. 2 illustrates, in general, facilities and activities and exposure situations within the scope of IRRS and how the core regulatory processes interface with them. The importance of the regulatory body's management system is emphasised by its position in the diagram, overarching all processes and activities. Relevant safety standards are listed and associated with key overarching safety standards GSR Part 1 (rev. 1) and GSR Part 3 are set out. The details of the modular structure of the IRRS, based on GSR Part 1 (Rev. 1), are described in Appendix I.

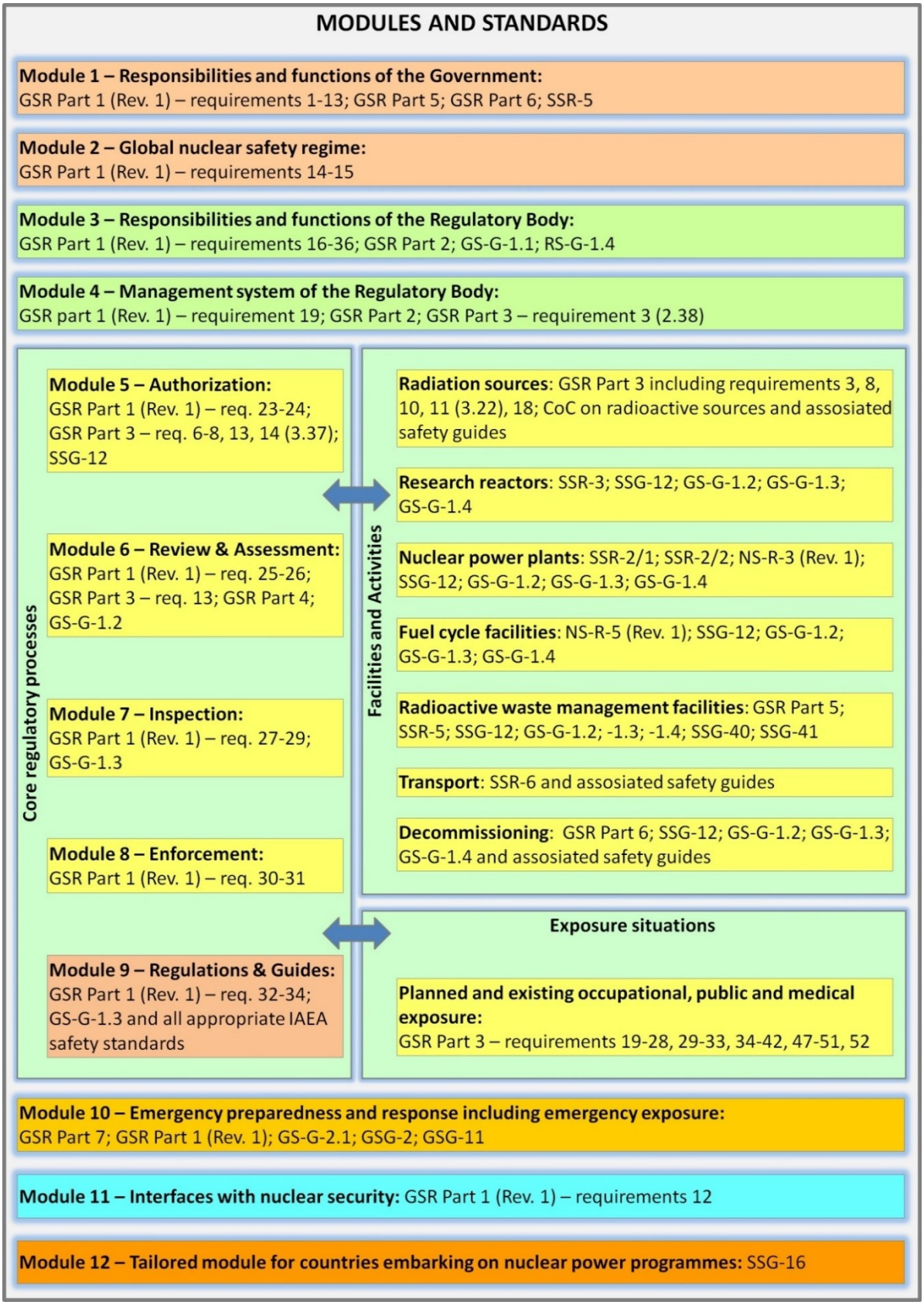

FIG. 2. The modular structure of the IRRS.

IRRS Modules 1 to 4 cover the essential elements of the legal framework for safety, regardless of the nature and number of facilities and activities or exposure situations to be regulated.

Modules 5 to 9 address the five main regulatory processes. Each of these processes (namely Authorization, Review & Assessment, Inspection, Enforcement, and Regulations and Guides) is applied to all regulated facilities and activities and exposure situations (excluding emergency exposure situations, covered in Module 10).

Module 9 differs from Modules 5 to 8 since it comprises two levels of review:

— The first level is part of the core modules of the IRRS and is related to the process of developing regulations and guides. It addresses requirements R32 to R34 of GSR Part 1 (Rev. 1).

— The second level relates to the content of regulations and guides issued by the regulatory body. It addresses compliance of regulations and guides with the corresponding IAEA Safety Requirements and Safety Guides.

Module 10 deals with the regulatory aspects of the nuclear or radiological emergency preparedness and response of the host country, i.e. with regulating the on-site emergency arrangements of licensees/operating organizations.

Interfaces with Nuclear Security may be included in the scope of the IRRS as an additional technical issue and is incorporated in Module 11.

The specific issues for countries embarking on a nuclear power programme are covered by Module 12. This consists of a review against the actions listed in SSG-16 and the respective IAEA safety standards; see Section 4.4 for short descriptions of this additional area.

4.2.2. Basis for technical areas

The basis for the review of technical areas is the IAEA safety standards, which reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories: Safety Fundamentals; Safety Requirements; and Safety Guides.

Safety Fundamentals

The IAEA Fundamental Safety Principles [1] establish the fundamental safety objective and principles of protection and safety and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that should be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures should be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment of a national regulatory framework. The safety requirements use ‘shall’ with statements of associated conditions to be met.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides set out international

good practices, and increasingly reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as 'should' statements.

4.2.3. Basis for core review areas

IRRS core review areas address IAEA Safety Requirements set out in:

— GSR Part 1 (Rev. 1): Governmental, Legal and Regulatory Framework for Safety [2];

— GSR Part 2: Leadership and Management for Safety [3];

— GSR Part 3: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [4];

— GSR Part 7: Preparedness and Response for a Nuclear or Radiological Emergency [8] (requirements relevant for regulatory aspects).

GSR Part 1 (Rev. 1) constitutes the backbone of the IRRS. GSR Part 1 (Rev. 1) comprises 36 overarching requirements (hereafter R1 to R36), organized in the following manner:

— Responsibilities and functions of the government (R1-R13);

— Global nuclear safety regime (R14-R15);

— Responsibilities and functions of the regulatory body (R16-R36).

The various modules of the IRRS correspond to the various requirements of GSR Part 1 (Rev. 1). Other IAEA Safety Requirements, including GSR Parts 2-7 are used as appropriate, in order to cover the detailed scope of regulatory control for nuclear, radiation, radioactive waste and transport safety. These are detailed in Appendix I.

4.3. POLICY DISCUSSIONS

4.3.1. Purpose of policy discussions

The IRRS policy discussions are intended to promote a constructive sharing of views, experience and lessons learned between the host country and the IRRS Team on regulatory policy and strategic matters. They may also help the host country to identify potential strategies for solving regulatory challenges. The topics proposed for discussion may range across legal, technical and organisational areas relevant to the regulation of nuclear and radiation safety in the host country.

Policy discussions between the IRRS Team members and their host country counterparts are also used to further understanding of the attributes of an effective regulatory body and provide feedback for developing criteria to assess the effectiveness of regulatory systems. Policy discussions are usually held at a senior level, it is important that they are conducted in a transparent and inclusive manner and falls within the scope of the IRRS mission.

Wherever possible, policy discussions are linked to IAEA safety standards. In such cases IRRS recommendations may be made as with technical issues. Occasionally, there may be no direct link with IAEA safety standards and in such cases, it is important to explain why the topics will be addressed and what outcome is expected.

4.3.2. Basis for identification of policy discussion issues

The host country is responsible for identifying policy issues that it considers relevant to its circumstances but, where possible, focussing on those having potential global interest or impact. In addition, the IAEA may also propose policy issues for discussion. The policy issues are then agreed with the IRRS Team Leader and the IAEA Coordinator taking into account the scope of IRRS missions and the availability of relevant expertise within the IRRS Team.

Material that may help to generate policy issues includes IAEA publications on regulatory and safety conferences and other relevant international meetings and forums; reports on safety issues and trends; results from other IAEA review missions; INSAG Reports; insights from the analysis of operational experience feedback from the IAEA's Incident Reporting System (IRS) and others.

Documents and commitments generated by the host country as part of its self-assessment and initial action plan may also lead to the identification of policy issues. Examples of typical policy issues are provided in Appendix II.

4.4. MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER PROGRAMMES

The IAEA has developed a safety guide (SSG-16, [38]) whose objective is to provide guidance on the establishment of the national safety infrastructure, in accordance with the IAEA safety standards, to countries considering or preparing to embark on a national nuclear power programme. SSG-16 constitutes a road-map of safety-related actions to be taken in the first three phases (see Fig. 3 below) of the development of the nuclear power programme in order to achieve a high level of safety throughout the lifetime of nuclear power plants (NPP), including decommissioning and waste management.

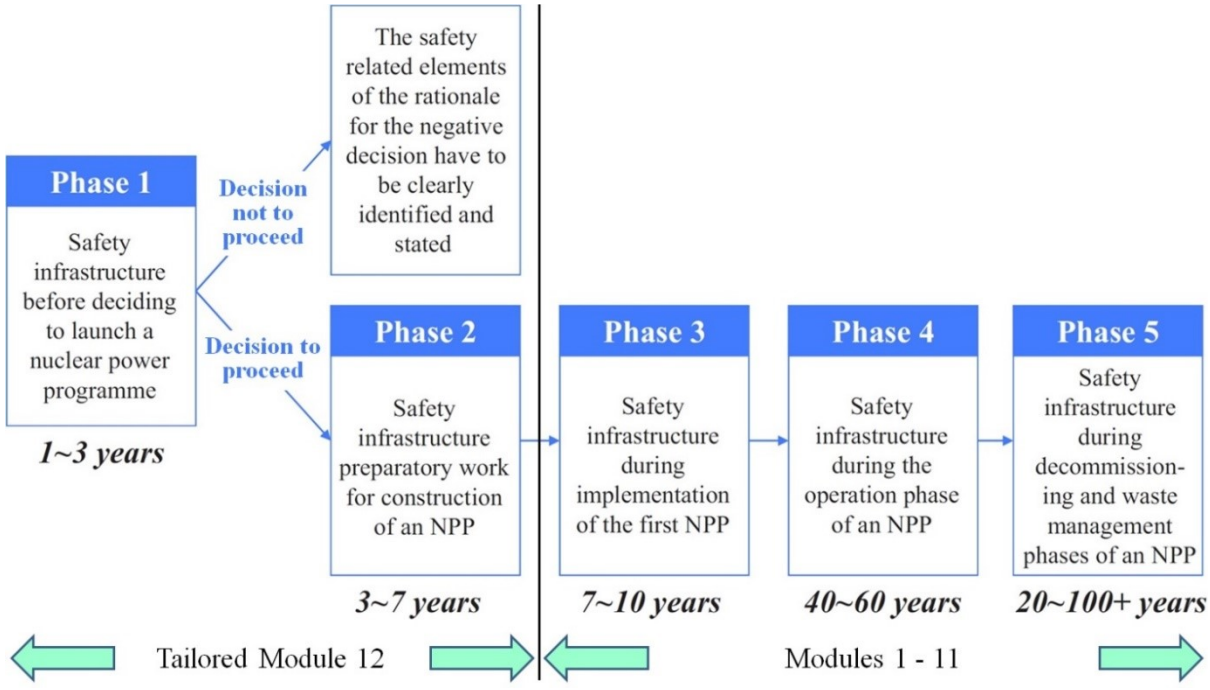

FIG. 3. Relationship between IRRS modules and national safety infrastructure phases.

This tailored module comprises a review against actions set out in SSG-16, as described in Appendix III. Depending upon the level of development of the national safety infrastructure the host country, when agreeing the scope of the mission, will determine the phases it wishes to have subject to review. However, if the host country selects phase 2 for instance, then for completeness the actions of phase 1 will also be reviewed. Appendix III shows the sub-sections of the tailored module. Appendix III also contains supplemental guidance for IRRS missions to embarking countries.

Usually the tailored module is not performed for countries that are in Phase 3 of SSG-16 (e.g. an NPP is under construction). By this time the country should have its regulatory framework almost completely in place and, therefore, a full scope IRRS mission is conducted that will include the review of the regulatory oversight of the NPP(s).

5. IRRS PREPARATION

5.1. GENERAL OVERVIEW

During preparation for the IRRS mission the IRRS Team Leader, IAEA Coordinator and host country will communicate and exchange information regularly (see Section 5.8 and Appendix IV for the description of these roles).

The preparatory phase includes:

— initial formal governmental request to the IAEA for IRRS;

— development of an agreement between the IAEA and the host country on the initial scope of the proposed IRRS;

— an information meeting if requested, on the IRRS process and self-assessment to be conducted by the host country;

— a preparatory meeting, usually conducted in the host country;

— completion of a self-assessment by the host country (a prior self-assessment seminar can be organized by IAEA upon the request of the host country);

— agreement on, and preparation for, policy issue discussions;

— forwarding to the IAEA of the Advance Reference Material (ARM) prepared by the host country, including self-assessment report, Advance Reference Material summary report and initial action plan arising from the self-assessment outcomes;

— identification of information that must remain confidential;

— selection of the IRRS Team;

— pre-mission preparation by IAEA participating officers and IRRS Team members;

— mission agenda and logistics preparation.

5.2. INITIAL REQUEST BY THE STATE

The initial request by the State is usually made 2-3 years in advance of the proposed date of the IRRS mission. This allows sufficient time to conduct the self-assessment and prepare for the IRRS mission. The formal request for an IRRS mission is submitted to the IAEA Deputy Director General for Nuclear Safety and Security. States are encouraged to request IRRS mission simultaneously with follow-up mission in 2-4 years period (see 8.2).

Alternatively, for some Member States where the IAEA believes an IRRS would be beneficial, a recommendation to consider requesting an IRRS mission, together with a draft proposal, may be forwarded to the State.

On receipt of the formal request, the IAEA reviews the request and begins dialogue with the State. An IAEA staff member is designated as 'IAEA Coordinator' and he or she contacts the host regulatory body in order to:

— identify the host country Liaison Officer for the mission;

— arrange a date for the information meeting (if requested) and the preparatory meeting with the organization(s) involved;

— discuss the scope and expectations for a regulatory self-assessment in preparation for the review mission.

Whilst not a member of the IRRS Team itself, an important link between the host country and the IRRS Team is the person nominated by the host country to be the Liaison Officer. This person needs to be knowledgeable on all matters relating to the IRRS and have a good understanding of what the host country will provide with respect to the IRRS Modules being reviewed as well as a good overview of the national regulatory infrastructure. The host country Liaison Officer usually has the characteristics of a team leader in order to access resources, and have credibility with host country officials, staff and IRRS Reviewers.

IAEA selects the IRRS Team Leader and Deputy Team Leader as early as possible (for example, within one month after the information meeting if it takes place) and fixes the preparatory meeting and mission dates.

5.3. INFORMATION MEETING

An information meeting may be requested by the host country. The objective of the information meeting is to explain the IRRS process so that the host country has a clear understanding of the time and resources necessary to prepare for the IRRS mission. The information meeting may be arranged in different ways (remote or face to face), and combined with other IRRS related events such as a self-assessment seminar.

Typically, a 12 to 18 month time interval between the information meeting and the IRRS mission is needed to enable the host country to start and complete its self-assessment in a timely manner.

5.4. MISSION SCOPE AND BASIC ELEMENTS DETERMINATION

The scope of the IRRS includes technical areas related to the regulatory infrastructure and agreed policy issues (section 4.1.2). The final scope is agreed during the preparatory meeting (section 5.5 below). Any IRRS mission, except the first one, focuses on reviewing progress in implementing the recommendations and suggestions that were open and not closed by previous IRRS missions.

5.5. PREPARATORY MEETING

A preparatory meeting will be conducted six to nine months prior to the mission. The meeting, typically of two days' duration, is attended by the IRRS Team Leader and the IAEA Coordinator and, for a host country with large nuclear programmes or in the event of specific problems/topics, a larger preparatory meeting team may be selected with the involvement of

the Deputy Team Leader, IAEA Deputy Coordinator and other representatives of appropriate IAEA Divisions. The preparatory meeting would normally be held at the regulatory body's headquarters with the participation of senior management and other stakeholder organizations in the host country. As an alternative, the preparatory meeting may be held at IAEA Headquarters. During the preparatory meeting the IRRS Team Leader and IAEA Coordinator will discuss the details of the mission with the host. The discussion includes scope of the review, the status of the self-assessment, and potential policy issues. Emphasis is placed on ensuring that the host prepares a high-quality self-assessment and summary document, and supplies sufficient ARM for the IRRS Reviewers to thoroughly prepare for the mission. Emphasis is also placed on ensuring that the government and all associated organizations support and participate in the mission.

The main purpose of the preparatory meeting is for the IRRS Team Leader and IAEA Coordinator to:

— meet with regulatory body staff (counterparts, senior management) and exchange contact details;

— introduce the IRRS mission lead to the host country;

— inform the regulatory body about how the IRRS review process works;

— identify the regulatory body's priorities, aims and objectives for the mission;

— explain the roles and responsibilities of IRRS Team members and the way they interact with the regulatory body, other organizations and facility representatives;

— explain the role of the host country Liaison Officer and counterparts before and during the review;

— discuss and confirm the dates and scope of the mission and which policy issues will be reviewed, the ARM (section 5.6) the regulatory body will provide in advance and primary counterparts nominated by regulatory body and involved organizations in each specific review area/module;

— explain the importance of the regulatory body's providing comprehensive written replies to the self-assessment including self-analysis/conclusions and a subsequent initial action plan;

— agree an outline schedule for the mission and the logistical aspects;

— explain pertinent IAEA policies (e.g. funding, contact with the media);

— answer any questions the regulatory body and other involved organisation representatives may have and address their concerns to the extent possible.

An outcome of the preparatory meeting is the agreement in the form of documented Terms of Reference for the IRRS mission. It is endorsed by the representative of the host country (typically by the host country Liaison Officer) and the IAEA Coordinator. The Terms of Reference summarize the milestones relevant to the preparation process for the IRRS mission and provide clarity on the commitments of the host country and the IAEA, including arrangements for monitoring progress in implementing the action plan – for example, by means of a follow-up mission. This will facilitate long-term planning by both parties.

A six to nine month time interval between the preparatory meeting and the IRRS mission is typically needed to enable the host country to complete its preparation in a timely manner (the longer period is needed in particular where translation of documents into English is required).

Self-assessment could require several months depending on the extent of facilities and activities in the host country and staffing level of the regulatory body.

IAEA and the host country agree the provision of necessary support facilities. All IRRS reviews are conducted in English and the host country thus provides the necessary interpretation facilities to enable IRRS Reviewers to do their work effectively.

In the event, if the host country does not provide a timely high-quality self-assessment, summary document and ARM to support the mission, the mission may be postponed. However, this step is only taken as a last resort and the decision is made by the IAEA Coordinator in consultation with the IRRS Team Leader and IAEA management as required. During the preparatory meeting the IRRS Team Lead makes it clear that a good quality ARM submitted in time is a precondition of conducting the mission.

The main elements of and a sample agenda for the preparatory meeting are detailed in Appendix V. Appendix VI provides a list of preparatory activities for an IRRS mission. The template for the Terms of Reference is provided in Appendix VII.

5.6. SELF-ASSESSMENT AND ADVANCE REFERENCE MATERIAL

Regulatory self-assessment is an integral part of the IRRS process and is conducted by the host country in preparation for the IRRS mission. The IAEA Self-Assessment Methodology and the associated software (SARIS) provide a detailed approach and comprehensive information on this important part of the IRRS process.

According to the IAEA Self-Assessment Methodology, a complete self-assessment comprises five main phases:

— preparation;

— answering;

— analysis of results;

— initial action plan;

— implementation and follow-up

The first four phases are necessary preparation for an IRRS review. These phases provide a comprehensive picture of how the regulatory body is performing against IAEA safety standards. The IRRS sets out to be a peer verification of the host's self-assessment findings, thus, the considerable effort and time needed for completing the self-assessment should not be underestimated.

The scope of the self-assessment conducted as an integral part of the IRRS process should be consistent with the agreed scope of the IRRS mission.

At the request of the host country the IAEA may organize and deliver a national self-assessment seminar, describing the self-assessment methodology and process (including tools where appropriate) as well as providing practical exercise of its application for those taking part in the self-assessment of the host country.

All agencies collectively comprising the national regulatory body, and assigned regulatory responsibilities, take part in the self-assessment and preparation of the ARM. Stakeholders such as other governmental departments relevant to safety regulation and other interested parties are involved early in the preparation of IRRS.

To provide a basis for consistent review against IAEA safety standards, the IAEA has prepared a set of questions for each module of the IRRS. These are based on the requirements of the relevant safety standards. SARIS, an electronic tool incorporating these question sets, has been made available on the IAEA website and can be freely downloaded.

The self-assessment according to the IAEA SARIS methodology and tool must be completed well in advance of the mission. SARIS question sets address both compliance and performance aspects (i.e. whether the regulations are in place and actually in use), and comprehensively reference the pertinent IAEA safety standards. SARIS question sets for any particular IRRS mission contain the relevant standards-based material for the selected mission scope, and are structured in a modular format. Question sets addressing Modules 1-10 and the optionally included are provided within SARIS. In addition, if Module 12 for a country embarking on nuclear power programmes is selected as part of the scope of the IRRS mission, the self-assessment for this module is conducted according to the Integrated Review of Infrastructure for Safety for states establishing the safety infrastructure for a nuclear power program (IRIS) methodology [54] utilizing that IRIS module also available within the SARIS tool.

The self-assessment is to be completed thoroughly as it provides essential information to the IRRS Team about the host country's regulatory infrastructure for nuclear, radiation, radioactive waste and transport safety and the interface with security, as applicable. This self-assessment may take nine months or longer, depending on the availability of information and the resources of the regulatory body. The information provided as a result of the self-assessment will be verified by the IRRS Team during the mission (see section 8.4.2 'Interviews').

The regulatory body includes the completed self-assessment report (question-sets with responses, conclusions and initial action plan) as part of the Advance Reference Material. It is essential that the questions be answered and the analysis of results and identification of actions carried out as thoroughly and completely as possible. Wherever possible, the regulatory body is encouraged to reference responses with the applicable regulatory documents. The responses to the questionnaire and the attached documentation form the bulk of the ARM provided by the regulatory body to the IRRS Team. Relevant parts of documents (responsibilities, licensing requirements, etc.) that are referenced in the ARM are translated to English and made available to the IRRS Team as described in Appendix IX.

In most Member States English is not an official language and therefore the responses to the questionnaire and many ARM documents have to be translated. There is a need for a quality check of English translations of documents submitted to the IRRS Team.

Upon completion of a self-assessment, including self-analysis of the questionnaire responses, an initial action plan is developed by the host country to address deficiencies revealed during the self-assessment. The initial action plan in response to the self-assessment is considered as an essential part of the ARM. The initial action plan collates the recognised shortcomings in the national legal, governmental and regulatory framework for safety identified during the self-assessment, describe the proposed improvement programme, including responsible persons/institutions and time frames, and set the priorities of the government, regulatory body and other organisations involved in the regulatory programme. The regulatory body (and other involved organisations, as appropriate) will determine the most appropriate way to prepare the initial action plan. For instance, where a planning process exists as part of the regulatory body's management system, it may be used for developing and revision of the action plan.

The outcomes of the self-assessment and resulting initial action plan, together with the ARM summary report, are forwarded to the IRRS Team via the IAEA Coordinator. IAEA provides

an ARM summary report template to assist in the drafting of this very important document and promote consistency. The ARM is submitted at least 2 months prior to the start of the mission. A justification for supplying specific documents later may be made, but they need to be provided in sufficient time to enable a proper review. The IAEA Coordinator in liaison with the IRRS Team Leader decides on whether the self-assessment and ARM are sufficiently complete to enable a meaningful IRRS mission to take place. If the submitted material does not meet expectations, and is essentially not reviewable, the mission is postponed as outlined in 5.5.

Wherever possible the ARM includes text and material relating to the identified policy issues.

The ARM of the IRRS mission is retained by both the host country and the IAEA for further use and comparative review during the follow-up mission.

5.7. PREPARATIONS FOR POLICY DISCUSSIONS

Thorough preparation for IRRS policy issue discussions is essential and early identification of these issues maximises the time available for all parties to prepare fully for the discussions.

The host country is expected to develop views and discussion points relating to the identified policy issues, particularly as to how these issues apply to its regulatory framework. The host country forwards these views and discussion points to the IAEA Coordinator for circulation to all IRRS Team members no later than the first day of the mission, but some basic background on the policy issues is provided beforehand, incorporated with the ARM.

IRRS Team members will take note of the policy issues, host country views and discussion points; develop initial impressions regarding implications of the policy issues for their technical review areas; and maintain awareness of the potential policy implications as they complete their technical reviews.

The IRRS schedule includes discussions associated with policy issues. The IRRS Team Leader, in consultation with the host country, may schedule additional policy discussions. Policy discussions take place no later than the beginning of the second week of the mission.

5.8. SELECTION OF THE IRRS TEAM MEMBERS

The IRRS Team is led by a senior regulator from a Member State designated as the IRRS Team Leader. The IRRS Team comprises both designated IAEA staff and experienced regulators recruited from Member States and selected by the IAEA in consultation with the host country and paying attention to avoiding conflict of interests.

The agreed scope of the IRRS mission determines the number, key knowledge, skills and experience of the staff required for the mission (among both the international IRRS Team and the host counterparts).

5.8.1. IRRS Team size and composition

IRRS missions typically comprise 12-21 international experts (see Appendix X for standard IRRS Team composition). For large IRRS Teams and broad scope reviews, two team members may be assigned joint responsibility for certain review areas. The size of the IRRS Team and the duration of the mission are primarily determined by and graded according to the legal, administrative and technical complexity of the host country's infrastructure for nuclear, radiation, radioactive waste and transport safety and by the range of facilities, activities and practices included in the scope of the IRRS.

An IRRS Team, as appropriate, includes:

— IRRS Team Leader, recruited from a Member State;

— IRRS Deputy Team Leader, also recruited from a Member State;

— IAEA Coordinator, an IAEA staff member;

— IAEA Deputy Coordinator, also an IAEA staff member;

— IAEA Review Area Facilitators (for large or complex review missions; typically one for nuclear installations, one for radiation, transport and waste safety and one for emergency preparedness and response), drawn from IAEA staff;

— IRRS Reviewers recruited from Member States and who may additionally include, where necessary, experts drawn from IAEA staff or external consultants to the IAEA;

— IAEA Administrative Assistant;

— Observers from other States or bodies such as the European Commission may participate with the agreement of the host country.

If the host country has a limited national programme of nuclear energy use, and depending on the needs of the host country, the IAEA Coordinator may be assigned the additional responsibility of Deputy Team Leader and there is no IAEA Deputy Coordinator.

Ideally, at least half of the IRRS Reviewers in an IRRS Team have previous IRRS experience (reviewer or hosting counterpart). The IRRS Team Leader, in particular, is an experienced reviewer. IRRS Reviewers are assigned into groups during IRRS missions and each group includes at least one experienced IRRS Reviewer. It is recommended that potential reviewers take part in IRRS training organized by the IAEA.

5.8.2. Recruitment of IRRS Team members

IRRS Team members are recruited from Member States and external consultants to the IAEA. The IRRS Team members are experienced regulators and experts in specific topics. National regulators identify a pool of experts to be available for IRRS missions and communicate this to the IAEA. However, IAEA also invites team members through national contact points, and subject to the agreement of their organisations, where appropriate. It is important that IRRS Team members recognize the collective responsibility they have as part of the team. This will be emphasized by the IRRS Team Leader, who clearly communicates the expectations of the IRRS Team and the mission. It is emphasized both to the nominating organizations and nominated experts that IRRS Team members must dedicate sufficient time for reviewing the ARM and other necessary preparations well in advance of the mission.

All IRRS Team members including the IRRS Team Lead have well developed general attributes for this undertaking, including:

— good communication skills;

— good verbal and written English;

— sound knowledge of the IAEA safety standards related to their review area;

— good knowledge of the IAEA Safety Glossary;

— professional knowledge and experience;

— good technical knowledge together with an appreciation of the ‘bigger picture’;

— good report-writing skills;

— an ability to work under pressure;

— a sense of responsibility for the mission as a whole;

— the ability and willingness to work in a team.

The following specific attributes are relevant:

— The IRRS Team Leader is a senior regulator from a Member State, experienced in the regulatory aspects of nuclear and/or radiation safety. The personal characteristics of this individual are fundamental to ensuring the success of a mission. In addition to the relevant professional and technical attributes the IRRS Team Leader has:
  - known leadership qualities;
  - effective communication skills with good spoken and written English;
  - a clear mission vision;
  - known ability to build effective teams;
  - recent knowledge of global and local regulatory issues;
  - a clear understanding of the peer review process and what needs to be done received through the participation in IRRS or specific training.

— The IRRS Deputy Team Leader has:
  - experience as the chair of multi-disciplinary meetings;
  - a good knowledge of the relevant technical areas and an understanding of the wider peer-review process;
  - the experience to reconcile varying points of view;
  - good team building and management skills;
  - a good overview of the team’s activities.

— The IAEA Coordinator and the IAEA Deputy Coordinator are experienced in the regulatory aspects of nuclear or radiation safety and in conducting international regulatory infrastructure reviews.

— The IAEA Administrative Assistant has experience in advanced IT and document control techniques and a working knowledge of the IRRS process.

— IRRS Team members (e.g. IRRS Team Leader, IRRS Deputy Team Leader, IAEA Review Area Facilitators, IRRS Reviewers) have experience in the regulatory aspects of nuclear or radiation safety and in the review of regulatory infrastructures. Previous IRRS experience is encouraged.

— No-one from the host country may be included in the IRRS Team.

— Ideally, as many IRRS Team members as possible are able to communicate in one of the official or commonly spoken languages of the host country (in addition to English).

— IRRS Team members adopt an open attitude towards systems and approaches that vary from those with which they are familiar.

In the case of missions to countries receiving assistance from the IAEA, there may also be involvement by relevant IAEA Department of Technical Cooperation (TC) staff. Interactions with TC will be in accordance with established IAEA procedures.

For IRRS follow-up missions (see section 8), depending on the extent and significance of the findings of the initial mission, not all IRRS Team positions need to be filled. The IRRS Team Leader and the IAEA Coordinator consider whether other IRRS Reviewers can adequately address those areas where few findings have been identified. This ensures that the follow-up mission is appropriately targeted and resource-efficient. Detailed responsibilities of the IRRS mission participants are provided in Appendix IV.

After determining the initial scope of the IRRS mission, the IAEA Coordinator in conjunction with the host country recruits an IRRS Team Leader and Deputy Team Leader. The IAEA Coordinator, after appropriate consultation with the IRRS Team Leader and IRRS Deputy Team Leader and in cooperation with the IAEA Deputy Coordinator, contacts potential IRRS Team members through national contact points regarding their availability for the IRRS mission. IRRS Team members will then be recruited and cleared for the mission in accordance with IAEA procedures and established agreements.

5.9. INITIAL IRRS TEAM COMMUNICATION

Tasks and responsibilities are assigned to IRRS Team members (e.g. IRRS Deputy Team Leader, IAEA Deputy Coordinator, IAEA Review Area Facilitators, IRRS reviewers) at the earliest opportunity so they may concentrate on their specific responsibilities. Using the IRRS mission scope and provisional schedule, the IAEA Coordinator, in consultation with the IRRS Team Leader, assigns specific tasks to selected IRRS Reviewers and confirms that each agrees with and accepts his or her assigned responsibilities. During this the IAEA Coordinator takes into consideration that for each module a leading expert is to be assigned.

Early team building and orientation of team members are vital steps in maximising the effectiveness of the teams during the mission. At the earliest opportunity, but at least around 4 weeks prior to the mission, the IRRS Team Leader, in coordination with the IAEA Coordinator, will contact IRRS Team members as part of the team building process. Experience has demonstrated that early interaction facilitates mission preparation by providing initial insights and answering IRRS Team members' questions and concerns. The IRRS Team Leader communicates to IRRS Team members the expectations for the mission and he/she:

— Reaffirms what modules will be assigned to individual IRRS Team members;

— Explains that the Mission Report Template is to be used from the very beginning;

— Invites IRRS Team members to familiarise themselves with Modules 1, 2 and 3 of the ARM and ARM summary and carefully study modules for which they are responsible;

— Invites IRRS Team members to consult the web site of the regulatory body of the host country;

— Invites IRRS Team members to prepare a 3-4 minutes presentation about him/herself - both professional as well as personal - for the initial team meeting;

— Invites IRRS Team members to write initial impressions about their modules in the First Impressions Template and send them to the IRRS Team Leader and IAEA Coordinator at least two weeks before the mission;

— Invites IRRS Team members to prepare a preliminary list of questions belonging to their assigned modules;

— The IRRS Team Members' initial impressions of the host country self-assessment and initial action plan are summarized by the IRRS Team Leader and are circulated to IAEA Reviewers and the host immediately pre-mission.

5.10. PREPARATION BY IRRS TEAM MEMBERS

IRRS Team members are provided all the information needed to complete their review. The information to be provided in advance of the mission includes:

— Advance Reference Material;

— IAEA Reference Material (safety standards);

— IRRS Guidelines;

— Previous IRRS reports;

— Reports of previous EPREV[1] or OSART[2] missions (if there were such missions);

— Report template;

— Initial impression guidance;

— Other mission instructions/training.

Prior to the mission IRRS Team members will review the ARM (Appendix IX) provided by the IAEA, including a detailed review of those parts of the host country's completed self-assessment, initial action plan and other ARM (see 7.5) for which they have accepted review responsibility. Each IRRS Reviewer is expected to:

— allocate sufficient time for a thorough review of the ARM;

— review the initial information related to policy issues and identify any additional issues relating to their assigned technical areas;

— assess the ARM against the relevant IAEA safety standards;

— form an initial opinion of the subject area to which they have been assigned and identify priority technical areas for review during the IRRS mission;

— at least two weeks prior to the mission, provide written feedback to the IAEA Coordinator and the IRRS Team Leader on any significant issues identified for their assigned review areas so that, if necessary, there will be sufficient time to adjust the mission programme and logistics in response to team member inputs.

Each IRRS Team member prepares a short summary after the review of the ARM, including the self-assessment and his/her initial observations (often referred as "initial impressions" or "first impressions") according to the relevant template and sends it to the IRRS Team Leader and IAEA Coordinator at least two weeks before the mission and presented at the initial IRRS Team meeting (see 6.1). Pre-drafting of relevant parts of the IRRS mission report is encouraged.

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[1] Emergency Preparedness Review (EPREV) Service.

[2] Operational Safety Review Team (OSART) mission.

5.11. MISSION AGENDA AND LOGISTICS

As a general rule, IRRS missions will be 9 to 15 days in duration.

5.11.1. Mission agenda

With the consideration of the programme and agenda samples from Appendix VIII the IAEA Coordinator develops the initial programme and agenda for the mission in conjunction with the host country Liaison Officer and the IRRS Team Leader.

Based on the assignment of specific tasks to IRRS Team members there may be modifications to the original schedule. Any such modifications must be agreed with the host country counterpart, who may also wish to propose modifications.

In finalizing the IRRS mission schedule, attention is paid to ensure sufficient time is available for each part of the schedule, including travel time.

5.11.2. Mission logistics

In preparation for the IRRS mission, the IAEA Coordinator will:

— confirm and finalise all resourcing arrangements for the mission, particularly the source of funding;

— confirm dates for the mission with the host country Liaison Officer, taking due account of any holidays, national vacation periods, work week structure and working hours;

— confirm that appropriate travel arrangements have been made by the IRRS Team, ensuring that all team members are scheduled to arrive in the host country in sufficient time to attend the initial team meeting;

— ensure necessary security training and clearance for the IRRS Team, if needed.

The host country Liaison Officer will:

— make the necessary hotel reservations;

— make arrangements for adequate working space for the IRRS Team to enable them to work together and to hold discussions in reasonable privacy;

— make arrangements for administrative support throughout the review (the IAEA will provide administrative support if it is not available locally or as a dedicated support function for the IRRS Team);

— make arrangements for printers, paper, computer, projector and audio-visual equipment;

— make arrangements for communication (internet access, phones) between the IRRS Team members and their base organizations (especially the IAEA), and between team members in the host country;

— arrange local transportation;

— make arrangements for translators and technical escorts, if required;

— make the necessary arrangements for entry to the facilities, including clearance and any required training.

Each IRRS Team member will:

— obtain a visa, if required;

— bring a laptop computer with the appropriate electrical adapter, word processing, presentation and other software, as required, or inform the IAEA Coordinator if this is not possible, so that alternative arrangements may be made;

— undergo, as appropriate, the IAEA online training courses for Basic Security in the Field and Advanced Security in the Field;

— arrange to receive the required immunizations in good time;

— make travel arrangements and provide their travel details to the host country Liaison Officer and IAEA Coordinator.

It is important to note that security clearance and obtaining visas for entry to the host country may take a considerable time. Underestimating this time factor may pose a risk to the scheduling or conduct of a mission.

6. CONDUCT OF THE IRRS MISSION

6.1. INITIAL IRRS TEAM MEETING

When all IRRS Team members have arrived in the host country, an initial team meeting will be conducted (prior to commencement of the IRRS mission) to discuss the specifics of the mission including the methodology for the review and the evaluation. This will also include expectations regarding matters such as behaviours, team-working, communication, time-keeping etc.

Depending on the experts' previous experience, it may be necessary to devote a full day to the initial team meeting. Appendix XI shows a typical agenda for the initial team meeting. It is important that all team members have a common understanding of the background, context and objectives of the IRRS, the basis for the review (i.e. IAEA safety standards and the State's completed IRRS self-assessment with initial action plan), type of information needed and the way it will be evaluated.

The IAEA Coordinator will brief the IRRS Team on issues, sensitive areas, priorities, schedule, approaches and expectations regarding the format and content of the deliverables by the IRRS Team members. The IAEA Coordinator will remind the team of the need to finish and agree on the report well before the end of the mission. During the initial team meeting the host country Liaison Officer shares information related to logistics, security and others important for the successful conduct of the IRRS mission. IRRS Team members will also report their first impressions of their subject area based on their in-depth review of the ARM.

6.2. ENTRANCE MEETING

An entrance meeting will be conducted on the first day of the mission with senior management of the host country's regulatory body (be it one or several authorities) and relevant government officials. At the meeting, both the IRRS Team and the host country present their primary objectives for the IRRS. The IRRS Team Leader presents a brief outline of the plan, approach and expectations for the mission, emphasising that it is not an inspection or audit, but will be conducted as a peer review in cooperation with the relevant host country organizations. A sample agenda for the entrance meeting is shown in Appendix XII. The entrance meeting does not take more than half a day in order to optimise time for interviews.

If necessary, there may be a more detailed introductory and information meeting with senior representatives from key organizations scheduled to be visited during the mission. This step may secure the goodwill and fullest cooperation of such organizations. If practicable, there are

benefits to be gained from inviting as many as possible of the host country's personnel directly involved in the review, so that all are prepared and know what to expect. At this meeting IAEA Coordinator could give a general presentation on IRRS upon request from the host country.

6.3. IRRS TEAM MEMBERS' COOPERATION AND CROSS-CONTRIBUTION

The IRRS Team Lead has a clear responsibility to ensure effective team communication. Training and detailed discussion of the cross-contribution table in the report template enhances the understanding by the IRRS Reviewers of their respective roles and need for coordination. The IRRS Team Lead establishes a systematic and simple process for ensuring that crosscutting inputs are provided. In-group and inter-group discussions are a further tool for communication and co-operation. Cross-reading of the draft mission report by other IRRS Team members is essential.

6.4. DAILY REVIEWS

IRRS Reviewers use three methods to acquire sufficient information to allow an objective review of regulatory effectiveness and identification of the important regulatory technical and policy issues:

— A review of written material;

— Interviews with personnel and other officials;

— Direct observation of regulatory body activities in the office and at facilities.

The review will predominantly concentrate on national regulatory responsibilities, functions and activities against relevant IAEA safety standards. However, adequate attention is also paid to wider policy issues having a significant impact on aspects of regulatory work. Observations are to be properly recorded in technical notes and reflected in the mission report.

It is vital to the effectiveness of the review and success of the mission that all observation and review activities are conducted in a frank and open atmosphere.

6.4.1. Review of written material

The review of the written material has two stages. The first stage occurs prior to the start of the mission. IRRS Reviewers study information provided by the host country (mainly the ARM,) together with other documents supplied by the IAEA. Results of the regulatory self-assessment including identification of actions for improvements as given in the initial host country action plan, are of particular importance. The results of this first stage are summarized in the written feedback report provided by each IRRS Reviewer and form the basis of the initial opinion/impressions presented by each reviewer at the initial team meeting.

The second stage takes place during the mission. Additional material in the form of regulatory body documents, presentations and examples of their work will be reviewed. This information will be taken into consideration in analysing and formulating conclusions, recommendations and suggestions, and identifying good practices.

Good quality written material provided by the regulatory body improves the efficiency of the reviews, facilitates preparation of the mission report, minimizes risk of misunderstanding and helps concentrate minds on the areas considered important by the regulatory body.

6.4.2. Interviews

Interviews will be conducted with representatives of all bodies involved in the regulation of nuclear, radiation, waste and transport safety including emergency preparedness and response and, as appropriate, other government departments performing regulatory functions or having responsibility for the regulatory body, together with technical support organizations, research institutes and regulated organizations etc. The prime objective of the interviews is to gather information not covered by the written material and where necessary, to seek clarification of written information provided. In some cases, it may be appropriate to hold discussions with parliamentary committees (or similar) involved in preparation of relevant legislative acts.

IRRS Reviewers check whether the relevant IAEA safety requirements are covered by the national regulations and guides and how the compliance with these regulations and guides is verified.

The IRRS Reviewers' extensive use of the self-assessment as a guide enhances the need for thoroughness in the host country's preparation and presentation of the self-assessment outcomes and the depth of detail required. The self-assessment provides a systematic and effective basis for discussions and helps to focus discussions on topics most relevant to the IRRS mission. IRRS Team members will verify the information provided in the self-assessment and ARM and enquire further where necessary to ensure they have full understanding. IRRS Reviewers may deviate from the structure and content of the self-assessment where alternative approaches might be beneficial in resolving untypical, difficult or contentious issues. When particular strengths become apparent during the discussions, IRRS Reviewers ensure they are highlighted for inclusion in the report and, if appropriate, identified as good practice. In line with the review of the relevant written material, interviews are linked to the relevant aspects of the host country's self-assessment and used to:

— review initial open issues arising out of the documentation review;

— identify the arrangements, authorities, duties and responsibilities of the regulatory body;

— compare these regulatory and administrative arrangements with the IAEA safety standards and determine potential differences, as well as make an informed judgement on the adequacy of the host regulatory body's national practices;

— examine the relationship between the regulatory body, its stakeholders and all those bodies involved in the process of the subject area (e.g. authorization);

— identify additional regulatory technical and policy issues;

— judge whether there is a need to propose a recommendation or suggestion in the topic area reviewed.

Interviews represent an important component of the mission, since in addition to complementing and verifying written information, they provide an opportunity for host regulatory body staff to discuss their practices and professional opinions with the IRRS Reviewers. Thus, interviews are conducted as a mutual exchange of views and not as an interrogation. The IRRS Reviewer leads the interview but allow time for counterparts to explain and contribute to the body of knowledge on the topic area. Encouraging the description or demonstration of examples of the work carried out is an effective way to illustrate specific points.

To the extent practicable, questions are prepared in advance and asked in a logical sequence. A general question is followed by the appropriate supplementary questions in order to obtain

sufficient evidence to support the original response. In order to avoid repetition and work more efficiently IRRS Reviewers coordinate interview questions in cross-cutting areas between the different modules.

6.4.3. Direct observation

Direct observation of regulatory work activities provides an opportunity for personal contact between regulators and IRRS Reviewers, improves understanding of existing regulatory technical and policy issues and allows the mission to be an exchange of professional knowledge and experience rather than a one way flow of information. The prime focus of the IRRS will inevitably be the regulatory body and its activities and it is to be expected that work activities of the various sections or groups within the regulatory body may have to be separately observed.

Opportunities to observe work activities are taken both at the regulatory body offices and during site visits (see section 6.7). Direct observation of work activities can provide valuable information complementary to the review of written material and the interviews. A precondition for using observation as a data source for conclusions is that the context of the observed activity is understood by the IRRS Reviewer. Useful activities to observe could be management meetings, safety committee meetings, meetings with licensees and other stakeholders, project review meetings, planning and conduct of inspections, management system audits and training sessions.

From these observations the IRRS Reviewer gains an improved understanding of:

— how regulatory and administrative procedures are applied in practice;

— attitudes and commitment of the regulatory staff;

— work effectiveness;

— the use of electronic documentation systems and other administrative aids;

— traceability of regulatory activities and the decision-making process, etc.

6.5. SITE VISITS

6.5.1. Purpose of a site visit

Certain interviews and direct observations of regulatory practices and activities, typically inspections, are carried out on the sites of authorized organizations to obtain a better understanding of how the regulatory body discharges its responsibilities and to give an opportunity for direct conversations with licensees.

Through observations of work activities and interviews with the regulatory body, as well as with authorized organization staff, the types of information to be gathered may include:

— perceived and actual roles and responsibilities of the regulator at the organization being visited;

— resources available to fulfil those responsibilities, including facilities, equipment and staffing;

— manner and effectiveness of the discharge of responsibilities;

— knowledge, skills and abilities of the host country's regulatory inspectors to perform inspections;

— effectiveness of regulatory processes;

— elements relevant to policy issues;

— relations between the regulatory body and the licensee.

6.5.2. Preparation for a site visit

To minimize travel time and reduce disruption for the visited organizations, only one visit needs to be arranged to each broad category of organization or facility. Since all relevant topics should be covered in the single visit more than one person (interviewee) from the organization may have to be available by prior arrangement during the visit. Site visits, especially those for observations of the regulatory inspections, are scheduled as early in the mission as possible, but not later than the fourth day, and carefully organized so that observations made during these visits may be properly incorporated in the IRRS Report's conclusions. Similarly, and to the extent possible, visits to government offices and/or other agencies for information gathering are scheduled in the first four days of the mission. Visits to government offices to discuss mission findings are scheduled to minimize the disruption of necessary mission tasks (report writing, exit meeting preparations etc.).

Prior to a site visit, IRRS Team members:

— are satisfied that relevant representatives of the organisation to be visited have been briefed well in advance on the purpose, aims and objectives of the visit (and of the IRRS itself);

— gain an understanding of the role and functions of the organization;

— identify those topics relevant to the IRRS and that organization;

— be aware of issues raised so far during the mission and their relevance to the visited organization;

— ensure that suitable arrangements have been made by the host organisations with regard to personal safety and security aspects.

6.5.3. Conduct of a site visit

The visit starts with an opening statement from the IRRS Reviewers to the site host, which includes a summary of the scope of the IRRS mission, the purpose of the visit and questions to be addressed. This is particularly important if the visited organization was not represented at the IRRS entrance meeting. Although the success of a visit depends on good preparation, IRRS Reviewers are to be prepared to accept changes in scheduling and arrangements made by the visited organization while making every effort to cover all the topics on their agenda.

It is important that staff of the visited organisation understand in advance that the visit is not an IAEA review of their facility or them, but is conducted solely to observe regulatory procedures in practice and the actions of regulatory body staff. Additionally, to inspectors a host country counterpart may accompany IRRS Team members to facilitate the logistics of the visit. The IRRS Reviewer also interviews the senior manager at the visited facility to discuss the nature of the relationship with the regulatory body. During interviews with licensees, the preference would be that the host country's regulatory body is ***not*** present, in order to facilitate open and frank discussions.

At the conclusion of the visit, IRRS Reviewers discuss their observations with the full IRRS Team at the daily team meetings.

Short information on the site visits are placed in the appropriate part of the IRRS report; for example, the site visit description can be added to the section that describes the inspection activities for the specific type of facilities.

6.6. RECORDING AND EVALUATING OBSERVATIONS

During interviews and direct observations, IRRS Reviewers make detailed notes of all relevant information gained (observations), together with its source. The notes on observations are to be updated regularly, at least on a daily basis. The writing of notes serves as a tool in developing the draft IRRS Report. IRRS Reviewers may compile a considerable volume of observations on various subjects and, thus, it is essential to record every observation at the earliest opportunity, preferably during interviews and site visits. Working in pairs provides a better opportunity for accurate recording. Technical notes may include:

— The official names or titles designating the organizational units and positions of persons interviewed/met;

— A summary of points recorded or actions observed during the interview or visit and their source(s);

— Comments on any regulatory technical issue or policy issue observations;

— Comments on the role, responsibilities and effectiveness of the organization;

— Documentation obtained or reviewed, additional documentation/evidence requested but not yet provided;

— Comments on strengths and areas for improvement within the organization, as perceived at the time;

— A list of issues to be brought to the attention of other IRRS Team members;

— The full meaning of abbreviations or acronyms used.

6.6.1. Recommendations

Recommendations are proposed where arrangements to meet the IAEA Safety Requirements are missing, incomplete, or inadequately implemented. Recommendations are specific, realistic and designed to result in tangible improvements to regulatory effectiveness. Recommendations are based on IAEA Safety Requirements, and the basis (i.e. the relevant Requirement(s)) for the recommendation is clearly documented in the mission report. All identified non-compliances against IAEA Safety Requirements lead to a recommendation. Recommendations may also have an additional reference to the Code of Conduct on the Safety and Security of Radioactive Sources where these have been agreed as part of the basis for the IRRS review. Recommendations are formulated such that they are succinct and self-explanatory. They clearly specify the responsible party and use "*should*" language (for example, "the regulatory body should…"; "the Government should…"). Recommendations that counterparts consider may take a long time to be implemented, or that the IRRS Team considers as a high priority, include interim goals, which would be set out in the IRRS report and in due course, by agreement, transferred to the host country's updated action plan.

6.6.2. Suggestions

IRRS Reviewers may identify opportunities for improvement not directly related to inadequate conformance with IAEA Safety Requirements. Suggestions are means of achieving this aim. Suggestions may contribute to improvements in national regulatory arrangements, but are primarily intended to stimulate the regulatory body's management and staff to consider new or different approaches to regulatory technical and policy issues that may enhance performance. Each suggestion has a basis either in IAEA Safety Requirements or in Safety Guides, as appropriate. The basis for the suggestion is clearly documented in the mission report. Suggestions are formulated such that they are succinct and self-explanatory. They clearly specify the responsible party and use "*should consider*" language (for example, "the regulatory body should consider…"). A suggestion may be proposed in conjunction with a recommendation or may stand on its own following a discussion of the associated background.

6.6.3. Good practices

A good practice is identified in recognition of an outstanding organization, arrangement, programme or performance superior to those generally observed elsewhere. It will be worthy of the attention of other regulatory bodies as a model in the general drive for excellence. Good practices also reference a basis similar to suggestions, and the basis is clearly documented in the mission report. Notable aspects of organization, arrangement, programme or performance that does not fully meet the Good practice criteria can be highlighted in the text of the report.

6.7. DAILY TEAM MEETING

Each IRRS Reviewer summarizes the day's observations and records insights and judgements in notes to support effective discussion of all subject review areas at a team meeting to be held at a defined time at the end of each day. The IRRS Team and the host country Liaison Officer are expected to attend this daily team meeting. The purpose of the daily meeting is to discuss the main observations of the day and to coordinate the next day's activities. This meeting offers the opportunity for IRRS Reviewers to consolidate their views, reach consensus where necessary and formulate the way in which their observations are to be captured in the final report.

The IRRS Team Leader will establish the style and conduct of these meetings. It is important for the daily team meetings to be conducted in an efficient manner in order to allow IRRS Reviewers enough working time on their issues. Daily team meetings are not intended to provide a forum for detailed reporting by IRRS Reviewers of their activities. They are to be as short as possible and concentrate on the presentation of issues which form the basis for recommendations, suggestions or good practices and information that might be relevant to other module IRRS Reviewers. A standard agenda might:

— Highlight the day's key observations in each review area, particularly significant concerns or positive features which may form the basis for recommendations, suggestions or good practices. Starting from the middle of the first mission week the "Observation" tables/boxes are discussed in detail;

— Report issues which need to be brought to the attention of other IRRS Reviewers, especially issues that have a bearing on the remainder of the IRRS;

— Identify gaps, overlaps and areas where the information is not clear or is inconsistent;

— Determine whether any of the day's observations might affect the remaining schedule for the mission;

— Summarize the visits / interviews to be conducted during the next day to enable all team members to provide input on the key topics to be addressed;

— Exchange information among the IRRS Reviewers contributing to the same module(s) and also among those responsible for different modules regarding their plans for future interviews;

— Determine the status of each IRRS Reviewer's written input to the draft IRRS report.

During daily team meetings, IRRS Team members share insights and observations regarding the implications of regulatory technical and policy issues pertinent to their review area(s). The IRRS Deputy Team Leader moderates the meeting and keeps a strict pace in order to keep the meeting as short as possible (typically one hour).

6.8. POLICY ISSUE DISCUSSIONS

Policy issue discussions are open to host country counterparts and attended by as many IRRS Reviewers as possible, according to their availability.

The IAEA Coordinator provides support for the review of policy issues during the mission. In fulfilling this role, the IAEA Coordinator works closely with the IRRS Team Leader, IRRS Deputy Team Leader and the IAEA Deputy Coordinator to resolve review concerns; provide support to IRRS Reviewers in integrating policy insights and key elements into their technical review activities and preliminary report input; and coordinate with the host country to schedule interviews and meetings on policy issues and provide advice on policy issues.

The IRRS Team Leader may also schedule interviews or small group discussions with the host country during the mission to be attended by a targeted group of host country representatives and the IRRS Team Leader, IRRS Deputy Team Leader, the IAEA Coordinator and the IAEA Deputy Coordinator.

The IRRS Team Leader ensures that principal insights and conclusions regarding regulatory technical and policy issues identified in the policy issue discussions are documented in the preliminary IRRS Report.

6.9. PREPARATION OF PRELIMINARY REPORT

The IRRS report is drafted using a report template that is provided to the IRRS Team by the IAEA Coordinator together with the ARM. The report template includes guidance for reviewing IRRS Modules; scope; relevant IAEA safety standards; topics/subjects covered; relationships with the other modules; and a possible need for cooperation with other IRRS Reviewers (inputs to and outputs from other parts of the report).

IRRS Reviewers are providing daily written inputs to the draft IRRS Report, commencing at the earliest opportunity. Their inputs are updated as necessary throughout the mission.

The evaluation of observations is expressed in concise conclusions. Conclusions must have their basis in known facts and formally documented evidence relating to IAEA safety standards. For example, a finding might be that legislation contains a provision addressing a particular topic. The conclusion would state whether this provision is consistent with IAEA safety standards and, if not, how it may be deficient. Additional information provided by other team members at the daily meetings are taken into consideration in refining the conclusions. Conclusions logically form the basis for development of recommendations, suggestions and good practice.

In developing conclusions, IRRS Reviewers:

— consider how effectively laws, regulations, procedures, etc., are implemented in practice relative to IAEA safety standards;

— consider the key elements of any policy issues;

— identify where elements of national regulatory infrastructure differ from those of the IAEA safety standards;

— identify the significance of differences relative to IAEA safety standards.

As information is gathered and evaluated, conclusions specific to a topic (such as inspection) may be developed. Specific conclusions in multiple topic areas are reviewed to determine if a generic conclusion may be derived or to confirm that the conclusion is limited to the one topic area. This is important to avoid the repetition of recommendations and suggestions throughout the IRRS Report.

The report text is concise without unnecessary details. At the same time the IRRS report includes all details needed to support each observation. The IRRS report text clearly documents the validation (or otherwise) of the host's self-assessment and initial action plan as a preface to the IRRS Reviewer's findings. Where the IRRS Team identifies recommendations or suggestions that have already been identified in the host country's self-assessment and initial action plan this is acknowledged in the report. This approach is made clear to the host country prior to the mission. In particular, it is clearly noted that the numbers of recommendations, suggestions and good practices, are not a measure of the current performance of one regulatory body relative to any other.

Observations are separated from the text of the report in the form of a table/box. Observations may be formulated as recommendations, suggestions or good practices as defined below. The observations table/box has 3 fields for: "Observation"; "Basis from the IAEA Standards"; and "Recommendation, Suggestion, Good practice".

The "Observation" field contains a short paragraph summarizing the facts that have been explained in the text. When a recommendation or suggestion is given, the "Observation" field states the fact that leads to the non-compliance with the IAEA safety standards. The "Observation" field includes a reference to the initial action plan if the Action Plan includes the appropriate action for improvement.

The "Recommendation, Suggestion, Good practice" field for the recommendations and suggestions is directed to the organization responsible for implementation (e.g. Government, Regulatory Body etc.).

To avoid duplication of recommendations or suggestions when a similar issue is identified across different parts of the report, the observation box is placed in the part of the report where it has the most significance. Due reference to this recommendation or suggestion appears in all those parts of the report for which the recommendation or suggestion is applicable.

"Module leaders" (assigned for the modules by the IRRS Team Lead) are responsible for compiling all the inputs of the other IRRS Reviewers into the appropriate chapter of the report. The IRRS Team Lead checks whether each recommendation and suggestion is specific, measurable, achievable, realistic and timely according to the information on national circumstances available to the IRRS Team. This approach is followed to improve recommendations and suggestions proposed by the IRRS Reviewers, and to ensure consistency.

The IRRS Team Leader, during the daily team meeting, provides for discussions and formulation of the team's conclusions/observations (the potential recommendations,

suggestions and good practices. IRRS Team Leader and the IAEA Coordinator ensure that the report is factually correct and agreed rather than try to resolve differences in reporting styles.

The IRRS Team Lead continuously cross-checks the developing preliminary report draft for comprehensive coverage of the scope of regulatory oversight, for accuracy and for contradictions or inconsistencies. IRRS Reviewers are encouraged to communicate the recommendations/suggestions/good practices that have been preliminarily agreed with the team, and the report text, to the counterparts at the earliest opportunity so that the counterparts' feedback can be obtained.

6.10. FINALIZATION OF THE PRELIMINARY REPORT AND COUNTERPART REVIEW

During the latter part of the mission, the IAEA Coordinator, together with the IRRS Deputy Team Leader with the involvement of the IAEA Administrative Assistant, will compile a preliminary IRRS Report comprising the individual and collective inputs from the IRRS Team, in order to capture the results of the review of the host country's regulatory infrastructure and any regulatory technical and policy issues. It is important that the mission schedule allows sufficient time for the IRRS Team to review and agree the significant points and for the host country's counterparts to review this preliminary report. The IRRS Team seeks to have an opportunity to discuss any final points made by the host, particularly where these may lead to adjustments to the content of the preliminary report.

The IRRS Team Leader ensures that there is cross-reading of the draft preliminary report by the team members that were not involved in the interviews and drafting of the report parts that they are cross-reading. This cross-reading is done to confirm comprehensive coverage of the scope of regulatory oversight, accuracy and the absence of contradictions or inconsistencies.

Final checking of the preliminary report by the IRRS Team Leader and Deputy Team Leader is arranged to avoid repetition in description and findings of different modules. The host is invited to comment on the report to ensure technical and factual accuracy and common understanding of its content. Recommendations, suggestions and good practices included in the preliminary report are in a finalized stage and should not be modified further. Keeping in mind that the final decision regarding its conclusions belongs to the IRRS Team, the IRRS Team Lead should ensure that recommendations and suggestions to Government are realistically achievable and understood by the host country. The IRRS Team Leader should also seek assurance that due priority and resources will be given to their implementation in accordance with the host country's updated action plan.

The IRRS Team Leader together with the Deputy Team Leader and IAEA Coordinator and Deputy Coordinator develops the executive summary. The executive summary sets out the background to the mission, including the mission dates, composition of the IRRS Team, the scope of the mission and the policy matters that are addressed. Acknowledgement is given to the host country's preparation of its self-assessment and initial action plan and management of the mission arrangements. The executive summary acknowledges those areas where recommendations and suggestions made by the IRRS Team had been identified by the host country prior to the mission and addressed in the initial action plan. It also indicates areas of good practice that the IRRS Team considers to be drawn out. This is a means of giving visible credit to the observations and commitments of the host country. Reference is made to the issue of a press release.

At the end of the mission, a copy of the preliminary report is handed to the host. Previous missions have indicated that timely delivery of the preliminary report can be a challenge, so it is important this aspect receives appropriate attention by the IRRS Team Lead.

For an agreed period following the mission, the host may further review and comment on the preliminary report. Comments addressing factual and editorial aspects of the report are to be forwarded to the IAEA Coordinator in accordance with an agreed time schedule.

6.11. COLLECTING FEEDBACK

The day before the exit meeting the IAEA Coordinator solicits feedback from the IRRS Reviewers and the host country through the Liaison Officer, regarding the effectiveness of the IRRS process including whether the IRRS mission objectives were attained. The feedback includes proposals for potential improvements to the IRRS process and IAEA safety standards.

6.12. EXIT MEETING

The IRRS mission concludes with an exit meeting. The exit meeting is normally attended by:

— the IRRS Team;

— host country counterparts;

— the head of the regulatory body;

— representatives of other organizations involved in the IRRS.

The exit meeting includes a presentation by the IRRS Team Leader on the main observations of the mission. The format of the exit meeting presentation may vary. It includes a description of the mission, the composition of the IRRS Team, the areas reviewed, the activities conducted, the strengths identified, the areas for improvement, and other observations the IRRS Team feels need to be highlighted to the host country. IRRS Team members may, as appropriate, provide a brief verbal report of conclusions in their own topic review areas. The IRRS Team Leader explains to the host country that the preliminary report will require further review and subsequent approval by both the host and the IAEA before a final mission report is issued.

The exit meeting is closed by the IAEA official statement. To make this statement an IAEA official may join the IRRS mission few days before the exit meeting. The IRRS Team Leader and the IAEA Coordinator brief IAEA official on the results of the mission.

IAEA press release is prepared by the IAEA Press Officer assigned by the IAEA Office of Public Information and Communication in cooperation with the IAEA Coordinator of the mission. The IAEA press release is based on the executive summary that is provided by the IAEA Coordinator to the IAEA Press Officer as early as possible, but at least one day before the exit meeting (see Appendix VIII on IRRS mission programme and schedule). Press release is disseminated by the IAEA Press Officer and published on the IAEA website after the exit meeting.

During the preparatory meeting it is decided if the host country would like to have a press conference. Press conference is prepared by the IAEA Press Officer who is assigned one month before the mission. IAEA Press Officer joins the mission two days before the end of the mission and prepares the press conference in cooperation with the IRRS Team Leader, IAEA Coordinator and host country Liaison Officer.

7. POST-MISSION ACTIVITIES

7.1. FINAL REPORT

The host country Liaison Officer will collate the preliminary report comments of all participating organizations within the host country and submit the complete set to the IAEA Coordinator. Comments from the host country are limited to issues relating to factual correctness of information contained in the preliminary report, not to the agreed recommendations and suggestions. The host country returns final comments to the IAEA Coordinator as quickly as possible within the agreed time frame (see Section 6.10 above).

Upon receipt of comments from the host country, the IAEA Coordinator in conjunction with the IRRS Team Leader, and with appropriate coordination with other team members, will assess the host country comments and draft the final IRRS Report; the goal being to issue this final report within two months following receipt of host country comments. Editing of the final IRRS Report is organized by the IAEA Coordinator. The final report is approved by the Team Leader before the final issuance. The report is submitted through official channels to the State concerned. Distribution of the final IRRS Report is restricted to the host country, IRRS Team members and appropriate IAEA staff. During first 90 days any further distribution will be at the discretion of the host country.

In the interest of openness, countries are encouraged to make their IRRS mission report public. If this is not done within 90 days of the IAEA transmittal letter; the report will be made available to the public by the IAEA unless the host country specifically requests that it remains restricted.

The results of the IRRS mission may be considered as inputs for future IAEA activities, such as TC support projects, extra-budgetary programmes and identifying regulatory trends and issues.

7.2. ACTION PLAN

Working from the IRRS Report, the host country updates its initial action plan (originally derived from the self-assessment). The updated action plan will be used to implement recommendations and suggestions set out in the IRRS Report. In some cases, the updated action plan may also indicate what on-going IAEA input or assistance might be provided to the State (e.g. documentation, expert missions, training, provision of inspection equipment, etc.). However, the decision to implement an updated action plan to address the IRRS recommendations and suggestions lies entirely with the relevant authorities of the country concerned. The host country may decide to request an IAEA expert mission to advise how recommendations and suggestions can be addressed and review progress with implementation of the updated action plan. Such missions cannot be considered as a substitute for the IRRS follow-up mission. The updated action plan and schedule of the follow-up mission may be made public by the host country if the IRRS report is made public.

8. IRRS FOLLOW-UP MISSION

8.1. OBJECTIVES OF THE IRRS FOLLOW-UP MISSION

Recognizing the importance of continuous improvement, the host country is encouraged to request a follow-up mission in a timely manner and to incorporate self-assessments in its integrated management system (potentially using the SARIS tool). The purpose of an IRRS

follow-up mission is to review the State's progress in implementing the initial IRRS mission recommendations and suggestions. If requested by the State, an IRRS follow-up mission may also include the review of specific topical areas not previously covered (in which case, it would usually be defined as an 'extended follow-up' mission). In such a case the IRRS Guidelines relevant to the initial mission apply to these areas.

The purpose of an IRRS follow-up mission is:

— to review progress in implementing improvements resulting from the initial IRRS mission recommendations or suggestions;

— where appropriate, to address areas of significant change since the last mission including new topics as requested.

8.2. REQUESTING AN IRRS FOLLOW-UP MISSION

An IRRS follow-up mission will normally be requested formally by the State to the IAEA Deputy Director General for Nuclear Safety and Security. In some circumstances the IAEA may suggest the State considers a follow-up mission. Typically, a follow-up mission will take place two to four years following the initial IRRS. Two years allow significant progress to be made with the implementation of the recommendations and suggestions of the initial IRRS mission. Beyond four years the effectiveness of the follow-up process may be limited.

A minimum of nine months is normally required to prepare a follow-up mission.

8.3. PREPARATORY PHASE OF AN IRRS FOLLOW-UP MISSION

On receipt of a request for an IRRS follow-up review an IAEA Coordinator will be assigned who will arrange for the:

— establishment of liaison contacts with the regulatory body;

— recruitment of the IRRS Team Leader (in conjunction with the State concerned);

— recruitment and briefing of IRRS Team members in conjunction with the IRRS Team Leader.

A preparatory meeting is conducted approximately six months before the follow-up mission. The preparatory meeting is attended by the IRRS Team Leader and, the IAEA Coordinator and, as necessary, the Deputy Team Leader and other representatives of the appropriate IAEA Divisions. At the same time, the host organization nominates a counterpart in each review area to be the primary contact with respective IRRS Team members. Where possible, the preparatory meeting is to be held at the regulatory body's headquarters to allow senior management and other organizations involved to participate. The meeting considers the:

— specific purpose of the IRRS follow-up mission in order to determine whether significant changes since the initial mission or the additional topic areas proposed can be effectively addressed within the scope of an 'extended follow-up' mission;

— impact of any extension in order to determine the appropriate duration and the team size;

— regulatory body's preparation for the follow-up review, including a list of the documentation required during the review;

— preparation of the ARM;

— logistical support required.

An outcome of the preparatory meeting is the agreement in the form of documented Terms of Reference for the IRRS follow-up mission. It is endorsed by the representative of the host country (typically by the host country Liaison Officer) and the IAEA Coordinator. The template for the Terms of Reference is provided in Appendix VII.

8.3.1. IRRS follow-up mission team composition

The team will comprise an IRRS Team Leader and an IAEA Coordinator, and a Deputy Team Leader and Deputy IAEA Coordinator if necessary, together with the appropriate number of IRRS Reviewers. For reasons of continuity it is preferable that the follow-up mission includes the IRRS Team Leader, IAEA Coordinator and IRRS Reviewers who participated in the initial mission, or at least reviewers with previous IRRS experience. If the follow-up review will encompass new review areas, additional IRRS Reviewers with the appropriate expertise are recruited. As with the initial mission, no one from the host country may be included in the IRRS Team. The inclusion of observers from other States may be proposed by the IAEA for consideration by the host country.

The roles and responsibilities of IRRS Team members for the follow-up mission are similar to those assigned for the initial mission.

8.3.2. Advance Reference Material for the IRRS follow-up mission

Prior to the start of the follow-up mission IRRS Team members will review the Advance Reference Material (ARM) provided by the IAEA, which includes the report prepared by the host country in preparation for the follow-up IRRS mission. The ARM outlines any significant changes to the ARM provided for the initial mission and also includes an evaluation of the status of recommendations and suggestions set out in the initial IRRS mission report. The results of a self-assessment undertaken in preparation for the follow up mission, if applicable, and the status of implementation of the updated after the initial mission action plan is also submitted by the host country and included in the ARM. The ARM is provided at least two months in advance so there will be adequate time for a thorough review of the material.

The ARM from the initial IRRS mission is also made available to the follow-up IRRS Team.

In the case of an ‘extended follow-up’ mission the ARM will also give full information related to the extended parts according to the guidance applicable to initial missions.

Prior to the IRRS follow-up review the IAEA and host country will agree the provision of necessary support facilities (see 5.5).

8.4. CONDUCT OF AN IRRS FOLLOW-UP MISSION

8.4.1. Review of host country responses to IRRS initial mission findings

The review of responses to the recommendations and suggestions made during the initial IRRS mission will be carried out following these IRRS Guidelines. In the same way as for the initial mission, information needed to reach a judgement will be gathered by a combination of the review of written material, interviews with personnel and direct observation of organizations, practices and activities.

The main written materials for this activity will be the ARM, including the updated action plan developed by the host country after the initial IRRS mission and further self-assessments on progress against the action plan items. However, additional written material would be necessary to demonstrate the measures implemented and progress made. The IRRS Reviewers

will be looking for evidence of the progress and may consequently provide further advice as appropriate.

8.4.2. Review of additional topics

If additional subject areas are included in the scope of the mission, they will be reviewed in accordance with the guidance applicable to the initial mission and presented in previous sections of this guidelines; the results of the review is reported in the same way as for an initial mission.

8.4.3. Documentation

During the course of the follow-up review, IRRS Reviewers write notes on their observations and conclusions. For the review of progress of the improvement plan actions, the reviewers will assess:

— actions completed;

— actions in progress;

— further review necessary.

Additional advice may be provided using new recommendations or suggestions. For areas that were covered in the initial mission and that are subjects to new recommendations or suggestion, it has to be emphasized that the benchmark (i.e. the IAEA standards to be used as basis) is the one that was available at the time of the initial mission. If a new or revised IAEA standard is published between the initial mission and the follow-up mission, it should not be used during the follow up mission. However, the host country will always be encouraged to adopt in a timely manner the latest version of the IAEA safety standards.

On completion of the review, the IAEA Coordinator will prepare the IRRS Follow-up Report summarizing the team's main observations, conclusions, recommendations, suggestions and identified good practices. Before the text is finalized, the regulatory body will be given the opportunity to comment regarding the accuracy and clarity of the report's contents. The editorial works of the IRRS Follow-up Report are organized by the IAEA Coordinator. The finalised report will be submitted through official channels to the host country.

8.4.4. Analysis of observations from an IRRS follow-up mission

The follow-up mission's review of progress made by the State in implementing actions in response to IRRS mission recommendations or suggestions will be expressed as conclusions. The following categories are used for expressing these conclusions:

A. Recommendation / suggestion remains open;

B. Recommendation / suggestion is closed on the basis of progress made and confidence in effective completion in due time;

C. Recommendation / suggestion is closed.

In exceptional circumstances, a recommendation or suggestion raised during the initial IRRS mission may no longer be relevant to the IRRS follow-up mission. This may for instance, be due to changes that have occurred in regulatory organization, regulatory framework or processes in the intervening period. Where such an instance occurs, the initial recommendation and/or suggestion may be amended accordingly or closed.

8.4.5. Schedule

An IRRS follow-up mission must be of sufficient duration to thoroughly review the actions taken in response to previously identified recommendations and suggestions. The duration also allows for the preparation of a comprehensive preliminary report of the follow-up mission prior to the exit meeting. Experience has shown that in addition to the review period, a further two days may be required for final discussions and drafting of the preliminary report.

The programme for the mission is agreed in advance. All follow-up missions have formal entrance and exit meetings. The first half-day of the follow-up mission would normally involve presentation of information contained in the most recent ARM. A standard Follow-up mission schedule is given in Appendix VIII.

The date of the next IRRS mission can be discussed at the end of the follow-up mission, but this is not essential.

8.4.6. Updating IRRS database

IRRS follow-up missions are designed to monitor progress in implementing recommendations and to update mutual understanding of the current status of the national legal and regulatory framework for safety, in terms of its compliance with IAEA safety standards. Information on improved compliance (i.e. implementation of IRRS recommendations and suggestions) derived from IRRS follow-up missions, other progress review missions and/or progress reports are periodically entered into relevant IAEA databases.

9. IRRS INITIAL AND FOLLOW-UP MISSIONS PROCESS REVIEW

Following both IRRS initial and follow-up missions, the IAEA Coordinator conducts a meeting with all IAEA staff involved in the mission(s). The purpose of this meeting is to elicit feedback from IAEA participants in the mission and to discuss lessons learned from the mission(s). The meeting considers any feedback on the SARIS methodology and tool, IRRS process and the mission itself submitted by the IRRS Reviewers or presented as a view of the IAEA participants in the mission. Should any insights arose from the mission for the future strengthening of the IAEA safety standards, the IAEA Coordinator and Deputy IAEA Coordinator raise these insights at the meeting for assessing their relevance. Agreed outcomes and lessons learned from the mission are documented in a memorandum to file and distributed to the appropriate Division Directors (including Technical Cooperation, if applicable). These proposals may be taken, into account, as appropriate, in the formal process for strengthening the IRRS process, SARIS methodology and tool as well as in the review of IAEA safety standards.

Upon conclusion of the mission, the IAEA Coordinator ensures that principal insights and conclusions regarding the regulatory technical and policy issues review (as documented in the preliminary IRRS Report) are provided to appropriate IAEA technical officers.

Consideration are given to holding international workshops to promulgate lessons learned from IRRS missions, both in terms of process and technical matters.

APPENDIX I: TECHNICAL AREAS

I.1. MODULE 1: RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

Core module (always included in the scope of the IRRS).

A fundamental prerequisite for regulatory effectiveness is a sound legislative and statutory framework, which establishes the regulatory regime needed to regulate the safety of facilities (nuclear facilities, facilities in medicine, industry, education and research, etc.), activities (production and use of sources of ionizing radiation, transport, waste management, etc.) and radiation protection in all exposure situation: planned exposure situation (occupational exposure, public exposure, patients protection); emergency exposure situations (public exposure and exposure of emergency workers, see Section I.6 in Appendix I defining the scope of review for emergency preparedness and response) and existing exposure situations (occupational exposure, patients protection, public exposure).

The law establishing the regulatory body provides for effective independence of the regulatory body from political and other interference or influence that may diminish its ability to impartially fulfil its mandate, in particular, to regulate nuclear and radiation facilities, activities and practices based on facts, sound judgement and decision-making. Thus, the regulatory body is accountable to the national legislative or executive bodies and its framework or processes for regulatory decision making is not subject to political decision.

Other facets of effective independence include effective and proper separation between the regulation and promotion of the use of nuclear energy and radiation sources; authority, competence and adequate resources to discharge the regulatory mandate; objective decision-making based on facts and objective criteria; and unfettered communication with stakeholders.

Sub-sections of Module 1		**GSR Part 1 (Rev. 1)**	**Other safety standards**[3]
1.1	National Policy and Strategy	R1	
1.2	Establishment of a Framework for Safety	R2	GSR Part 3
1.3	Establishment of a Regulatory Body	R3	GSR Part 3
1.4	Independence of the Regulatory Body	R4	
1.5	Prime Responsibility for Safety	R5	
1.6	Compliance and Responsibility for Safety	R6	
1.7	Coordination of Different Authorities with Responsibilities for Safety within the Regulatory Framework	R7	
1.8	System for Protective Actions to Reduce Existing or Unregulated Radiation Risks	R9	GSR Part 3
1.9	Provision for Decommissioning of Facilities and the Management of Radioactive Waste and Spent Fuel	R10	GSR Part 5, GSR Part 6, SSR-5
1.10	Competence for Safety	R11	
1.11	Provision of Technical Services	R13	

[3] Other safety standards for Module 1 crosscutting provisions are covered under Modules 5-9.

I.2. MODULE 2: GLOBAL NUCLEAR SAFETY REGIME

Core module (always included in the scope of the IRRS).

It is important that the regulatory body is aware of, and contributes to, the Global Nuclear Safety Regime. As such it recognizes its international obligations and arrangements for cooperation, in addition to sharing operational and regulatory experiences.

Sub-sections of Module 2		GSR Part 1 (Rev. 1)	Other safety standards
2.1	International Obligations and Arrangements for Cooperation	R14	
2.2	Sharing of Operating Experience and Regulatory Experience	R15	

I.3. MODULE 3: RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Core module (always included in the scope of the IRRS).

The responsibilities and functions for carrying out the various regulatory activities are defined and assigned. In fulfilling its statutory obligations, the regulatory body defines policies, safety principles and criteria as a basis for its regulatory actions – promotion/adoption of regulations and guides, authorization and inspection process and enforcement actions.

The regulatory body may have some additional functions to provide some technical services but in this case it is ensured that they do not conflict with the main regulatory functions.

The regulatory body establishes appropriate cooperation with other relevant authorities and agencies.

Sub-sections of Module 3		GSR Part 1 (Rev. 1)	Other safety standards
3.1	Organizational Structure of the Regulatory Body and Allocation of Resources	R16	GSR Part 2, GSR Part 3[4], GSG-12, RS-G-1.4
3.2	Effective Independence During Conduct of Regulatory Activities	R17	GSR Part 2, GSG-12, RS-G-1.4
3.3	Staffing and Competence of the Regulatory Body	R18	GSR Part 2 GSG-12, RS-G-1.4
3.4	Liaison with Advisory Bodies and Support Organizations	R20	GSG-4 GSG-12, RS-G-1.4
3.5	Liaison Between the Regulatory Body and Authorized Parties	R21	GSR Part 2 GSG-12, RS-G-1.4
3.6	Stability and Consistency of Regulatory Control	R22	GSR Part 2 GSG-12, RS-G-1.4

[4] GSR Part 3 Module 3 crosscutting provisions are covered under Modules 5-9.

Sub-sections of Module 3		GSR Part 1 (Rev. 1)	Other safety standards
3.7	Safety Related Records	R35	GSR Part 2 GSG-12, RS-G-1.4
3.8	Communication and Consultation with Interested Parties	R36	GSR Part 2 GSG-6, GSG-12, RS-G-1.4

I.4. MODULE 4: MANAGEMENT SYSTEM OF THE REGULATORY BODY

Core module (always included in the scope of the IRRS).

A management system, when properly implemented, is recognized as a valuable tool to improve efficiency and effectiveness of organizations. A management system is a set of interrelated or interacting elements (system) that establishes policies and objectives and which enables those objectives to be achieved in an effective and efficient way. It encourages the identification, definition and control of processes, and provides a framework for continual improvement. It will therefore provide a mechanism for the regulatory body to perform effectively.

Integrated management systems bring together all aspects of managing an organization and thereby define a set of arrangements and processes which, when fully implemented, allow an organization to meet its objectives. These objectives may include safety, health, environmental, security, quality and economic considerations. The definition of a particular organization's processes forms the basis of its management system.

		GSR Part 1 (Rev. 1)	Other safety standards
4	The Management System of the Regulatory Body	R19	GSR Part 2 GSR Part 3

I.5. MODULES 5 TO 9: MATRIX OF THE CORE REGULATORY PROCESSES

Core modules (always included in the scope of the IRRS).

The matrix includes the main regulatory processes in general and their application to the various facilities and activities and exposure situations except emergency exposure situation (see Section I.6 in Appendix I addressing emergency preparedness and response). The main regulatory processes and the respective general safety requirements and other relevant safety standards are listed first, the facilities & activities and exposure situations and the respective IAEA safety standards are given at the end of this section. In particular, core modules include such areas as control of medical exposures, occupational radiation protection, control of radioactive discharges and materials for clearance, environmental monitoring associated with planned exposure situations, control of existing exposure situations.

I.5.1. Module 5: Authorization

Authorization is defined as, "The granting by a regulatory or other governmental body of written permission for an operator to perform specified activities. Authorization could include, for example, licensing, certification, registration, etc.".

In order to fulfil its statutory duties, it is essential that the regulatory body be provided with the authority to allow it to conduct its regulatory activities. This authority is written into legislation, or adequately established by other means. The regulatory body shall have the authority to issue authorizations as well as attaching any conditions necessary to ensure safety. The regulatory body shall also have the authority to amend, suspend or revoke authorizations.

Effective regulatory bodies define and document the processes for granting authorizations. An authorization can include instruments such as licences, registrations, permits, and certificates, written statements of no objection, letters/memoranda or other documents that provide written permission for a licensee to proceed beyond a hold-point or for agreeing to the activity proposed by the licensee.

Prior to granting an authorization, the regulatory body requires the applicant to submit a detailed demonstration of safety, the safety case. The regulatory body determines whether this safety case adequately demonstrates the safety of the activity and the protection in specific exposure situations and that the regulatory body's safety objectives, principles and criteria have been satisfied. The authorization of activities is a continuous process which may start at the planning and feasibility study for a site and continue through the design, commissioning, operation, decommissioning or closure phases of the facility.

To facilitate this process the regulatory body may issue guidance on the format and content of the documents and information to be submitted.

		GSR Part 1 (Rev. 1)	Other safety standards
5.1	Authorization by the Regulatory Body	R23	GSR Part 3, SSG-12
5.2	Demonstration of Safety for Authorization	R24	

I.5.2. Module 6: Review and assessment

The objective of review and assessment is to determine whether the applicant's safety case adequately demonstrates the safety of the activity and protection of people in specific exposure situations and that the regulatory body's safety objectives, principles and criteria have been satisfied. In performing the review and assessment the regulatory body needs to satisfy itself that:

— the available information provided by the applicant demonstrates the safety of the proposed activity;

— the available information provided by the applicant demonstrates the protection of all exposed persons in the specific exposure situation;

— the information contained in the safety case is accurate and sufficient to enable confirmation of compliance with the regulatory body's protection and safety objectives; and

— the technical solutions, in particular novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of protection and safety.

The review and assessment shall encompass normal operation, anticipated operational occurrences, design basis events as well as design extension conditions as appropriate. The results of review and assessment are used by the regulatory body in formulating conclusions and decisions on its authorization activities.

Effective regulatory bodies define and document the processes for reviewing and assessing safety cases and manage the process to ensure that the review and assessment is completed prior to authorizing an activity.

To facilitate this process the regulatory body shall define and make available to the applicant the principles and associated criteria on which its judgements and decisions on the safety case are based and may issue guidance on the format and content of the documents and information to be submitted by the applicant.

		GSR Part 1 (Rev. 1)	Other safety standards
6.1	Review and Assessment of Information Relevant to Safety and Protection	R25	GSR Part 3, GSR Part 4 (Rev. 1) GSG-13
6.2	Graded Approach for Review and Assessment	R26	

I.5.3. Modules 7 and 8: Inspection and enforcement

Regulatory inspection and enforcement activities cover all areas of regulatory responsibility. Inspections allow the regulatory body to satisfy itself that the operator is in compliance with the conditions set out, for example, in the authorization or in the regulations.

The principal objectives of regulatory inspection and enforcement are to provide a high level of assurance that all activities performed by the operator at all stages of the authorization process and all stages during the lifetime of a facility or duration of an activity are executed safely and meet the safety objectives and licence conditions.

Regulatory inspection is performed to make an independent check on the operator and to provide a high level of confidence that the operators are in compliance with the protection and safety objectives, principles and criteria prescribed or approved by the regulatory body.

An inspection may result in a need for additional review and assessment or, in the case of non-compliance, for enforcement actions. Regulatory enforcement actions are intended to modify or correct any aspects of the operator's procedures or practices or of a facility's structures, systems or components as necessary to ensure safety. Enforcement actions may also include the imposition or recommendation of civil penalties and other sanctions and is commensurate with the seriousness of the non-compliance.

The regulatory body shall have the legal authority for conducting and coordinating its inspection and enforcement responsibilities.

		GSR Part 1 (Rev. 1)	Other safety standards
7.1	Inspection of Facilities and Activities	R27	GSR Part 3, GSG-13
7.2	Type of Inspection of Facilities and Activities	R28	
7.3	Graded Approach for Inspections	R29	
8.1	Establishment of Enforcement Policy	R30	
8.2	Enforcement of Regulatory Requirements and Conditions	R31	

Written inspection reports are prepared and the conclusions are communicated to the inspected organization.

An effective regulator will have documented processes for monitoring and verifying compliance with its requirements following the granting of an authorization. Effective regulators also document processes for enforcing non-compliance or bringing nuclear and radiation facilities, activities and practices back into compliance with regulatory requirements.

I.5.4. Module 9: Regulations and guides

A system of regulations and guides shall be chosen so as to suit the legal system of the State and the nature and extent of the facilities and activities to be regulated and exposure situations in which people are to be protected; for example, in providing a balance between the need for flexibility as in the performance based approach and the need to include detailed requirements as in the use of a prescriptive approach.

In developing regulations and guides, the regulatory body shall take into consideration feedback from experience and take due account of internationally recognized standards, such as the IAEA safety standards. Effective regulatory bodies have processes for developing, reviewing, updating, publishing and distributing regulatory standards and guides.

		GSR Part 1 (Rev. 1)	**Other safety standards**	
			Process of developing regulations and guides	***Content*** of regulations and guides
9.1	Regulations and Guides	R32	GSR Part 3, GSG-13	any safety standard of the list below
9.2	Review of Regulations and Guides	R33		
9.3	Promotion of Regulations and Guides to Interested Parties	R34		

I.5.5. Module 5 to 9: Facilities, activities and exposure situations

The core modules are applied to all facilities and activities regulated by the regulatory body and all exposure situations under peer review. Thus, an IRRS mission covers all facilities and activities and all exposure situations that fall into the scope of the mission for all regulatory activities of Modules 5 to 9.

Facilities and Activities	**Applicable IAEA safety standards and Guides**
Radiation sources applications	GSR Part 3; Code of Conduct on the Safety and Security of Radioactive Sources + associated safety guides
Research reactors	SSR-3 + SSG-12, GSG-13, NS-G-4.1
Nuclear power plants	SSR-2/1 (Rev. 1) SSR-2/2 (Rev. 1) NS-R-3 (Rev. 1) + SSG-2, SSG-3, SSG-4, SSG-12, SSG-25, SSG-28, SSG-50, GSG-13
Fuel cycle facilities	SSR-4 + NS-R-5 (Rev. 1), SSG-12, GSG-13
Waste management facilities	GSR Part 5; SSR-5 + SSG-12, GSG-1, GSG-13
Decommissioning	GSR Part 6 + associated safety guides
Transport of Radioactive Material	SSR-6 (Rev. 1) + associated safety guides

Exposure situations	Applicable IAEA safety standards and Guides
Planned exposure situations	GSR Parts 3, 5 and 6, SSR-5, GSG-7, GSG-9, GSG-13, SSG-12, SSG-40, SSG-41, SSG-46, WS-G-3.1
Existing exposure situation	GSR Part 3, WS-G-3.1, RS-G-1.8 + associated safety guides

I.6. MODULE 10: EMERGENCY PREPAREDNESS AND RESPONSE

Core module (always included in the scope of the IRRS).

The questions for regulatory aspects of emergency preparedness and response (EPR) are based on relevant requirements from GSR Part 1 (Rev. 1) and GSR Part 7. It is important to note that the primary focus of this module is related to regulatory aspects of EPR, i.e. to regulations and guides for EPR for operating organizations and to verification of compliance through review and assessment, approval of on-site emergency plan, inspection and enforcement as well as through evaluation of some of exercises conducted by the operating organizations. However, a limited review is performed in this module of the responsibilities assigned to the RB in a nuclear or radiological emergency and its internal capability to fulfil the assigned responsibilities. The peer review of overall EPR for a nuclear or radiological emergency of a country goes beyond the scope of Module 10 of an IRRS mission and it is covered in the scope of the Emergency Preparedness Review mission (EPREV, another IAEA service).

		GSR Part 1 (Rev. 1)	Other safety standards
10.1	Authority and responsibilities for regulating on-site EPR of operating organizations	R8	GSR Part 7 GS-G-2.1 GSG-2 GSG-11 GSR Part 3
10.2	Regulations and guides on on-site EPR of operating organizations		
10.3	Verifying the adequacy of on-site EPR of operating organizations		
10.4	Roles of the RB in a nuclear or radiological emergency		

I.7. MODULE 11: INTERFACES WITH NUCLEAR SECURITY

Optional module.

Safety measures and nuclear security measures shall be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise nuclear security.

		GSR Part 1 (Rev. 1)	Other safety standards
12	Interfaces with Nuclear Security	R12	SSR-3, SSR-4

APPENDIX II: POLICY ISSUES AND KEY ELEMENTS

This table provides an initial list of policy issues and their associated key elements and will be periodically updated based on insights and feedback from completed IRRS missions.

Issue	Summary/Background	Key Elements
1. Independence of Regulatory Body	Although increasing numbers of States have effective independent regulators, the issue of independence and, in particular, independent decision making at all stages in the lifetime of a facility or the duration of an activity, can be an issue.	• Legislation establishes effectively independent regulatory body • Independence from organizations promoting nuclear technology • Access to independent resources and technical advice • Funding independence • Balance between the operator and regulator responsibilities • Ability to make independent judgements and decisions, and if necessary to conduct enforcement, in accident conditions.
2. Openness, transparency and Stakeholders involvement (including public communications)	Openness and transparency in regulation is essential to encourage continuous improvement of performance and building public confidence. The international community promotes openness through several services. However, finding a proper balance between public availability of information and protection of confidential data remains a challenge.	• Strategies for engagement of stakeholders • Stakeholder involvement in regulatory decision making • The basis for regulatory decisions made available to stakeholders • Use of electronic communication, including the internet, for communication to stakeholders • Low threshold for informing stakeholders of nuclear and radiation safety related information

Issue	Summary/Background	Key Elements
3. Enhancing Regulatory Effectiveness and Competence	Challenges in maintaining and enhancing regulatory effectiveness and competence remain in many States. There is still no consensus on how to measure regulatory effectiveness.	• Harmonization with international practices • Commitment to resource planning • Commitment to knowledge management • Assessment of workforce competencies • Commitment to staff training and development • Commitment to continuous improvement and safety management systems • Promote sharing of regulatory knowledge, experience and lessons learned, both nationally and internationally • Use of regulatory performance indicators
4. Leadership and management of safety	Leadership in nuclear and radiation safety matters has to be demonstrated at the highest levels in an organization. The importance of human and organizational aspects of safety and safety culture is widely accepted. An effective management system is considered essential to support leadership in order to maintain and continuously enhance a good safety culture. Assessment tools for safety culture are being developed. However, recent events have led to concern over complacency in some operating organizations and lack of regulatory effectiveness in identifying and proactively responding to early symptoms of emerging safety culture problems.	• Safety policy defined • Safety management system • Integration of the elements of the safety management system (safety culture, environment, quality, financial etc.) • Internal assessment of safety culture • Safety culture - maintaining a questioning attitude both internally and on expert advice, e.g. by Technical Support Organization (TSO) • Open dialogue between regulatory body and senior industry executives • Internal decision-making appeal process • Value and ethics programmes • Self-assessment • Oversight of operator safety culture • Regulatory experience included in appointing senior executives

Issue	Summary/Background	Key Elements
5. Use of insights from operation experience feedback (OEF) into the regulatory process	Nuclear power plant (NPP) operational safety performance, in general, has remained at a high level throughout the world. Radiation doses to workers and members of the public due to NPP operation are well below regulatory limits. However, we still see recurring events in nuclear installations. Enhanced operational feedback systems of both NPP operating experience and regulatory experience, are needed to support the sharing of actions taken by operators and regulators towards risk reduction.	• Collecting OEF • Analysing OEF and identification of root causes • Collecting and analysing other regulatory body's responses to international OEF • Make appropriate changes based on OEF • Disseminating results of OEF, nationally and internationally • Maintaining a safety culture that promotes consideration of low level events
6. Long Term Operation and Ageing Nuclear Facilities	Eighty per cent of the reactors operating worldwide could be proposed for long term operation. Member states have demonstrated common initiatives and are at different stages in the process while varying in their national practices. Long term operation of NPPs includes Member States' practices such as plant licence renewal, life extension, continued operation and life management. Long term operation is economically attractive to plant owners while it offers Member States added energy security, environmental quality and economic growth. The long-term operation of NPPs is one unique nuclear safety issue to be addressed by the international nuclear community.	• Regulatory approach • Existing process for renewing / extending / re-licensing beyond original operating term • Use of periodic comprehensive safety reviews and re-evaluation of safety margins • Control of modifications • Regulatory requirements and guidance • Regulatory inspection and monitoring process • Additional regulatory strategies to reduce the collective doses arising from long-term periodic inspections and extensive maintenance activities.
7. New Build and New Technologies	New build programmes are increasingly being proposed which involve use of foreign technology, investment and resource, including the supply chain. Ensuring that a country has a robust regulatory body capable of setting	• Suitability of existing arrangements for authorization to address challenges such as privatized utilities, use of contractors, international nuclear companies • The mechanisms identified for ensuring safety of the new build plants

Issue	Summary/Background	Key Elements
	expectations and regulating in such circumstances can present a challenge.	• Retention of intelligent customer capability • The establishment of a contact forum with the aim of producing a joint plan for an integrated licensing process • Stepwise licensing of new NPP projects • Cooperation with regulatory bodies that have reviewed and possibly licensed the NPP designs proposed to be built
8. Regulatory Approach Risk-informed and Deterministic. Performance-based Approach (functional based) and Prescriptive.	In some Member States, there is a trend towards a risk-informed and performance-based approach to regulation, rather than a prescriptive approach. Similarly, new licensing procedures are being developed to improve predictability of the process and help to reduce financial risks of nuclear power plant construction. It is therefore important to consider how such a transition is managed.	• Guidance exists for risk informed regulatory decision making • Process for determining the safety significance of regulatory actions • Defined outcomes based on promoting safety • Prioritize regulatory activities based on safety significance • Expectations for balancing risk-informed and deterministic decision-making • Implications for regulatory body staff competence and experience
9. Participations on legal and non-legal binding international instruments and globalization of the Nuclear Community	Solutions for increased nuclear safety and security require a multilateral approach that takes into consideration interests of, and learning from, key stakeholders, national policies and global trends. The	• Multilateral exchanges • Bilateral or multilateral agreements • Participation in Conventions • Commitment to Codes of Conduct • Participation in international safety review services • Demonstrated openness to improvement and mutual learning

Issue	Summary/Background	Key Elements
10. Response to renewed interest in nuclear power	International nuclear regulatory groups have been formed to address common problems and strengthen cooperation and coordination. Both nuclear power plant vendors and operating organizations have consolidated. Many vendors have evolved into global enterprises, and large generating companies and management organizations now operate many plants. Multilateral research and development (R&D) has become an important part of the future for nuclear energy. Advances in information technology and communications have led to stronger interactions between operating organizations, regulatory authorities, and concerned stakeholders, and greater public awareness of nuclear safety issues. However, great effort is needed for emerging and mature nuclear Member States to ensure that necessary nuclear safety infrastructures are in place to maintain a viable nuclear programme. A priority of nuclear safety for new installations in their design, siting, construction and operation will be important.	• Commitment to resource planning • Commitment to knowledge management • Assessment of workforce competencies to meet emerging technologies (R&D from TSO or regulatory body itself) • Collaborative efforts with other regulators on the review of new designs and technologies
11. Human Resources and Knowledge Management	In many regions, the human resource of the nuclear community is aging. There is a movement towards revitalization of the human resource in some Member States. The need for knowledge management and creation of new knowledge, preservation of existing resource, and knowledge sharing is recognized. The new move towards network building for global knowledge sharing and management is showing promising results. Efforts in this direction need to continue to ensure	• Plans to attract and retain staff • Existing strategies to identify, capture, and transfer knowledge internally and externally • National or Regional training centres • Identified specialized skills and identified strategies to maintain and build competence • Appropriate emphasis on regulatory research and technical support organizations

Issue	Summary/Background	Key Elements
	availability of resources. Also, facilities critical to the conduct of important safety research need to be preserved.	
12. Continuous improvement	There is an accepted international requirement for regulatory bodies to emphasise the continuous enhancement of safety by requiring authorized parties to identify improvements by evaluating operating experience, progress in science and technology and periodically performing comprehensive safety reviews. These improvements could go beyond national requirements. The regulatory body is required to ensure that any reasonably practicable safety improvements identified in the reviews are implemented in a timely manner.	• Legislative requirements relating to continuous enhancement of safety • Periodic evaluation of operating experience and progress in science and technology • Enforcement of reasonably practicable safety improvements
13. Justification	Justification of practices is a requirement of the IAEA safety standards. However practical implementation needs special guidance and competence from regulatory body and the radiation sources users.	• Legislative and regulatory requirements for the justification of practices • Methodology • Examples from the practice, including justification of human imaging in nonmedical areas
14. New complex radiation sources medical applications licensing	Technologies for medical use of radiation sources are rapidly developing. These complex medical applications are introduced when no national or international guidance for the authorization of such applications has yet been developed. Regulatory bodies are prepared to use a flexible but still comprehensive approach for the safety review and authorization in such cases.	• Regulatory approaches for the new complex radiation sources application licensing • International expertise utilization

APPENDIX III: MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER PROGRAMMES

III.1. OVERVIEW OF THE TAILORED MODULE

Sub-Sections of Tailored Module		Actions of the Safety Infrastructure Guide SSG-16		
		Phase 1	**Phase 2**	**Phase 3**
1	National policy and strategy	1-4	5-8	9-10
2	Global nuclear safety regime	11-13	14-16	17-19
3	Legal framework	20-21	22	23
4	Regulatory framework	24-26	27-32	33-38
5	Transparency and openness	39-40	41-42	43-47
6	Funding and financing	48-51	52-55	56-60
7	External support organizations and contractors	61-62	63-66	67-71
8	Leadership and management for safety	72-74	75-77	78-84
9	Human resources development	85-89	90-94	95-98
10	Research for safety and regulatory purposes	99-100	101-103	104
11	Radiation protection	105-107	108-113	114-116
12	Safety assessment	117	118	119-121
13	Safety of radioactive waste, spent fuel management and decommissioning	122-123	124-127	128-132
14	Emergency preparedness and response (regulatory aspects)	133-134[5]	135-139[3]	140-145[3]
15	Operating organization	146-148	149-154	155-159
16	Site survey, site selection and evaluation	160	161-166	167-169
17	Design safety	170-171	172-176	177-184
18	Preparation for commissioning	-	-	185-188
19	Transport safety	189	190-191	192
20	Interfaces with nuclear security	193	194-196	197-200

III.2. SUPPLEMENTAL GUIDANCE FOR IRRS IN EMBARKING COUNTRIES

III.2.1. General scope

The purpose of an IRRS mission is to evaluate a host country's regulatory infrastructure in relation to IAEA safety standards. The prime IAEA safety standard is General Safety Requirements GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety. The IRRS review mission considers the responsibilities and functions of the

[5] Although these actions relate to EPR not all of them are relevant or equally relevant for the scope of IRRS mission (see Section I.6 in Appendix I regarding EPR scope of IRRS).

government – principally enacted through an appropriate legal framework (law), the regulatory body and how the regulatory body discharges its functions. The primary counterpart is usually the regulatory body for nuclear and radiation safety. For embarking countries, the scope of the IRRS mission addresses the existing regulatory infrastructure for control of sources and other currently regulated facilities and activities, as well as the implementation of the IAEA safety standards during development of the safety infrastructure for a nuclear power programme.

IAEA Safety Guide SSG-16, establishing the Safety Infrastructure for a Nuclear Power Programme, addresses the roles of the government, regulatory body, and operating organization. *For the implementation of an IRRS mission as related to a State's development of its nuclear power regulatory infrastructure, the SSG-16 actions considered would be those to be implemented by the government and/or the regulatory body*.

Regarding actions directed to the operating organization(s), the focus of the IRRS review would be to ensure there are appropriate regulations in place or planned, such that the required actions are taken by the operating organization. Examples are:

— Phase 2, Action 75, states both the regulatory body and the operating organization should start developing and implementing effective management systems. For this action related to the operating organization, the regulatory body should have within its regulations the requirements for the operating organization to implement a management system.

— Action 76 states both the regulatory body and operating organization should develop competences in managing the growth and change in the organization. This action, although required in GSR Part 2, may or may not be explicitly stated in the national regulations. If it is not explicitly addressed in national regulations, the IRRS Reviewer may consider proposing a suggestion in the context of GSR Part 1 (Rev. 1), Requirement 32, "The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based."

In addition, if the action is within a "licensing process or authorized activity," the IRRS Reviewer reviews the action in the context of the regulatory body fulfilling its regulatory functions (i.e., authorization, review and assessment, inspection). The implementation of the operating organization's respective actions is to be peer reviewed by other IAEA safety review services such as a preliminary Operational Safety Review Team (pre-OSART) mission in Phase 3.

III.2.2. Phased application of the embarking countries module in relation to the IRRS

The level of development of the regulatory infrastructure will influence when the Member State requests an IRRS mission, the organization of the mission, and the subsequent documentation. The approach is discussed and agreed to as early as practicable and confirmed during the IRRS preparatory meeting.

Phase 1

Embarking countries in Phase 1 may request to host IRRS missions, including the tailored module for NPP, to raise awareness to the government's long-term commitment for safety. The mission could include policy discussion relative to the regulatory body/programme for Nuclear Safety. The embarking country is expected to use the findings of the IRRS mission to develop and or update its action plan for the development of the safety infrastructure.

Phase 2

For programmes in Phase 2, the approach is consistent with the expectation contained in Section 4 of these Guidelines, i.e. there will be a review of the preparedness of the national regulatory infrastructure using the 20 elements contained in SSG-16 and documented accordingly. In Phase 2, embarking countries continue to update their IRIS self-assessment. In performing the self-assessment, the State evaluates Phase 2 actions as these will be included in the scope of the IRRS review. In addition, the State may consider evaluating Phase 1 actions. The State may consider the inclusion of Phase 3 actions if plans for Phase 3 action implementation have been sufficiently developed. Where Phase 3 actions might be included in the IRRS review, these would be subject to a formal request and confirmed during the preparatory meeting.

IRRS Reviewers addresses relevant actions of SSG-16 during the review of the core modules of the IRRS[6]. This will ensure the completeness and consistency of the review.

Phase 3

In Phase 3, it is expected that a State would have developed its regulatory infrastructure and that the organization of the mission and advance review material would follow the format of an IRRS for countries having developed nuclear power programmes. In addition, the State is cognizant of the actions in SSG-16 in order to identify and implement corrective actions to address discrepancies with the IAEA safety standards identified during the IRRS mission.

Therefore, the State requests an IRRS mission consistent with that for a country with a developed nuclear power programme. Certain requirements related to regulatory oversight of NPP operation may not need to be in place until later during the construction, commissioning, operation and decommission phases of the NPP. In this case, in its self-assessment summary, the State identifies any future activities needed to address any gap with SSG-16 Phase 3 actions. Any actions associated with resolution of the gaps are also included in the State's initial action plan developed based on the results of its self-assessment.

If an initial mission was conducted in Phase 2 and the follow-up is taking place in Phase 3, the scope of the follow-up mission is to be extended to include a full scope review of the regulation of the NPP, consistently with that for a country with a developed nuclear power programme. That will be an 'extended follow-up' mission. In such a case the IRRS Guidelines relevant to the initial mission apply to NPP issues.

III.2.3. Documentation of results

IRRS Reviewers document their evaluations and observations using the guidance for IRRS. The formulation of recommendations, suggestions and good practices follows guidance provided in Sections 6.6.1, 6.6.2, and 6.6.3, respectively.

III.2.4. Feedback on SSG-16

SARIS and IRIS serve different purposes: SARIS is a tool to verify compliance with IAEA Safety Requirements; whereas IRIS is a tool to help planning and to verify the status of development of safety infrastructure of a nuclear power programme using the phased approach.

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[6] IAEA will provide guidance for reviewers.

IRRS Reviewers discuss with their counterparts the host's experience in using SSG-16 and the associated SSG-16 self-assessment tool. The resulting insights are provided to the IAEA Coordinator.

APPENDIX IV: RESPONSIBILITIES OF MISSION PARTICIPANTS BY ROLE

IV.1. IRRS TEAM LEADER

It is important that the IRRS Team Leader is able to get an overview of all activities that take place during the mission and that he/she has enough time to take leadership. The IRRS Team Leader is usually not assigned a function in reviewing a module. The IRRS Team Leader is primarily responsible for:

— serving as IRRS liaison, in conjunction with the IAEA Coordinator, with the government/regulatory body and external stakeholders during the mission;

— working closely with Deputy Team Leader, IAEA Coordinator and IAEA Deputy Coordinator early in advance of the mission;

— coordinating with IAEA Coordinator for external interaction related to the conduct of IRRS mission;

— actively contacting the IRRS Team members and structuring the preparation phase;

— providing leadership and explaining his/her expectations;

— helping IRRS Team members to overcome initial stress and starting to create team spirit;

— determining the division of responsibilities between the IRRS Team Leader and deputy;

— directing the team early towards main objectives, identifying deliverables, assigning tasks and responsibilities to the IRRS Team members;

— leading the IRRS mission including supervising the review, ensuring schedules are met and providing leadership in the resolution of issues that may arise;

— leading the initial team meeting, entrance and exit meetings;

— ensuring that the IRRS Team works in a consistent and cohesive manner;

— cross checking the draft report for comprehensive coverage of the scope of regulatory oversight, for accuracy and for contradictions or inconsistencies;

— recognizing and managing strengths and weaknesses of team members;

— communicating with IRRS Team members on a regular basis prior to and during the mission, in order to ensure team members are adequately prepared and informed;

— ensuring that the objectives of the IRRS are met;

— providing guidelines for the conduct of the daily meetings;

— developing an overall picture of the effectiveness of the regulatory body, to be reflected in the executive summary and press release, using the requirements as a reference;

— coordinating with the regulatory body and the IAEA Coordinator to prepare public information needed during the mission;

— conferring on appropriate changes to the draft report in consultation with the IRRS Team members, based on comments received from the host country

— the approval of the final report before the final issuance.

IV.2. IRRS DEPUTY TEAM LEADER

The IRRS Deputy Team Leader is able to support the IRRS Team Leader in his/her functions. On missions to countries with large nuclear programs the IRRS Deputy Team Leader does not have a formal function in reviewing a module. In smaller missions he/she can support Group A (see Appendix X). The IRRS Deputy Team Leader is primarily responsible for:

— working closely with IRRS Team Leader, IAEA Coordinator and IAEA Deputy Coordinator early in advance of the mission;

— identifying appropriate IRRS Team members based on the established work plan, in conjunction with the IRRS Team Leader and IAEA Coordinator;

— conducting daily team coordination meetings;

— sharing leadership responsibilities with the IRRS Team Leader especially with the daily coaching of the IRRS Team;

— ensuring together with the IAEA Deputy Coordinator that all observations relevant to non-compliance with IAEA Safety Requirements lead to the appropriate recommendation and basis.

— assisting the IAEA Coordinator with preparation of the preliminary IRRS report;

— assisting the IRRS Team Leader with the initial team meeting, entrance meeting and exit meeting;

— undertaking roles as assigned by the IRRS Team Leader.

IV.3. IAEA COORDINATOR

The IAEA Coordinator is primarily responsible for:

— serving as official IAEA liaison with the government/regulatory body prior to, during and after the IRRS mission;

— assuring IAEA representation at meetings with government officials, if IRRS mission related;

— preparing a briefing for the host country on the IRRS process, including providing a copy of this IRRS Guidelines;

— after consulting with appropriate IAEA technical officers, determining the scope and terms of reference of the IRRS mission, paying due regard to the IAEA cooperation plan for the country (if the country is receiving IAEA assistance);

— supporting consistency with other IRRS missions and lead activities before and after the mission and ensuring the standardized timing of pre-mission and post mission activities;

— requesting completion of the self-assessment, ARM by appropriate organizations in the host country, and ensuring their receipt by IAEA in a timely manner (preferably two months prior to commencement of the IRRS mission);

— working closely with IRRS Team Leader, Deputy Team Leader and IAEA Deputy Coordinator early in advance of the mission;

— identifying appropriate IRRS Team members, in conjunction with the IRRS Team Leader;

— recommending to the IRRS Team Leader the assignment of tasks and responsibilities to the IRRS Team members;

— managing resources, such as financial arrangements for the IRRS Team, coordinating travel for the IRRS Team members, and ensuring the provision of special equipment and logistics, as required;

— interacting with the appropriate section/divisions of the IAEA;

— providing IRRS Team members with appropriate pre-mission information, in particular providing access to the ARM after it is submitted to the IAEA and providing the information on the review of ARM, mission report template, information on the preparation of the initial opinion, preparation for interviews and preliminary report drafting;

— providing guidance to the IRRS Team Leader and IRRS Deputy Team Leader to help ensure that the objectives of the IRRS are met;

— ensuring policy issues are adequately addressed;

— collating the preliminary report of the IRRS with the assistance of the IRRS Deputy Team Leader, based on the contributions from the IRRS Team members; and determining which, if any, portions of the report need to be in a confidential annex;

— assisting the IRRS Team Leader and the regulatory body to prepare public information relating to the mission;

— preparing the draft report based on the preliminary report and comments received from the host country and IRRS Team members;

— submitting the draft report to the host country for comments following IAEA approval;

— finalizing the report based on the comments received from the host country;

— issuing the final report to the host country following IAEA approval;

— co-ordinating with other IAEA Sections or Divisions for input that might be applicable to the review.

IV.4. IAEA DEPUTY COORDINATOR

The IAEA Deputy Coordinator is primarily responsible for:

— working closely with IRRS Team Leader and Deputy Team Leader early in advance of the mission and providing support to the IAEA Coordinator;

— providing expertise and support to IRRS Team members with regard to application of IAEA safety standards and IAEA review process;

— alerting IRRS Reviewers and counterparts where misunderstanding/misinterpretation of a requirement from IAEA safety standards is evident;

— gathering feedback on the application of IAEA safety standards and formally reporting it to IAEA. Special attention is paid to requirements that appear to be interpreted variably.

— ensuring together with the IRRS Deputy Team Leader that all observations relevant to non-compliance with IAEA Safety Requirements lead to the appropriate recommendation and basis.

— assisting the IAEA Coordinator in preparation of the preliminary report;

— assessing the effectiveness and efficiency of IRRS and check the conciseness of the draft report during the mission.

— serving as an IRRS Reviewer as assigned by the IRRS Team Leader.

IV.5. IAEA REVIEW AREA FACILITATOR

The IAEA Review Area Facilitator (if needed) is primarily responsible for:

— providing expertise and support to IRRS Team members with regard to application of IAEA safety standards and IAEA review process;

— assisting the IRRS Reviewers with preliminary report input preparation;

— assisting the IAEA Coordinator with preparation of the preliminary report;

— serving as an IRRS Reviewer as assigned by the IRRS Team Leader.

IV.6. IRRS REVIEWERS

IRRS Reviewers are responsible for:

— making necessary preparations for the IRRS, on the basis of information from the IAEA Coordinator;

— reviewing and studying the self-assessment results, ARM and host country Action Plan and preparing the feedback report;

— conducting the IRRS as directed by the IRRS Team Leader;

— participating in the initial team and entrance meetings;

— taking the lead during the interviews with their review area counterparts; before entering into details discussions with the counterparts reaching common understanding of the applicable IAEA safety standards requirements which will form the basis for observations;

— reviewing the assigned regulatory areas against IAEA safety standards;

— evaluating their observations;

— making recommendations for all identified non-compliances against IAEA safety requirements.

— jointly reviewing with the IRRS Team all observations, conclusions, recommendations, suggestions and good practices;

— providing input to the preliminary report daily, as directed by the IRRS Team Leader;

— reviewing the completed preliminary report;

— maintaining appropriate confidentiality of sensitive information in accordance with their confidentiality agreement; and

— providing comments to the IAEA on the IRRS process, after completion of the mission.

IV.7. IAEA ADMINISTRATIVE ASSISTANT

The IAEA Administrative Assistant acts in full coordination with IAEA Coordinator and is primarily responsible for:

— contributing to the scheduling of the mission and the identification of team members;

— liaison with the host organization (and/or Permanent Mission of the host country or IAEA Technical Cooperation Department) on the funding and administrative preparation of the mission;

— preparation of a cost estimate and acceptance of the extra-budgetary funding to cover the expenditure for the mission;

— requesting governmental nomination of IRRS Team members where necessary and official invitation of the IRRS Team members;

— liaison with and providing information to IRRS Team members on various organizational and logistics aspects of the mission and compiling information on these matters from IRRS Team members to be forwarded to counterpart;

— ensuring that share point repository is ready for the mission and give access to all experts to review the Advance Reference Material; upload to the repository support documents (IAEA safety standards, IRRS Mission reports, IRRS Guidelines, etc.);

— collecting individual dosimeters and distributing them during the mission, keeping track of serial number vs. expert.

— assisting in coordination with the Press Officer if press conference is planned;

— preparation of the IRRS mission specific for the host country report template based on IRRS report template;

— administrative liaison with the host organization, including transportation, meeting points and venues including site visits;

— acting as a focal point for IRRS Team members, providing guidance and support on organizational, administrative aspects and mission logistics, checking that all IRRS Team members have arrived at the duty station;

— briefing the IRRS Team on procedures for report inputs/contributions preparation and their submission (e.g. to ensure version control of the mission report);

— compiling the mission report and ensuring correct orthography, syntax and grammar; and assisting with language and formulations in the report during cross-reading and discussions;

— keeping actual master copy of the draft mission report and its dissemination for the IRRS Team members as agreed with the IRRS Team Lead;

— assisting in preparation of the preliminary report of the mission;

— finalizing the mission report after Member States' comments resolution by the IRRS Team lead and IAEA coordinators;

— official IAEA clearance procedure and distribution the mission report;

— finalizing accounts and invoicing/returning balance.

IV.8. OBSERVER

The main purpose of an observer taking part in an IRRS mission is to provide another Member State's regulatory body with first hand insight into the IRRS process. The scope of the observer's involvement is agreed to by the IRRS Team Leader, the host regulatory body and the observer's regulatory body prior to the start of the mission. Typically an observer would be

expected to participate / attend the IRRS Team activities and prepare notes concentrating on aspects of benefit to the observer's own country and discuss them with the IRRS Team Leader.

IV.9. HOST COUNTRY LIAISON OFFICER

The host regulatory body appoints a Liaison Officer who is an experienced, senior member of staff. The Liaison Officer has a key role in the effective coordination of the mission and the role includes:

— arranging logistics, administration, scheduling and documentation;

— being the main contact and focal point with the IRRS Team Leader and IAEA Coordinator in the preparatory phase and during the mission;

— being the conduit between the IRRS Team and the regulatory body;

— assisting in regulatory staff appreciation of what the mission entails;

— attending team meetings throughout the mission; and

— being available throughout the mission.

For large missions, the host regulatory body considers appointing a Deputy Liaison Officer to assure continuity of support for the IRRS Team during the mission.

IV.10. HOST COUNTRY COUNTERPARTS

A counterpart is a staff member of the host regulatory body who is the primary contact with the IRRS Reviewer(s) for a particular area of review throughout the mission. A counterpart would normally be a senior staff member whose responsibility corresponds to the area(s) of review and would be expected to remain with, or available to the IRRS Reviewers throughout the relevant portion of the mission. The counterparts:

— lead the preparation of the written responses to the IRRS questionnaire in their specific subject area(s) and ensure the relevant documentation is provided as part of the ARM;

— provide a coordination function and call in specialist staff as required;

— participate in the review related to their area(s) of responsibility; and provide complete and correct information and facilitate understanding.

APPENDIX V: MAIN ELEMENTS OF THE PREPARATORY MEETING

1. Discussions on the aims of the IRRS to be held between the IRRS Team Leader, Deputy Team Leader, IAEA Coordinator and Deputy Coordinator and representatives from the IAEA's IEC and the host country senior management. The objective of the discussion is to:
   a. confirm the scope of the review;
   b. identify the counterparts;
   c. agree the composition of the IRRS Team, i.e. expertise required, numbers and specific requests for IRRS Reviewers; and
   d. agree, as appropriate, on the participation of observers.
2. Presentations by the host regulatory body to the IRRS Team representatives. This part of the meeting gives the regulatory body the opportunity to explain the status of its organization and provides the team information that will be used to recruit suitable IRRS Reviewers for the mission, by covering:
   a. the regulatory body structure, organization and independence; and
   b. the main responsibilities of the regulatory body and its current activities.
3. Presentation by representatives of the IRRS Team on the IRRS methodology to the host regulatory body staff. This part of the meeting allows the IRRS Team to:
   a. explain the IRRS methodology covering:
      - the overall process;
      - the roles and responsibilities of all the participants;
      - the schedule;
      - the entrance meeting;
      - document review, interviews and direct observation;
      - development of observations, conclusions, recommendations, suggestions and good practices;
      - the drafting of the mission report;
      - the exit meeting.
   b. explain (and provide) the IAEA SSs, which are used as the basis of the IRRS;
   c. explain the nature and purpose of the self-assessment;
   d. explain that it is important for the success of the mission that the regulatory body provides comprehensive written replies in English to the IRRS self-assessment question-sets including how the regulatory body complies with each attribute in the question-sets;
   e. explain that the self-assessment forms a starting point for the review and ensure an objective, consistent and systematic approach to the review;
   f. present example results of previous IRRS missions to give regulatory body personnel an understanding of typical results and what is expected.

4. Discussions with counterparts. Meetings of 15 to 20 minutes may be arranged with the individual counterparts covering the scope of the mission. These meetings take place after the presentation by the IRRS Team and are held between the IRRS Team members and each of the counterparts in turn. Their purpose is to:

    a. allow the counterpart to explain the regulatory approach and practices in their area(s) of review (approximately 5 minutes);

    b. provide the counterpart with an opportunity to ask questions about the mission;

    c. identify the ARM that the regulatory body needs to submit to the IAEA;

    d. establish which of the ARM needs to be made available in English before the start of the mission;

    e. discuss any specific requests from the regulatory body with regard to the focus of the IRRS review;

    f. identify locations where direct observation of working practices of the regulatory body could be carried out and the need for IRRS Reviewers to make visits away from the regulatory body main offices, e.g. nuclear installations, radiation practices, technical support offices, regulatory body regional or local offices, other licensed activities/locations and emergency centres.

5. Discussion of the practical and logistical aspects of the mission between the IRRS Team and the host country Liaison Officer. Several basic logistical items need to be discussed so that an understanding is reached on what will be provided. These discussions cover the:

    a. mission schedule including logistics for the members of the IRRS Team to visit other locations, e.g. a nuclear installation;

    b. planning of the entrance meeting;

    c. arrangements for the arrival of the IRRS Reviewers in the host country, accommodations, meals, etc.;

    d. working areas within the regulatory body offices, clerical/secretarial support in English with at least one room at the disposal of the IRRS Team to enable them to work and to hold discussions in reasonable privacy;

    e. forms to be filled out in advance for visas, security badges, and detailed contact information;

    f. need for interpretation and translation of documents;

    g. safety equipment (safety shoes, safety glasses, etc.);

    h. dosimetry requirements.

The table below shows a sample agenda for the preparatory meeting of an IRRS mission.

First Day		
Morning session	Welcome, Introductions Objectives of this IRRS preparatory meeting Introducing the TL and DTL	Hosts / IAEA
Morning session	Regulatory framework overview, Presentation on progress with the self-assessment using SARIS.	Host country
	Coffee break	
Morning session	Continued: Regulatory framework overview, Presentation on progress with the self-assessment using SARIS and module by module approach	Host country
	Lunch break	
Afternoon session	The IRRS review methodology and process and IAEA policy on the conduct of the review.	IAEA
	Coffee break	
Afternoon session	Scope of the mission and duration of the mission Funding Discussion on policy issues and technical areas to be addressed during the IRRS mission Confirm dates of the IRRS mission.	Host country / IAEA
	Review of the day. Summary	
Second Day		
Morning session	Logistics for the IRRS mission, e.g.: • Roles and responsibilities of IRRS Team members, the host country Liaison Officer and the counterparts; • Hotel and local transport arrangements (including site visits, etc.); • Working areas and facilities for individuals and teams (at the Host Institution and off-site, including the hotel); • IT, data-projectors, secretarial support etc.; • Arrangements for communication between IRRS Team members and counterparts; • Translators and technical escorts, if required;	Regulatory Body / IAEA

	• Process of interviews and document review; • Necessary arrangements for entry to facilities, including clearance and any required training. • Initial Team Meeting (time, venue participants); • Entrance Meeting (time, venue participants); • Direct observation and site visits (date(s), duration, venue(s) participants); • Discussion and agreement on advance reference material (ARM, including SARIS report) • Policy issues review (time, venue participants); • Exit Meeting (time, venue participants); • Media relations; • Meetings with State officials etc.; • Social event	
	Coffee break	
Morning session	Detailed Mission Programme	Host country / IAEA
	Lunch break	
Afternoon session	Terms of reference preparation and signing Summary of meeting and Follow-up items End of preparatory meeting	Host country / IAEA

APPENDIX VI: PREPARATORY ACTIVITIES FOR AN IRRS MISSION

Task		Responsibility
Request from a State		
1.	Receive request from a State or identify IAEA requirement: • for information relating to IRRS • to conduct an IRRS	IAEA
2.	Prepare briefing for host country on IRRS process, including a copy of this IRRS Guidelines Arrange Information Meeting if necessary	IAEA
3.	If IRRS is to proceed, appoint IRRS Team Leader, IAEA Coordinator, Deputy Team Leader and Deputy IAEA Coordinator	IAEA
4.	Appoint the host country Liaison Officer and potential counterparts	Host country
5.	Define provisional scope of the IRRS; propose and provisionally agree with host country	IRRS Team Leader, IAEA Coordinator and host country
Preparatory phase		
6.	Arrange for IRRS preparatory meeting	IRRS Team Leader, IAEA Coordinator and host country
7.	Define the exact scope, terms of reference and provisional schedule of the IRRS Plan resources (size, duration of IRRS mission)	IRRS Team Leader, IAEA Coordinator and host country
8.	Identify IRRS Team members: • consider scope of IRRS • identify appropriate personnel • potentially observer	IRRS Team Leader and IAEA Coordinator
9.	Assemble background information	IAEA Coordinator
10.	Request completion of the IRRS self-assessment and preparation of the self-assessment report	IAEA Coordinator and host country
11.	Resource planning (size, duration of IRRS mission)	IRRS Team Leader, IAEA Coordinator, host country
12.	Send completed self-assessment question-sets to IAEA at least two months before commencement of IRRS mission	Host country

Task		Responsibility
13.	Recruit IRRS Team members	IRRS Team Leader and IAEA Coordinator
14.	Provide background information to IRRS Team members	IAEA Coordinator
15.	Review ARM and develop initial impression	IRRS Team members
16.	Prepare mission agenda	IRRS Team Leader, IAEA Coordinator and host country Liaison Officer
17.	Prepare visit coordination/schedule	IAEA Coordinator, IRRS Team members and host country Liaison Officer

APPENDIX VII: TEMPLATE FOR THE IRRS TERMS OF REFERENCE

Terms of Reference

Integrated Regulatory Review Service – IRRS

yyyy

Host Country

Version No. XXXX

BACKGROUND

IRRS MISSION DATES

SCOPE

AGENCIES THAT LEGALLY AND COLLECTIVELY PROVIDE THE FULL SCOPE OF THE NATIONAL REGULATORY RESPONSIBILITIES AND FUNCTIONS

FACILITIES AND ACTIVITIES, EXPOSURE SITUATIONS

MODULES

IRRS TEAM COMPOSITION

MAIN COUNTERPARTS

CONDUCT OF MISSION

SELF-ASSESSMENT STATUS

MEDIA AND PRESS CONFERENCE

ACTION PLAN

FOLLOW-UP IRRS MISSION DATES

LOGISTICS

SCHEDULE

ADVANCE REFERENCE MATERIAL (ARM)

SCOPE

DATE OF DELIVERY TO IAEA

REPORT CONFIDENTIALITY

[DATE, SIGNATURES OF LO AND IAEA COORDINATOR]

ATTACHMENT I: ORGANIZATIONS AND LOCATIONS TO INTERVIEW AND VISIT DURING THE IRRS MISSION

The detailed list of organizations will be provided separately by the host country Liaison Officer.

No.	Organization	Location
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

ATTACHMENT II: SCHEDULE FOR THE IRRS MISSION

The proposed detailed schedule will be provided by the host country Liaison Officer.

REFERENCES

APPENDIX VIII: IRRS MISSION PROGRAMME AND SCHEDULE

VIII.1. STANDARD IRRS INITIAL MISSION

VIII.1.1. Model for standard IRRS initial mission programme

Sunday		
IRRS Initial Team Meeting		
13:00 - 18:00	Opening remarks by the IRRS Team Leader Introduction by IAEA Self-introduction of all attendees IRRS Process (IAEA) Report writing (IAEA) Schedule (TL, IAEA) First impression from IRRS Team members arising from the ARM (all team members): presentations Administrative arrangements (Regulatory Body, host country Liaison Officer, IAEA): detailed mission programme Groups preparation for interviews	Venue TBD Participants: IRRS Team + LO Module Leaders to prepare slides for the TL presentation for the Entrance Meeting
18:00 - 20:00	IRRS Team dinner	
Monday		
IRRS Entrance Meeting		
09:00 - 12:00	09:00 Arrival, registration, 09:30 Welcoming Address – (*official from the host country*) 10:00 IRRS Team Leader – Expectations for the Mission and introduction of the IRRS Team 10:30 IRRS Team members' and Counterparts' self-presentation 11:00 Host Institution presentation – Regulatory Overview, SARIS results (strength, challenges, action plan) 11:45 Questions	Venue: Participants: High Level Government Official, RB Management and staff, Official from relevant organizations, IRRS Team + LO
12:00 - 13:00	Lunch	
13:00 - 17:00	Interviews and Discussions with Counterparts (parallel discussions)	Counterparts and Offices:
17:00 - 18:00	Daily IRRS Team meeting	Venue: Participants: IRRS Team + LO

Tuesday		
Daily Discussions / Interviews		
09:00 - 17:00	Interviews and discussions with counterparts (parallel discussions)	Counterparts and Offices:
12:00 - 13:00	Lunch	
13:00 - 17:00	If applicable Visit to the Ministry: TL, TC, Reviewer Modules 1, 2 and 3	
17:00 - 18:00	Daily IRRS Team meeting	Venue: Participants: IRRS Team + LO
18:00	NPP site visit group departure	
Wednesday		
Daily Discussions / Interviews		
09:00 - 16:00	Interviews and discussions with counterparts for all modules and preparation of preliminary findings (recommendations, suggestions and good practices)	Counterparts and Offices:
	Site-visits	Sites
12:00 - 13:00	Lunch	
16:00 - 17:00	Preliminary findings delivery and compilation	IRRS Team
17:00 - 18:00	Daily IRRS Team meeting	Venue: Participants: IRRS Team + LO
Thursday		
Daily Discussions / Interviews		
8:00 - 9:00	Briefing from the site visits	IRRS Team + the LO
09:00 - 12:00	Follow-up Interviews and discussions with counterparts (parallel discussions)	Counterparts and Offices:
12:00 - 13:00	Lunch	
13:00 - 17:00	Report preparation	IRRS Team
17:00 - 18:00	Daily IRRS Team Meeting: recommendation, suggestions and good practices	Venue: Participants: IRRS Team + LO

Friday		
Daily Discussions / Interviews		
09:00 - 17:00	Follow-up Interviews as needed	Counterparts and Offices:
14:00 - 16:00	Policy issue discussion: parallel sessions if needed.	IRRS Reviewers and Counterparts and Offices:
16:00 - 18:00	Daily IRRS Team meeting: report preparation, finalize observations, bases, recommendations, suggestions and good practices	Venue: Participants: IRRS Team + the LO
Saturday		
Daily Discussions/ Interviews (if needed)		
09:00 - 18:00	• IRRS Team members draft the report and finalize recommendations, suggestions and good practices • Draft report cross reading • Finalization of the report by the entire IRRS Team	IRRS Team
20:00 - 22:00	IRRS Team Lead and IAEA Coordinator edit draft report	
2nd Sunday		
IRRS Team rest day + cultural events		
2nd Monday		
09:00 - 12:00	Parallel individual review and discussions of the report sections with the counterparts. Report writing	Venue: Participants: IRRS Team, Counterparts
12:00 - 13:00	Lunch	
13:00 - 17:00	Report finalising by the IRRS Team	IRRS Team
17:00 - 18:00	IRRS Team Lead finalize draft report editing	
2nd Tuesday		
Daily Discussions		
09:00 - 10:00	Finalize report text and submit to the Host Institution	Venue: Participants: IRRS Team + LO

10:00 - 18:00	Host Institution organises the review of the draft by all national counterparts and start review	
10:00 - 18:00	IRRS Team Lead and IAEA Coordinators draft: executive summary and prepare exit presentation	
2nd Wednesday		
Daily Discussions		
09:00 - 12:00	Host Institution finalises the review of the draft report and submit written comments to the IRRS Team	
12:00 - 13:00	Lunch	
13:00 -18:00	IRRS Team reviews Host's comments and finalizes draft report. Handover the report to the Host Institution	Venue: Participants: IRRS Team
2nd Thursday		
09:00 - 12:00	Discussions with Hosts on findings (if required)	Venue: Participants: IRRS Team and Host counterparts
12:00 - 13:00	Lunch	
13:00 - 17:00	Team meeting to for report finalization based on discussions with the Hosts Submission of the Final Draft Report to the Hosts	Venue: Participants: IRRS Team
17:00 - 18:00	Briefing of the IAEA official Press release finalization	Venue: IRRS Team Lead, IAEA Press-Officer
2nd Friday		
09:00 - 11:00	IRRS Exit meeting, remarks by IAEA Official	Venue TBD Participants: Government Officials, RB Management and staff, the IRRS Team + LO
	Main findings of the IRRS mission (Team Leader)	
	Remarks by the Host Institution in response to the mission findings.	
	IAEA Official: Closing	
11:00 - 12:00	Press conference (if decided)	Government Officials, IAEA Official, IRRS Team Leader

VIII.1.2. Standard IRRS initial mission schedule

<table>
<tr><th colspan="11">FIRST WEEK</th></tr>
<tr><th>Time</th><th>SAT</th><th>SUN</th><th>MON</th><th colspan="2">TUE</th><th colspan="2">WED</th><th>THU</th><th colspan="2">FRI</th><th>SAT</th><th>SUN</th><th>Time</th></tr>
<tr><td>08:00-09:00</td><td rowspan="8">Arrival of IRRS Team members</td><td></td><td></td><td colspan="2"></td><td></td><td rowspan="3">Site Visits</td><td>Briefing from the site visits</td><td colspan="2"></td><td></td><td rowspan="7">IRRS Team rest day</td><td>08:00-09:00</td></tr>
<tr><td>09:00-12:00</td><td rowspan="3"></td><td>Entrance Meeting</td><td colspan="2">Interviews (parallel discussions)</td><td>Interviews</td><td>Follow-up interviews</td><td>FU Interviews and report preparation</td><td>DTC writes introductory parts</td><td rowspan="6">IRRS Team members draft the report.
Finalization of recommendations, suggestions and good practices</td><td>09:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td colspan="2">Standing lunch</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td>12:00-13:00</td></tr>
<tr><td>13:00-14:00</td><td rowspan="3">Initial Team Meeting
• TL Opening remarks
• IAEA Introduction
• Self-introduction of all attendees
• IRRS Process, IAEA
• Schedule (TL, IAEA)
• Presentations of first impressions
• Administrative arrangements: Liaison Officer, IAEA</td><td rowspan="3">Interviews (parallel discussions)</td><td rowspan="3">Interviews</td><td rowspan="3">TBD, Visit Ministry: TL DTL, TC, M1, 2, 3 IRRS Reviewers</td><td>Writing first draft of preliminary findings R/S/GP</td><td>Site Visit</td><td rowspan="3">Report preparation</td><td colspan="2" rowspan="2">Policy issues discussion</td><td>13:00-14:00</td></tr>
<tr><td>14:00-15:00</td><td colspan="2">Written preliminary findings delivered</td><td>14:00-15:00</td></tr>
<tr><td>15:00-16:00</td><td colspan="2"></td><td colspan="2"></td><td>15:00 -16:00</td></tr>
<tr><td>16:00-17:00</td><td colspan="2"></td><td colspan="2">Daily Team Meeting for report preparation: finalization of observations, basis, R/S/GP</td><td>16:00-17:00</td></tr>
</table>

FIRST WEEK

Time	SAT	SUN	MON	TUE	WED	THU	FRI	SAT	SUN	Time
17:00-18:00		Groups to prepare for interviews	Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: Discussion of findings	Daily Team Meeting: Discussion of findings				**17:00- 18:00**
18:00-20:00	Infor mal dinner	Team Dinner	Dinner (D)	D	D	D	D	D		**18:00-19:00**
20:00-24:00			Report Writing (RW)	R W	RW	RW	RW	TL, DTL, TC edit the report		**20:00-24:00**

NPP group departs to NPP site

<table>
<tr><th colspan="8">SECOND WEEK</th></tr>
<tr><th>Time</th><th colspan="2">MON</th><th colspan="2">TUE</th><th colspan="2">WED</th><th>THU</th><th>FRI</th><th>Time</th></tr>
<tr><td>08:00-09:00</td><td colspan="2"></td><td colspan="2" rowspan="2">Finalization of the draft Report
Submission of the Draft Report to the Host</td><td colspan="2"></td><td></td><td></td><td>08:00-09:00</td></tr>
<tr><td>09:00-10:00</td><td rowspan="3">Individual discussions of report sections with counterparts</td><td rowspan="3">Report writing</td><td rowspan="3">Hosts review the Report Draft
Written Host’s comments are submitted to the Team</td><td rowspan="3">TL, DTL, TC finalize Executive Summary
TL finalises exit presentation
TC and AF draft the press release</td><td rowspan="3">Discussion with Host on findings if required</td><td rowspan="3">Exit Meeting
[Press Conference, if decided]</td><td>09:00-10:00</td></tr>
<tr><td>10:00-11:00</td><td rowspan="2">TL, DTL, TC draft Executive Summary</td><td rowspan="2">Hosts reviews the Report Draft</td><td>10:00-11:00</td></tr>
<tr><td>11:00-12:00</td><td>11:00-12:00</td></tr>
<tr><td>12:00-13:00</td><td colspan="2">Standing lunch</td><td colspan="2">Standing lunch</td><td>Standing Lunch</td><td>Lunch</td><td>12:00-13:00</td></tr>
<tr><td>13:00-15:00</td><td colspan="2" rowspan="2">Draft Report
cross-reading</td><td rowspan="3">TL, DTL, TC prepare exit presentation</td><td rowspan="3">Host reviews the Report Draft</td><td colspan="2" rowspan="3">IRRS Team members
Host’s comments</td><td>Team meeting for finalisation of the Report
Submission of the Final Draft Report to the Hosts</td><td rowspan="3">IRRS Team Members Departure</td><td>13:00-15:00</td></tr>
<tr><td>15:00-17:00</td><td>15:00-17:00</td></tr>
<tr><td>17:00-18:00</td><td colspan="2">TL, DTL, TC and „editors” finalise the report text</td><td>Briefing of the IAEA official (TBD)
Finalisation of the press release</td><td>17:00-18:00</td></tr>
</table>

SECOND WEEK						
Time	**MON**	**TUE**	**WED**	**THU**	**FRI**	**Time**
18:00-20:00	Dinner	Dinner				**18:00-20:00**
20:00-24:00	TL, DTL, TC and „editors" finalise the report text	TL, DTL, TC and „editors" finalise the report text				**20:00-24:00**

VIII.2. STANDARD IRRS FOLLOW-UP MISSION SCHEDULE

<table>
<tr><th>Time</th><th>SAT</th><th>SUN</th><th>MON</th><th>TUE</th><th>WED</th><th>THU</th><th>FRI</th><th>SAT</th></tr>
<tr><td>09:00-10:00</td><td rowspan="6">Arrival of IRRS Team Members</td><td rowspan="3">Team building meeting:
• 5 minutes/TM self-intro
• Refresher training</td><td>Entrance Meeting</td><td rowspan="3">Interviews</td><td rowspan="2">• TM write Report
• TL and DTL review introductory part</td><td rowspan="2">Finalisation</td><td>Discussion by the Team</td><td></td></tr>
<tr><td>10:00-11:00</td><td rowspan="2">Interviews</td><td rowspan="2">Discussion by the Host</td><td rowspan="2">• Exit Meeting
• Press Conference (alternative)</td></tr>
<tr><td>11:00-12:00</td><td>Draft text to TL</td><td>Submission of the Draft to the Host</td></tr>
<tr><td>12:00-13:00</td><td rowspan="2">Lunch</td><td>Standing Lunch</td><td>Standing lunch</td><td>Standing lunch</td><td>Standing lunch</td><td>Standing Lunch</td><td rowspan="9">Departures of IRRS Team Members</td></tr>
<tr><td>13:00-14:00</td><td rowspan="4">Interviews</td><td rowspan="2">Interviews</td><td rowspan="2">Policy Discussions</td><td rowspan="4">Host reads Draft</td><td rowspan="4">TL finalises the presentation</td><td rowspan="4">TC drafts the Press Release</td><td>Written comments by the Host</td></tr>
<tr><td>14:00-15:00</td><td rowspan="2">Initial Team Meeting:
• IRRS process
• Main objectives
• Report writing
• Schedule
• First observations</td><td rowspan="2">Finalisation of the Report</td></tr>
<tr><td>15:00-16:00</td><td>Secretariat edits the report
Cross-reading</td></tr>
<tr><td>16:00-17:00</td><td>Written preliminary findings delivered</td><td>Preliminary Draft Report Ready</td><td>Presenting the final Draft of the Report to the Host</td></tr>
<tr><td>17:00-18:00</td><td></td><td>Daily Team Meeting</td><td>Daily Team Meeting: discussion of findings</td><td>Daily Team Meeting</td><td colspan="3">Daily Team Meeting: discussion of Executive Summary</td><td>• Exit Meeting
• Press Conference (optional)</td></tr>
<tr><td>18:00-19:00</td><td rowspan="2">Informal dinner</td><td rowspan="2">Team Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td rowspan="2">Dinner</td><td colspan="3" rowspan="2">Dinner</td><td rowspan="2"></td></tr>
<tr><td>19:00-20:00</td><td>Farewell Dinner</td></tr>
<tr><td>20:00-24:00</td><td></td><td></td><td>Writing of the report</td><td>• Secretariat edits Report
• TM write Report</td><td>TM Read Draft</td><td colspan="3">Free</td><td></td></tr>
</table>

APPENDIX IX: ADVANCE REFERENCE MATERIAL

All the results of the self-assessment are documented in the ARM. The ARM includes:

— Self-Assessment report;

— Action plan;

— ARM summary report;

— Other ARM documents.

The ARM summary report is a key document that includes a summary for each module of self-assessment. The ARM summary report structure follows the IRRS ARM summary report template structure issued to the host country by the IAEA Coordinator. The ARM summary report is a comprehensive document to be read by all IRRS Reviewers in order to get acquainted with the whole legal and regulatory framework. The ARM summary report helps the IRRS Reviewer to evaluate compliance with the requirements of relevant GSR Part 1 (Rev. 1) and other IAEA standards specific to that module.

Summaries of each module give overall information on the identified strengths, weaknesses and opportunities for improvement based on the self-assessment. Specific aspects of the regulatory framework of the host country are highlighted and an overall perspective on the role of the regulator and a description of all stakeholders having a role in nuclear and radiation safety in the host country is given in the ARM. The ARM also includes the action plan setting out areas for improvement.

The host country prepares the ARM summary report in the same format and template used by the IRRS Team to prepare the mission report. The ARM is developed and distributed in electronic form. The host country ensures that the ARM is subject to thorough quality assurance before issue to IAEA. The ARM of the IRRS mission is preserved by both the host country and the IAEA for their further use and documentary purposes in compliance with management system requirements, and in particular for comparative review during the follow-up mission.

The IRRS Team Leader and IAEA Coordinator will agree with the host country Liaison Officer at the earliest opportunity on what parts of the ARM need to be translated into English, if the original documents are in another language. The following ARM is to be translated into English in all cases: the main laws that comprise the legislative framework for safety; a list of reference documents; relevant extracts from the documents, including legislation and regulations needed for demonstration of compliance; the action plan; and ARM summary report. The following ARM is to be translated, if needed, to demonstrate compliance with IAEA safety standards: main parts of the management system reflecting general safety requirements; policy documents; organizational documents and main procedures; and results of the self-assessment. The host country Liaison Officer is responsible for arranging translation of these documents in good time to be included in the ARM. The specific contents and designations of these documents may vary owing to particular national practices. Information that must remain confidential is to be clearly indicated. Documents that may be submitted as part of the ARM are listed below:

A. National legal framework

— National policy and strategy for safety;

— Law(s) and other legal instruments governing the siting, design, construction, commissioning, operation or decommissioning of nuclear installations, other facilities, activities and practices;

— Synopsis of the constitutional legislative system of the host country and the responsibilities of the various government departments that deal with nuclear installations;

— An outline of the administrative structure of government departments and other bodies dealing with nuclear installations and how they all interrelate;

— Legislation for the use of radiation sources and the management of the associated radioactive waste; and

— Regulations on nuclear, radiation, waste management, transport safety;

— Identification of the stakeholders and their expectations.

B. Regulatory body organization and procedures

— Legal status and responsibilities assigned by law to the regulatory body;

— Objectives of the regulatory body and how it maintains its effective independence;

— Regulatory body safety policy and management system manual (or equivalent) including an overall process map;

— Structure, organizational chart, staffing numbers and a demonstration of the sufficiency of the regulatory body resources and organizational structure;

— Requirements applicable to the activities of the regulatory body;

— Description of the authorization process;

— Procedures for assessment and review of technical submissions;

— Inspection practices;

— Enforcement practices;

— Roles and responsibilities of the regulatory body in relation to nuclear or radiological emergencies as assigned in respective legislation;

— Internal plans and procedures of the regulatory body to fulfil its assigned roles and responsibilities in a nuclear or radiological emergency;

— A typical licence; and list of applicable codes and standards.

C. Host country`s input to policy discussions and written response to the IRRS Self-Assessment Questionnaire

— Host country information questionnaire

— Modules 1-10

— Additional area questions (as applicable)

A useful source of this material is the Country's National Reports to the Convention on Nuclear Safety and to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The questions and answers to their national reports and additional documents, such as rapporteurs' reports, may also be useful. Other useful sources are the regulatory body's annual reports and the Radiation Safety Information Management System (RASIMS) Profile (RaWaSIP);

D. Self-assessment analysis and results

Suggested detailed material for (a), (b) and (c) as applicable:

— Legislation (including drafts) relating to the establishment, functions and operation of the regulatory body(ies). Where available, the legislation also is to be provided in electronic form.

— Legislation not directly related to, but with implications for radiation safety and security of radioactive sources and/or radioactive waste (e.g. in health, labour, environment).

— Legislation (laws, mandates and regulations, including drafts) governing the safety and security of radioactive sources, including import/export of radioactive sources and for the management of the associated radioactive waste.

— Details of any political commitment made regarding the Code of Conduct on the Safety and Security of Radioactive Sources.

— Regulatory guidance material (including drafts), such as codes of practice.

— Copies of other documents relevant to the national regulatory infrastructure, whatever their origin (e.g. internal to the host country or prepared by external consultants or reviewers).

— Organizational chart showing the regulatory body(ies) and its (their) relationships to ministries, government departments and other organizations involved in radiation safety and security of radioactive sources.

— Organizational chart of the regulatory body(ies), with a list of staff members and their functions.

— Training plan for regulatory body staff (qualifications, training received to date and planned for future).

— Membership of regulatory advisory committees or boards (if appointed), including the criteria for appointment.

— Last annual report of the regulatory body(ies) to the responsible minister or parliament or assembly (including national register of radiation sources).

— Copies of memoranda of understanding between the regulatory body and other national bodies, including customs, law enforcement and health.

— Copies of any informal working arrangements between the regulatory body and other national bodies, including customs, law enforcement and health.

— Details of the host country’s involvement in:
  - international treaties and conventions;
  - regional cooperation agreements and arrangements; and
  - bilateral or multilateral cooperation agreements and arrangements.

— Procedures for notification including the notification form.

— Procedures and conditions for authorization, including the application form.

— List of authorizations issued and renewed during the previous calendar year.

— Expected authorization programme for the coming calendar year.

— Procedures for and guidance governing inspections.

— Planned inspection programme for the current calendar year.

— List of inspections (numbers by practice type) carried out during the previous calendar year, including a breakdown by geographical region, e.g. urban and rural.

— Planned inspection programme for the coming calendar year.

— Investigation procedures and guides, such as those concerning overexposure.

— Enforcement powers, procedures and guidance.

— List of enforcement actions taken during the previous calendar year.

— Information publications relating to radiation safety and security of radioactive sources.

— Annual or other reviews of, for example, occupational exposures.

— The number of occupationally exposed workers (including the number of those, whose dose is individually monitored and number of those, for whom the occupational exposure is assessed on the basis of the results of workplace monitoring), the types and number of authorized activities, and the status of the TSO in charge of the monitoring and of the training of the occupationally exposed workers.

— Approval procedures for service providers, such as dosimetry laboratories.

— List of service providers in radiation safety and security of radioactive sources and the range of services provided.

— Quality assurance documentation, including internal procedural instructions.

— Reports of events involving stolen, lost, found or orphan sources.

— Reports of illicit trafficking of radioactive sources, such as those submitted to the IAEA's illicit trafficking database.

— Guidance material relating to patient protection.

— Information relating to a secondary standards dosimetry laboratory, if one is established.

— Information relating to radiological surveillance programme.

— Copy of the national waste management policy and strategy, if there is one.

— Information relating to a competent authority for radioactive waste safety, if one is established.

— List of agencies and services provided for the management of radioactive waste.

— Information relating to a competent authority for transport safety, if one is established.

— Information relating to the coordinating mechanism, if any, established in emergency preparedness and response area through which some[7] of the regulatory aspects and interfaces with other areas or organizations are coordinated.

— Information relating to a competent authority for the security of radioactive sources, if one is established.

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[7] Such information is intended to be used to identify how the regulatory body ensures that on-site emergency arrangements are coordinated and integrated, as appropriate, with other arrangements rather than to review the coordinating mechanisms itself. Overall review of the coordinating mechanisms is beyond the scope of IRRS.

— Copy of the national arrangements[8] for emergency preparedness and response, if appropriate and relevant in relation to regulatory aspects of emergency preparedness and response.

— Copy of the national arrangements for response to security incidents involving radioactive sources, if one is established.

— Copy of any national radiation safety and security of radioactive sources training plan.

[8] The aim is to support improved understanding of the regulatory framework in emergency preparedness and response. These materials are not intended to be used for a review of the national arrangements as such a review goes beyond the scope of IRRS.

APPENDIX X: STANDARD ASSIGNMENT OF MODULES

This appendix provides a standard assignment of modules to groups and guidance on the number of experts in an IRRS initial and follow-up mission.

<table>
<tr><th>IRRS Team activities[a)]</th><th>Small[f)]</th><th>Medium</th><th>Large</th><th>Follow-up[e)]</th></tr>
<tr><td>IRRS Team Lead (TL, DTL, TC, DTC)[b)]</td><td>3</td><td>3</td><td>3</td><td>3</td></tr>
<tr><td>Group A
Governmental responsibilities and functions (Module 1)
Global nuclear safety regime (Module 2)
Interface with security (Module 12)</td><td rowspan="2">3[c)]</td><td>1[c)]</td><td>2[c)]</td><td rowspan="2">2[c)]</td></tr>
<tr><td>Group B
Responsibilities of the regulatory body (Module 3)
Management system (Module 4)
Development of regulations and guides (Module 9)[d)]</td><td>2</td><td>3</td></tr>
<tr><td>Group C (all facilities and activities and exposure situations)
Authorization (Module 5)
Review and assessment (Module 6)</td><td rowspan="2">4</td><td>5</td><td>6</td><td rowspan="2">4</td></tr>
<tr><td>Group D (all facilities and activities and exposure situations)
Inspection (Module 7)
Enforcement (Module 8)</td><td>2</td><td>4</td></tr>
<tr><td>Group E
Emergency preparedness and response (Module 10)</td><td>1</td><td>2</td><td>2</td><td>1</td></tr>
<tr><td>Administration</td><td>1</td><td>1</td><td>1</td><td>1</td></tr>
<tr><td>Total</td><td>12</td><td>16</td><td>21</td><td>11</td></tr>
</table>

a) Numbers of experts include IAEA staff.
b) DTC is assigned to one of the Groups.
c) DTL supports Group A.
d) Groups C through E review the respective contents of the regulations and guides (provided it is in the scope of the mission) and report to Group B.
e) Numbers of experts of follow-up missions are relevant for large nuclear countries and are adjusted for small non-nuclear and medium size nuclear countries according to the actual needs.
f) Definitions:
Small: No NPPs, few Facilities/Activities.
Medium: Less than 5 NPP units (in construction, operating, to decommission), few Facilities/Activities.
Large: 5 or more NPP units, and/or many Facilities/Activities.

APPENDIX XI: SAMPLE AGENDA FOR INITIAL IRRS TEAM MEETING

The initial team meeting is attended by the IRRS Team Leader, IRRS Deputy Team Leader, representatives of the IAEA's NSRW, NSNI (one of whom will be the IAEA Coordinator and another the Deputy Coordinator) and IEC, IRRS Reviewers, observers and the host country Liaison Officer.

1.	Opening remarks. Introduce host country Liaison Officer	IRRS Team Leader
2.	Self-introductions: Each IRRS Team member to give a brief statement of their careers and current responsibilities (2 min). Observers introduce themselves.	IRRS Team members
3.	Remarks on host country background	IRRS Deputy Team Leader
4.	Host country information related to logistics, security and others important for the successful conduct of the IRRS mission	Host country Liaison Officer
5.	Presentation of the IRRS process	IAEA Coordinator
6.	Guidance for reporting/documenting	IAEA Coordinator
7.	Review of schedule	IRRS Team Leader
8.	Break for 15 minutes to work in review subject areas to prepare statements to the IRRS Team on first impressions in the assigned subject areas of the ARM. (working in subject area groups)	
9.	Report of initial review of ARM: IRRS Reviewers to briefly present their prepared statements on their initial impressions of the ARM. Where a pair of reviewers is working together they agree on who is to report to the meeting. This is also an opportunity to raise any initial concerns or specific requests for clarification with the host country liaison officer.	IRRS Reviewers
10.	Preparation for daily interviews: The IRRS Team members continue working in their subject areas, after the closure of the meeting, to agree on their approach for the conduct of the interviews	IAEA Review Area Facilitators
11.	Closing remarks	IRRS Team Leader

APPENDIX XII: SAMPLE AGENDA FOR ENTRANCE MEETING

Each IRRS is different and the entrance meeting agenda will need to be customized to suit the occasion, but it follows the pattern as shown below:

1.	Welcome and introduce senior attendees.	Regulatory Body Manager
2.	Short opening remarks (include as a minimum): • thanks to the host regulatory body for the arrangements; • thank the regulatory body staff making themselves available for the duration of the IRRS; • scope: initial mission or follow-up (mention previous IRRS involvement); • other related IAEA work, e.g. assistance programme.	IRRS Team Leader
3.	Introduce the IRRS Reviewers, IAEA Staff (and observer) each in turn to explain their background (2 minutes each).	All IRRS Team members
4.	Briefing for IRRS Team: • roles and responsibility of regulatory body; • structure of the regulatory body; • relationship of regulatory body to utilities (where applicable); • regulatory technical and policy issues; • why the IRRS Team is there; • what the regulatory body hopes to gain from the review; • any current issues that could impact the review; • how the regulatory body will use the results of the review.	Regulatory Body Manager
5.	Introductions and working arrangements: • introduce counterparts; • present detailed schedule; • discuss current regulatory body status and current plant status; • problems or activities that might impact the review; • any near-term activities the IRRS Team should be aware of, e.g. outage, major repairs/modifications, reorganizations.	Regulatory Body Manager
6.	Detailed presentations on each of the areas to be covered by the review.	Counterparts
7.	Closing remarks.	IRRS Team Leader

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006)

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[4] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).

[8] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, PREPARATORY COMMISSION FOR THE COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Design, IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), IAEA, Vienna (2016).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Power Plants: Commissioning and Operation, IAEA Safety Standards Series No. SSR-2/2 (Rev. 1), IAEA, Vienna (2016).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Research Reactor, IAEA Safety Standards Series No. SSR-3, IAEA, Vienna (2016).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. SSR-4, IAEA, Vienna (2017)

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Disposal of Radioactive Waste, IAEA Safety Standards Series No. SSR-5, IAEA, Vienna (2011).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (2018).

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Site Evaluation for Nuclear Installations, IAEA Safety Standards Series No. NS-R-3 (Rev. 1), IAEA, Vienna (2016).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety of Nuclear Fuel Cycle Facilities, IAEA Safety Standards Series No. NS-R-5 (Rev. 1), IAEA, Vienna (2014).

[17] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Communication and Consultation with Interested Parties by the Regulatory Body, IAEA Safety Standards Series No. GSG-6, IAEA, Vienna (2017)

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Organization, Management and Staffing of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-12, IAEA, Vienna (2018)

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