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Guidelines for IAEA International Regulatory Review Teams (IRRTs)



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FOREWORD

The IAEA International Regulatory Review Team (IRRT) programme provides advice and assistance to Member States to strengthen and enhance the effectiveness of the nuclear regulatory body whilst recognizing the ultimate responsibility of each Member State for nuclear safety. The IRRT programme, initiated in 1989, is not restricted to any particular group of Member States, whether developing or industrialized, but is available to all countries with nuclear installations in operation or approaching operation.

The basic concepts, purposes and functions of a national regulatory body are well recognized in all Member States having a nuclear power programme. The IAEA Safety Standards Series publication entitled "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety: Requirements", No. GS-R-1 (2000), provides a general consensus reference for the practices necessary for a national organization to fulfil the regulatory purposes and discharge the regulatory functions. The Requirements also defines the terms used in these guidelines.

The guidance given in the Requirements recognizes that the organizational structure and regulatory processes will vary from country to country depending on their existing constitutional, legal and administrative systems; the size and structure of their nuclear programme; the technical skills and professional and financial resources available to their regulatory body, and social customs and cultural traditions.

IRRT missions compare (insofar as this is possible) the nuclear regulatory practices in a Member State with existing international consensus guidelines and equivalent good practices elsewhere. These bases are formed by the IAEA Safety Standards Series publications, including the Requirements on Legal and Governmental Infrastructure and associated Guides, and the expertise of the IRRT members themselves. The IRRT Guidelines provide overall guidance for the experts to ensure the consistency and comprehensiveness of the regulatory review and have been prepared by the IAEA to complement the expertise of the IRRT members.

IRRT reviews are performance oriented in that they accept different approaches to the organization and practices of a national regulatory body that contribute to ensuring a strong nuclear safety regime in their country. Recommendations are made on items of direct relevance to safety, whereas suggestions made might enhance the national nuclear safety regime only indirectly but would certainly improve the organization or performance of the regulatory body. Commendable good practices identified may be communicated to other Member States for long term improvement.

The IAEA officer responsible for this publication was P. Hughes of the Division of Nuclear Installation Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

This publication was originally published in 1993 as IAEA-TECDOC-703 to provide advice to the participants of an International Regulatory Review Team (IRRT) mission on the conduct of the mission. The report was revised and further developed in November 1998 to take account of the extension of the IRRT service to cover Radiation and Radioactive Waste Safety. This new revision has been made to reflect several years experience in conducting IRRT missions and following the publication of the IAEA Safety Standards Series documents relating to the regulatory body [1–5]. The demand for IRRT missions remains high and this revised report will form the basis for the conduct of future missions.

1.2. OBJECTIVE

The objective of this report is to provide guidance on the basic structure of an IRRT mission and provide a common reference both across the various areas covered by an IRRT mission and across all the missions in the programme. As such, it is addressed, principally, to the team members of IRRT missions but it also provides guidance to a host regulatory body receiving a mission.

1.3. SCOPE

This report identifies the objectives of the IRRT mission and sets out the scope of the topic areas that are reviewed by the experts. The scope includes the working protocol that is adopted to conduct the missions, identifies the advanced reference material the regulatory body should provide together with review points and specimen questions that are used to help guide the interviews conducted by the experts. The report also provides guidance on the format and content of the mission report that is to be produced to record the findings of the mission.

2. IRRT MISSIONS

2.1. REGULATORY PRACTICES

It will be readily apparent that, with the reasonable and necessary variations in regulatory practices between different countries, there cannot be an absolute measure of the adequacy and effectiveness of the practices in any one country.

Typically differences will occur between those Member States having one or more reactor designers, a variety of reactor designs, a large number of operating plants and one or more applicant(s)/licensee(s) and those Member States having only one reactor, possibly imported. The codification of regulatory requirements will differ greatly between these two extremes. More subtle technological differences will probably produce still further differences in regulatory activities.

For these reasons, and because each Member State is ultimately responsible for the safety of nuclear facilities on its own territory, it is neither realistic nor proper to expect any international group to review and pass absolute judgment on a national regulatory body.

What can be achieved, however, is for an IRRT to compare, insofar as this is possible, the regulatory practices in a country with international standards and equivalent good practices elsewhere. The IRRT can, and should, be judgmental in evaluating the regulatory body with respect to these standards and practices; it can also provide recommendations and suggestions for improvement. For this comparison the team, as well as considering the arrangements of the regulatory body at its headquarters, should visit a nuclear installation to look at the regulator/operator interface from the regulatory point of view. Other reports by peer group inspection teams should also be taken into account in assessing the effectiveness of the national regulatory regime.

International standards referred to in this report are the IAEA's Safety Standards Series and related publications.

2.2. IRRT REVIEW

An IRRT review of the operation and effectiveness of a national regulatory body is based on its:

- national legislative and administrative structure;
- regulatory organizational structure and independence;
- development and implementation of regulations and guidance;
- authorization process and requirements on the applicant(s)/licensee(s);
- review and assessment procedures;
- inspection and enforcement practices;
- emergency preparedness;
- radioactive waste management;
- radiation safety and;
- transport safety.

This list is a summary of the subject review areas covered by the IAEA Safety Standards Series GS-R-1 "Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety: Requirements" [1]. Supporting [1], which is the basic reference that should be used are four IAEA general Safety Guides [2-5] that should also be applied. In addition other IAEA Requirements and Safety Guides and the International Nuclear Safety Advisory Group report on Safety Culture [6] should be included as necessary to cover the detailed scope of regulatory responsibilities for emergency preparedness, radiation, radioactive waste and transport safety. To provide a consistent review against these standards the IAEA has prepared a set of specimen questions, i.e. the IRRT Questionnaire [7] that is issued to the regulatory body for completion in advance of the mission. The questionnaire is compliance and performance based and is referenced to the clauses of the relevant safety standards. The information provided, by the regulatory body, through the questionnaire's completion is used extensively by the experts in the conduct of their review. The provision of these answers can, in its own right, be beneficial to the regulatory body as it offers an opportunity for self-assessment. The questionnaire forms a significant part of the advance reference material provided by the regulatory body.

In some instances the Member State requesting the IRRT review may additionally request the team to concentrate on specific details or areas of the review. If this occurs then it will be clearly noted in the final mission report.

This report is intended to help the experts to formulate their review in the light of their own experience. It is not intended to be all-inclusive, and should not limit the experts' investigations, but is better considered as illustrating the requirements for an adequate review.

2.3. IRRT OBJECTIVES

The IRRT is a peer review conducted by a team of international experts with direct experience applicable in the areas of evaluation. Judgments are made on the basis of the combined expertise of the international team. The review is therefore not a regulatory inspection or an audit against set codes and standards. Instead, it is a comparison (insofar as this is possible) of the regulatory practices of a country with international safety standards and an exchange of experiences and equivalent good practices aimed at strengthening the organization and the procedures and practices being followed.

This report is for use by the participants of an IRRT team in preparing to review the activities of a regulatory body. While these reviews generally concentrate on the regulation of nuclear reactors, the concepts presented in the report are applied, where appropriate, to the regulation of other facilities and/or activities e.g. bulk handling facilities, waste management, radiation and transport safety.

IRRT missions are tailored to address the specific needs or activities of the regulatory body, or to review a situation where the scope of regulatory responsibility is changing.

The key objectives of an IRRT mission are to enhance nuclear safety by:

- Providing the host country (regulatory body and governmental authorities) with an objective peer review of their nuclear regulatory practices with respect to international safety standards;
- Providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance falls short of internationally accepted standards;
- Providing key staff at the host regulatory body with an opportunity to discuss their practices with experts who have experience of other practices in the same field;
- Providing all Member States with information regarding good practices identified in the course of the review; and
- Providing experts from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.

In addition in preparing for the mission the IRRT:

• Provides the host country (regulatory body and governmental authorities) through completion of the IRRT questionnaire with an opportunity for self-assessment of its activities against International Standards.

3. GUIDANCE TO REGULATORY BODIES AND IRRT TEAM EXPERTS ON THE PREPARATION AND CONDUCT OF THE IRRT REVIEW

3.1. PREPARATION FOR AN IRRT MISSION

3.1.1. Protocol for an IRRT mission

In view of the fact that an IRRT review considers, amongst others, questions relating to the nuclear legislation and organizational issues in the country to be visited an IRRT review will only be initiated after the IAEA has been approached formally by a Member State at governmental level.

The review of a nuclear regulatory body should only be performed by a group of expert regulatory officials with both broad knowledge and long experience in the field, selected by the IAEA and supported by IAEA staff.

The report of the IRRT review will be made available unless the country specifically states otherwise. The decision to implement any findings of the report will lie entirely with the relevant authorities of the country concerned.

3.1.2. Initial arrangements

On receipt of a request for an IRRT review, the team leader designated by the IAEA will contact the host regulatory body to:

- establish who will be the liaison officer for the mission;
- arrange a date for the preparatory meeting with the organization(s) involved.

In addition the team leader will start to consider possible experts for recruitment and provide briefing as necessary.

At the same time, the host regulatory body and other organization involved should nominate counterparts in each review area who will be the primary contact with the experts in that area during the review.

3.1.3. Preparatory meeting

The preparatory meeting which lasts for about two or three days, should be held at the regulatory body's headquarters to allow senior management and other organizations involved to participate. The main purpose of the preparatory meeting is for the team leader to:

- make face to face contact with the regulatory body staff and exchange contact details;
- inform the regulatory body how the IRRT review process works;
- explain the roles and responsibilities of the IRRT team members and the way they should interact with the regulatory body and utility representatives;
- explain the role of the liaison officer and the counterparts during the review;
- discuss and confirm which subject areas will be reviewed and the material that the regulatory body needs to provide (i.e. the advanced reference material);

- provide a copies of the IAEA Standards [1] through [5], the IRRT Questionnaire [7] and to explain the importance of the regulatory body providing written replies to the questionnaire;
- agree an outline schedule for the mission and agree logistical aspect;
- explain IAEA policies, e.g. funding, contact with the mass media;
- answer questions the regulatory body staff may have and address their concerns.

There should be between 6 to 9 months time interval between the preparatory meeting and the IRRT mission to enable the regulatory body management to complete its preparation for the IRRT in a timely manner (the longer period is needed in particular where translation of documents into English is required).

The main elements of the preparatory meeting that need to be covered are detailed in Appendix I and the contents of the advanced reference material submission required from the regulatory body is covered in Appendix II.

3.1.4. Team composition

The team will comprise a team leader, who is always an IAEA staff member, and experts in the field of nuclear regulation being allocated to the subject review areas. Normally the experts will work in pairs. No one from the host country will be included in the team. In addition, the inclusion of an observer(s) may be proposed by the IAEA for consideration by the host country.

The experts are selected to provide a variety of national approaches to regulatory organization and implementation. Each expert invariably has, in addition to their particular area of expertise, knowledge of other national approaches and other relevant subject areas. Coupling this knowledge and experience with the IAEA Safety Standards Series publications allows judgments to be formed on the national practices under review and findings to be made in relation to the relevant international standards.

Appendix III defines the roles and responsibilities of the team members.

3.2. CONDUCT OF THE IRRT MISSION

3.2.1. Opening team meeting

The day prior to the start of the mission an opening team meeting is held with the experts, observers and the liaison officer to brief the team on the detailed schedule and process of the mission. The purpose of the meeting is to:

- introduce the team members to each other;
- explain the background and context of the IRRT;
- remind the team of the objectives of the IRRT;
- discuss and clarify the basis for the review (i.e. IAEA standards, TECDOC-703 and the IRRT Questionnaire);
- explain the need for team-working through daily meetings to reach consensus;
- set out the method of constructing recommendations from the findings;

- remind the team of the need to finish and agree the report before the end of the mission;
- get the experts to report their first impression on the advance reference material and;
- get the experts to prepare for the interviews.

Appendix IV sets out the agenda of the opening team meeting

3.2.2. Entrance meeting

The purpose of the entrance meeting is to:

- introduce the experts to the counterparts;
- present and discuss the detail of the mission schedule e.g. identify office locations for the interviews, times for site visits;
- give the counterparts the opportunity to make a brief presentation on the regulatory approach in their subject area and to explain the information provided to the experts in the advance reference material.

Appendix V provides an agenda for the entrance meeting.

3.2.3. The IRRT review process

The experts use three methods to acquire the information needed to develop their recommendations (as set out in Section 3.9.1 on Technical Notes). These are:

- a review of written material;
- interviews with personnel¹; and
- direct observation of organization, practices and activities both at the main regulatory headquarters and at a nuclear installation.

The experts are expected to cover each topic to the extent necessary to be able to make an informed judgment. Weaknesses identified should be investigated to the extent required to document the concerns accurately in the experts' Technical Notes and in sufficient detail to be readily understandable. Recommendations and suggestions should be formulated on the basis of the weaknesses identified. Similarly, good practices encountered in the review should be documented for the benefit of other Member States and described in the Technical Notes in sufficient detail as to be readily understandable.

3.2.3.1. Review of written material

The review of the written material takes place in two stages.

Stage 1: Prior to the start of the mission the experts are expected to read through the information provided by the regulatory body and the IAEA as part of the advanced reference material submitted to them (see Appendix II). The expert is expected to:

¹ Interviews as necessary are carried out with personnel from the regulatory body, other government departments, technical support organizations, research institutes and licensee organization(s).

- review this material with reference to the IAEA Safety Standards Series publications, this publication and the written responses provided by the regulatory body to the IRRT Questionnaire and to;
- form an initial opinion about the situation in the subject area to which they have been assigned and identify any initial findings or concerns.

A short summary of this review and their initial findings should be prepared and presented at the opening team meeting (Section 3.2.1). For example the expert might identify that the legislation is seemingly incomplete for one of the regulatory body's functions.

Stage 2: Throughout the mission itself additional material in the form of regulatory body presentations and examples of their work will be viewed. This additional material typically consists of:

- documents produced by the regulatory body or on its behalf, whether publicly available or internal documents (such as criteria, licences, safety guides, safety assessment reports, or analyses and reports of evaluations of special problems);
- documents usually available to both the regulatory body and operators in the form of general or specialized technical literature; and;
- documents received from applicant(s)/licensee(s) as part of the authorization process.

This information supplements the advanced reference material and should be reviewed by the expert and taken into when the expert is formulating findings.

3.2.3.2. Interviews

It is expected that during the interviews the experts will use the IRRT Questionnaire as a guide to ensure a complete² and systematic review of the subject area. In line with the review of the relevant written material, the interviews with the counterparts and other personnel can then be used to:

- gather additional information e.g. obtain additional information not covered by the documentation, to correct misunderstandings about the information provided;
- review initial findings issues arising out of the documentation review;
- identify what are the arrangements, authorities, duties and responsibilities of the regulatory body;
- compare these regulatory and administrative arrangements with the international 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);
- judge whether there is a need to propose a finding in the subject area reviewed.

 $^{^{2}}$ A complete systematic review of the subject area in the context of the IRRT means that each of the questions on the IRRT questionnaire/modules have been addressed in detail by the regulatory body to the satisfaction of the experts.

The interviews provide an opportunity for important information to be exchanged between experts and their counterparts. An interview should be a mutual exchange and not an interrogation of the counterparts by the experts. The expert should lead the interview but allow time for the counterparts to explain e.g. the use of real examples of the work carried out is the most effective way to illustrate specific points. Proper conduct, of these interviews is essential to the success of the review.

3.2.3.3. Direct observation

Direct observation of regulatory work activities should be complementary to the review of written material and the interviews. A substantial part of the review period should be devoted to practices in use. The observation of work should cover safety practices, use of procedures, drawings and instructions, regular and specific reporting and quality control measures in use, and should include a review of safety assessments and management control of work. From these observations, the expert will form a view of:

- how the regulatory and administrative procedures are put into effect at the point of work;
- the technical knowledge and skills of the regulatory staff;
- the attitude, morale and safety culture of the regulatory staff;
- their commitment to safety objectives;
- the effectiveness of the regulatory staff in influencing and enhancing nuclear safety;
- the formal traceability of safety assessments and the decision making process.
- whether there is need to make a finding supported by the observations made.

Following the interviews and observations, the experts should, if necessary, reconsider or elaborate their initial opinions developed for the opening team meeting (as these were based only on the review of the advanced reference material).

It may be that more than one iteration through document review, interview and observation will be necessary in order for the expert to make a final judgment and to formulate findings.

3.2.4. Reporting

3.2.4.1. Formulating findings

At the end of each working day of the mission, the team leader will call a brief team coordination meeting where each expert should summarize the findings for the day and any judgments they have made, including perceived strengths and weaknesses, succinctly, in order to allow all the subject review areas to be discussed at the same meeting. This co-ordination meeting creates the opportunity for team members to consolidate their views and to formulate the way in which their findings should be captured and reported.

The IRRT review compares observed regulatory practices with existing international consensus guidelines and equivalent good practices elsewhere. The experts should:

• consider how effectively laws, regulations, procedures, etc., are implemented in practice;

- identify where national practices differ from those of the IAEA Safety Standards Series Requirements and Guides, with account taken, as appropriate, of the regulatory body's written replies to the IRRT Questionnaire;
- identify the significance of these differences and offer recommendations and or suggestions to the regulatory body on how they may improve their effectiveness.

The experts should also have in mind that any changes to national practices are at the discretion of the authorities of the Member State concerned.

The findings should be written following the agreed format of reporting described in Section 3.8.2 Technical Notes. In summary, findings may result in recommendations, suggestions, or the identification of good practices in accordance with the following definitions, and referenced to the paragraph in the standards as the basis of the finding:

- *Recommendation:* A recommendation is advice on how improvements can be made in the national regulatory arrangements in the areas that have been reviewed and discussed as already described. Such advice is based on proven international practices and should deal with the root causes rather than the symptoms of the concerns raised. It can be, but need not necessarily be, an indication of shortcomings either in the national statutory legislative and regulatory regime or in the methods of fulfilling their requirements. Recommendations should be specific, realistic and designed to result in tangible improvements.
- Suggestion: A suggestion either is an additional proposal in conjunction with a recommendation or may stand on its own following a discussion of the associated background. It may indirectly contribute to improvements in national regulatory arrangements but it is primarily intended to make the regulatory body's performance more effective, to indicate useful expansions of existing programmes and to point out possibly superior alternatives to current work. In general it should stimulate the regulatory body's management and staff to consider ways and means of enhancing performance.
- Good Practice: A good practice is an indication of an outstanding organization, arrangement, programme or performance, superior to those observed elsewhere in the region. Often they are more than just the fulfilment of current requirements, or expectations. It has to be superior enough to be worth bringing to the attention of other nuclear regulatory bodies as a model in the general drive for excellence.

3.2.4.2. Technical Notes

During the course of the review, after each co-ordination meeting, team members will write detailed Technical Notes on their observations, findings and conclusions, including any recommendations, suggestions or good practices.

The Technical Notes are the "field notes" of the individual experts and are considered restricted documents by the IAEA. It is expected that these notes would not be released to the public or derestricted by the regulatory body (or other national authority).

3.2.4.3. Draft IRRT report

During the latter part of the mission the team leader compiles a draft IRRT report from the experts' Technical Notes, to capture all the findings of the mission. The counterparts are invited to comment on this draft during the mission to ensure technical accuracy and clarity of understanding of the findings reported. This draft IRRT report is treated as an official IAEA publication and its circulation is restricted.

(See Appendix VI, Guidelines for Drafting Technical Notes and the IRRT Report).

3.2.5. Exit meeting

The exit meeting is held on the last day of the mission and is attended by the senior personnel of regulatory body, the counterparts and all the members of the IRRT team. The IRRT team leader summarizes the main findings of the mission and provides the senior management of the regulatory body with a copy of the draft IRRT report. The IRRT team members provide a brief verbal report of the findings in their own subject review areas.

3.2.6. Final IRRT report

On completion of the mission, the IRRT team leader will edit and finalize the draft IRRT report at IAEA headquarters. The final report is circulated to the team members who are given the opportunity of offering comments before printing. The printed report is then formally issued, through official channels, to the Member State concerned. The IAEA restricts initial distribution to the authorities concerned, the contributors to the report and responsible IAEA staff. Any further distribution at the time of formal issue is at the discretion of the Member State. The IAEA will automatically derestrict the IRRT report ninety days after the formal issue of the report, unless otherwise instructed by the Member State.

3.3. FOLLOW-UP IRRT MISSION

Usually the team leader discusses the timing of a follow-up mission with the senior management of the regulatory body during the mission. Where possible an invitation for a follow-up mission should be agreed to in principle before the close of the mission. On return from the mission the team leader should indicate to the IRRT co-ordinator that a request has been made and a follow-up mission should be planned for between 18 to 24 months later. After a suitable period, e.g. nine months, the Member State will be approached by the IAEA with a view to obtaining a formal response to the IRRT report that identifies any actions taken on the basis of the report. If a follow-up mission is not completed before three years have elapsed, or there have been significant changes to the regulatory body then in may be appropriate to conduct a repeat mission. The objective and process for a follow-up IRRT mission is similar to the main IRRT and details are provided in Appendix VII.

APPENDIX I PREPARATORY MEETING FOR AN IRRT MISSION

There are five main elements to the preparatory meeting:

A.I.1. DISCUSSIONS BETWEEN THE IRRT TEAM LEADER AND SENIOR MANAGEMENT ON THE AIMS OF THE IRRT

The objective is for the team leader to:

- confirm the scope of the review, the topic areas to be covered and identify the counterparts;
- agree the team composition in outline (numbers and specific requests for experts) and;
- agree when appropriate the participation of an observer.

A.I.2. PRESENTATIONS BY THE HOST REGULATORY BODY TO THE IRRT TEAM LEADER

This part of the meeting gives the regulatory body the opportunity to explain the status of their organization and provides the team leader on information that will be used to recruit suitable experts for the mission, by covering:

- the regulatory body structure, organization and independence;
- the main responsibilities of the regulatory body and its current activities;
- the situation in the agreed areas of review;
- a description of any current management initiatives and;
- any current management concerns.

A.I.3. PRESENTATION BY THE IAEA TEAM LEADER OF THE IRRT METHODOLOGY TO THE HOST REGULATORY BODY STAFF

This part of the meeting allows the team leader to:

- explain the IRRT 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 findings;
 - the drafting of the mission report;
 - the Exit meeting.
- explain the need for the counterparts to make brief presentations (15 minutes) on their topic areas to the IRRT experts at the entrance meeting;
- explain (and provide) the IAEA Safety Standards which are used as the basis of the IRRT;

- explain that it is important for the success of mission that the regulatory body provide written replies in English to the IRRT questionnaire as this is the basic guideline for the experts, to form their starting point and to ensure an objective, consistent and systematic approach to the review;
- discuss example results of previous IRRTs to give regulatory body personnel an understanding of typical results and what is expected.

A.I.4. DISCUSSIONS WITH COUNTERPARTS

Meetings of 15 to 20 minutes should be arranged with the individual counterparts. These meetings take place after the presentation by the team leader and are held between the team leader and each of the counterparts in turn, covering all the agreed review areas. Their purpose is to:

- allow the counterpart to explain the regulatory approach and practices in their area(s) of review (approximately 5 minutes);
- provide the counterpart with an opportunity to ask questions about the mission;
- identify the advanced reference material that the Regulatory Body needs to submit to the IAEA;
- establish that the advance reference material will need to be made available in English two months before the start of the mission;
- discuss any specific requests from the Regulatory Body with regard to the focus of the IRRT review;
- identify locations where direct observation of working practices should be carried out and the needs for experts to make visits away from the regulatory body main offices e.g. nuclear installations, technical support offices, regulatory body regional or local offices, other licensed activities/locations and emergency centres.

A.I.5. DISCUSSION OF THE PRACTICAL AND LOGISTICAL ASPECTS OF THE MISSION BETWEEN THE IAEA TEAM LEADER AND THE 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:

- mission schedule including logistics for the expert's visits to other locations e.g. a nuclear installation;
- planning of the entrance meeting;
- arrangements for the arrival of the experts in the country, accommodation, meals etc.;
- working areas within the regulatory body offices, clerical/secretarial support in English with at least one room at the disposal of the team to enable them to work and to hold discussions in reasonable privacy;
- forms to be filled out in advance for visas, security badges, and detailed contact information;
- need for interpretation and translation of documents.

APPENDIX II ADVANCE REFERENCE MATERIAL

Typical documents, to be submitted (to the IAEA in English, translated if necessary) about 2 months prior to the IRRT review, are listed below. The specific contents and designations of these documents may vary owing to particular national practices.

(a) National legislation:

- law(s) governing the siting, design, construction, commissioning, operation or decommissioning of nuclear installations;
- synopsis of the constitutional legislative system of the 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 and;
- regulations on nuclear, radiation, waste management and transport safety.

(b) Regulatory organization and procedures:

- legal status and responsibilities assigned by law to the regulatory body;
- objectives of the regulatory body and how it maintains its independence;
- regulatory body safety policy and quality management system;
- structure, organization and staffing;
- description of the licensing process;
- procedures for assessment and review of technical submissions;
- inspection practices;
- enforcement practices;
- role and responsibilities in relation to nuclear emergencies;
- a typical licence; and list of applicable codes and standards.

(c) Regulatory body's written response to the IRRT Questionnaire [7].

A useful source of this material is the Country National Report to the Convention on Nuclear Safety and the regulatory body's annual reports.

The experts should assess these documents against the IAEA Safety Standards Series reports, notably the requirements for Legal and Governmental Infrastructure [1], and the four Safety Guides [2–5] and the report of the International Nuclear Safety Advisory Group on Safety Culture [6].

To assist the experts in this review the experts should use the written responses provided by the regulatory body to the IRRT questionnaire [7].

APPENDIX III ROLES AND RESPONSIBILITIES OF IRRT TEAM MEMBERS

A.III.1. TEAM LEADER

The IRRT team leader has overall responsibility for:

- official IAEA liaison with the government/ regulatory body;
- co-ordination of the IRRT;
- selecting the team members;
- participating in the entry and exit meetings representing the IAEA;
- supervising the review, including conducting daily team co-ordination meetings, ensuring that schedules are met, informing government officials, resolving issues requiring decision and preparing for the exit meeting;
- co-ordinating the preparation of all Technical Notes;
- producing the draft and final IRRT reports;
- helping the regulatory body to prepare public information needed during the mission.

The team leader will not normally participate directly in any of the detailed areas of review.

A.III.2. LIAISON OFFICER

The host regulatory body should appoint a liaison officer who:

- is an experienced, senior member of staff of the regulatory body;
- will be the main contact with the team leader during the preparation of the mission;
- will be available throughout the mission and;
- participates in the daily team meeting.

A.III.3. EXPERT

The expert is expected to:

- participate in the opening and entrance meetings;
- carry out a complete systematic review of assigned subject area;
- take the lead during the interviews with the counterparts (strike a balance between hearing presentations and asking questions);
- identify differences between the national approach and the international standards;
- make notes daily, elaborate recommendations, suggestions and good practices and report them to the daily team co-ordination meeting;
- develop an opinion of the adequacy and effectiveness of the regulatory system and the approach to regulation;
- jointly review with the team all recommendations, suggestions and good practices;

- follow IRRT guidelines/schedule as appropriate;
- participate in the daily team co-ordination meetings, take active part in discussions of all issues raised by team members;
- submit contributions to the report according to required format and timescale;
- co-operate with the other team members and respond to team leader requests;
- report the review results at the exit meeting.

A.III.4. OBSERVER

The main purpose of an observer taking part in an IRRT mission is to provide another Member State's regulatory body with first hand insight into the IRRT process. The scope of the observer's involvement shall be agreed by, the 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 in the opening and entrance meetings;
- attend all team activities;
- participate in the daily team co-ordination meeting;
- contribute to discussions and the drafting of the report;
- observe the overall IRRT process with regard to the roles and responsibilities of the participants, the methodology, the finding and report development;
- sit in on the discussions of the experts and counterparts;
- follow the direct observation activities;
- read and evaluate the material provided for the IRRT mission;
- maintaining observer status, seek clarification if necessary in any area;
- prepare notes concentrating on aspects of benefit to the observer's own country and discuss them with the team leader;
- participate in the exit meeting.

A.III.5. COUNTERPART

A counterpart is a staff member of the host regulatory body who is the primary contact with the expert(s) for a particular area of review throughout the mission. They would normally be:

- a senior staff member or their deputy whose sole responsibility corresponds to the area(s) of review;
- able to remain with experts throughout the mission.

The counterpart is not expected to know all the answers, but:

- provides a co-ordination function and calls in specialist staff as required;
- participates actively in the review;

- provides assurance of complete and correct information and assists in assuring full comprehension and;
- should lead the preparation of the written responses to the IRRT questionnaire in their specific subject area(s) and the documentation provided as part of the advance reference material.

APPENDIX IV AGENDA FOR IRRT OPENING AND ENTRANCE MEETING

A.IV.1. IRRT OPENING TEAM MEETING AGENDA

The opening team meeting is attended by, the team leader, the experts, observer(s) and the liaison officer.

1.	Opening remarks. Introduce liaison officer	Team leader
2.	Self-introductions:	Team members
	Each team member (experts and observer)to give a brief statement of their careers and current responsibilities (2 min). Observers should introduce themselves.	
3.	Remarks on Country Background	Team leader
4.	Presentation of the IRRT process (1.5 hours)	Team leader
5.	Guidance for Reporting	Team leader
6.	Review of Schedule	Team leader
7.	Break for 15 minutes to work in review subject areas to prepare statements to the team on first impressions in the assigned subject areas of the advanced reference material. (Working in subject area sub-teams.)	
8.	Report of Initial Review of Advanced Reference Material:	Experts
	Experts to briefly present their prepared statements on their initial impressions of the advanced reference material. Where a pair of experts is working together they should 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 liaison officer.	
9.	Preparation for daily Interviews	Team leader
	The team members should continue working in their subject areas, after the closure of the meeting, to agree their approach to the conduct of the interviews.	
10	Closing Remarks	Team leader

A.IV.2. ENTRANCE MEETING AGENDA

Each IRRT is different and the entrance meeting agenda will need to be customized to suit the occasion, but it should follow the following pattern:

1.	Welcome and introduce senior attendees	Regulatory Body Manager
2.	Short opening remarks (include as a minimum):	Team Leader
	• thanks to the host regulatory body for the arrangements;	
	• thank the regulatory body staff making themselves available for the duration of the IRRT;	
	• remark on the context of the IRRT e.g.	
	 full or reduced scope; first or follow-up (mention previous IRRT involvement) other related IAEA work, e.g. assistance programme. 	
3.	Introduce the experts (and observer) each in turn to explain their background (2 minutes each).	Team Leader then Experts in turn.
4.	Briefing for IRRT team	Regulatory Body Manager
	• role and responsibility of regulatory body;	
	• relationship of regulatory body to utilities;	
	• why the 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.	
5.	Introductions and working arrangements.	Regulatory Body Manager
	• 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 that team should be aware of, e.g. outage, major repairs/modifications, reorganizations.	
6.	Detailed presentations on each of the areas to be covered by the review	Counterparts
7.	Closing remarks	Team leader

APPENDIX V SCHEDULE FOR A TWO WEEK IRRT MISSION

A schedule is used to define the IRRT mission, through a list of the activities on a dayto-day basis. Flexibility is built into the schedule to allow for travelling to and from locations where direct observations are to be made.

	Pre-mission: Pre-briefing at IAEA or other suitable venue and/or by correspondence
Day 0	Arrival: Team opening meeting.
Day 1 (morning)	Entry meeting:
	Introductions and presentation by national regulatory body to cover its role and responsibility and the legal and administrative systems of the Member State. Also to address the objectives of the regulatory body, how these are achieved and how they are seen to compare with international standards.
	Presentation to the experts on the selected review areas.
	Daily team co-ordination meeting.
Days 1 (afternoon) to 5	Agreement between experts and counterparts on working arrangements:
	Interviews by experts of their regulatory body counterparts, divided into specialist areas:
	A – Legislative and Governmental Responsibilities,
	B-Authority, Responsibilities and functions of the Regulatory body
	C-Organization of the Regulatory Body
	D-Authorization Process
	E-Review and Assessment
	F – Inspection and Enforcement
	G-Development of Regulations and Guides
	H – Emergency Preparedness
	I – Radioactive Waste Management
	J-Radiation Safety
	K – Transport safety
	Daily team co-ordination meeting.
	For experts reviewing topics F, H a visit to a nuclear site should be arranged to allow one full day at site (Day 4 is recommended). Visits by experts to other facilities and/or organizations should be arranged as

necessary.

Days 6–7	Weekend: programme at the discretion of the team leader.
Days 8–9	<i>Further discussions between experts and counterpart to clarify understanding.</i>
	Draft Technical Notes team leader to start compiling Technical Notes into the draft IRRT report.
	Daily team co-ordination meeting.
Day 10	Complete drafting Technical Notes.
	Discuss findings and review with team members.
	Daily team co-ordination meeting.
Day 11	Issue draft IRRT report for counterparts to review.
	Discuss and agree findings regarding accuracy of the technical notes with counterparts.
	Prepare individual points to be raised at the exit meeting.
	Daily team meeting.
Day 12	Exit meeting:
	Experts will meet with the senior management of the regulatory body to present their findings, indicating how they arrived at the findings.
	The team leader will provide the regulatory body with a copy of the draft IRRT report.
	Post-mission: Team leader to edit draft IRRT report and circulate it to the experts for comment. It then progresses through IAEA channels before the submission of the final report to the Member State.

APPENDIX VI

GUIDELINES FOR DRAFTING TECHNICAL NOTES AND THE IRRT REPORT

A.VI.1. INTRODUCTION

Writing the Technical Notes is one of the IRRT reviewer's most important tasks. The team members, having followed the IRRT Guidelines and the IRRT questionnaire will collect a vast amount of information that must be recorded. These facts, impressions and conclusions must be written clearly and concisely in the Technical Notes. The compilation of the Technical Notes constitutes the draft IRRT Report.

The Technical Notes should be written, in English, day by day from the first day of review, and modified and supplemented as necessary throughout the entire period of the review.

In writing the Technical Notes, the following should be taken into account:

- emphasis should be given to the reviewer's objective observations, with clear conclusions and the minimum of description;
- the language should be clear, concise, objective and impersonal;
- short, direct sentences aid understanding;
- the official names (or official translation) should be used to designate organizational units, positions and systems and;
- if abbreviations or acronyms are used, they should be introduced upon their first use.

It should be emphasized that this guide on drafting Technical Notes:

- is not intended to substitute for the IRRT guidelines and the IRRT questionnaire and;
- is not to be used as a strict list with an obligation to describe every separate item or with a prohibition on any other items.

A.VI.2. FORMAT

A standardized report format is used. Each area of review is covered by a section of the report and is designated by a number and a heading (bold and capitalized). Specific topics are covered under each subject review area. It is the responsibility of the team leader to provide the Foreword and to write the Summary and Introduction to the report. A minimum set of the sub-areas is given in Figure 1.

Under the numbered section heading the name(s) (given name and family name) of the reviewer(s) should be provided. If there are several reviewers, their names should appear in alphabetical order, e.g.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Expert: John Doe

Or,

Experts: John Doe and Ann Other

FOREWORD

SUMMARY

INTRODUCTION

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

1.2. POSITION AND RESOURCES OF THE REGULATORY BODY

2. AUTHORITY, RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

3.2. QUALITY MANAGEMENT

3.3. STAFFING AND TRAINING

3.4. ADVISORY BODIES AND RESEARCH ORGANIZATIONS

3.5. INTERFACES AND LIAISON WITH LICENSEE(S) AND OTHER ORGANIZATIONS

3.6. INTERNATIONAL CO-OPERATION

4. AUTHORIZATION

4.1 TYPES AND STAGES OF AUTHORIZATION (e.g. facilities, components, activities, modifications,)

4.2 AUTHORIZATION and other PROCESSES (including issuing, amending, suspending, revoking)

4.3 DOCUMENTS PRODUCED BY THE REGULATOR

4.4. DOCUMENTS PRODUCED BY THE LICENSEE/APPLICANT

5. REVIEW AND ASSESSMENT

5.1. ESTABLISHMENT AND USE OF REVIEW AND ASSESSMENT CRITERIA

5.2. MANAGEMENT OF REVIEW AND ASSESSMENT

5.2. PERFORMANCE OF REVIEW AND ASSESSMENT

5.3. SELF-ASSESSMENT OF REVIEW AND ASSESSMENT ACTIVITIES

6. INSPECTION AND ENFORCEMENT

6.1. OBJECTIVES OF INSPECTION AND ENFORCEMENT

6.2. MANAGEMENT OF INSPECTION

6.3. PERFORMANCE OF REGULATORY INSPECTION

6.4. REGULATORY ENFORCEMENT

6.5. SELF-ASSESSMENT OF INSPECTION AND ENFORCEMENT ACTIVITIES

7. DEVELOPMENT OF REGULATIONS AND GUIDES

7.1. PROCESS FOR DEVELOPMENT OF REGULATIONS AND GUIDES

7.2. REVIEW AND REVISION OF REGULATIONS AND GUIDES

8. EMERGENCY PREPAREDNESS

9. WASTE MANAGEMENT AND DECOMMISSIONING

10. RADIATION PROTECTION

11. TRANSPORT OF RADIOACTIVE MATERIAL

APPENDICES

FIG. 1. Standardized contents of an IRRT report.

The report, which should be about three to five pages in length for each area of review, should commence with the general impressions that the expert has gained from the review to provide a perspective for the subsequent, more detailed, discussion of the individual subareas. These general impressions should be not more than half a page long and should be produced after the review is completed.

The sub-areas should be designated by a two-digit number and a capitals subheading, further subdivisions for topics should use three digit numbers and normal text as follows:

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Experts: John Doe and Ann Other

1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS

The principal laws and regulations...

- 1.1.1 Legislation
- 1.1.2 Regulations
- 1.1.3 Regulatory Guides
- 1.2. INDEPENDENCE OF THE REGULATORY BODY

The independence of the regulatory body is established through provisions in...

The final structure for each sub-area could be several paragraphs long, possibly together with recommendations, suggestions and good practices. These should be numbered and, if necessary, itemized.

For definitions of Recommendations, Suggestions and Good Practices, refer to Section 3.2.4.1 of this report.

A.VI.3. NUMBERING SYSTEM

Recommendations, suggestions and good practices are each to be identified by a fourdigit number. The first three digits give the area and sub-area of the review and the fourth digit will always be 1 for a recommendation or suggestion, or 2 for a good practice.

Recommendations and suggestions must be preceded and supported by bases. If there are several bases for recommendations and suggestions (or good practices) in one sub-area, they can be itemized accordingly and each individual item numbered (1), (2), (3), etc.

A "basis" is a recapitulation of the concern that gives rise to a recommendation or suggestion. It should briefly restate the issue, but not introduce new material or thoughts (such issues should be addressed in the preceding text). The basis should reference and quote in italics the requirement or guidance in the relevant IAEA Safety Standards Series publication.

If there are several recommendations, and or suggestions, in one sub-area related to one basis, these can be itemized accordingly and each individual item identified (a), (b), (c), etc.

If there is no "basis" for making a recommendation or suggestion, then the relevant subarea may contain the word "none". If there is neither a recommendation nor a suggestion then the relevant sub-area should include a suitable phrase to this effect, e.g. "In the area reviewed the performance corresponds with normal proven and effective international practices". If no good practices, as defined in Section I-5, are identified, then the sub-area number need not be included.

- 1.1. PRINCIPAL LAWS OR OTHER LEGAL PROVISIONS
- 1.1.1. Legislation
- 1.1.1.1 Recommendations and Suggestions
 - (1) **BASIS:** The IAEA Requirements for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standard Series GS-R-1 (hereafter called SSS GS-R-1) requires in paragraph 2.4.(8) that the legislation "...shall provide for continuity of responsibility when activities are carried out by several operators successively and for the recording of the transfer of responsibility."
 - a. Recommendation: The legislative framework regarding decommissioning, interim storage and final disposal of spent fuel and radioactive waste should be reviewed and amended...
 - b. Suggestion: This could be achieved by...
 - (2) **BASIS:** The IAEA Requirements for Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standard...
- 1.1.1.2. Good Practices
- 1.1.2. Regulations
- 1.1.2.1. Recommendations and Suggestions
- 1.1.2.2. Good Practices

APPENDIX VII GUIDELINES FOR FOLLOW-UP IRRT MISSIONS

A.VII.1. INTRODUCTION

An IRRT follow-up mission is available to requesting Member States. Its purpose is to continue the work of improving regulatory effectiveness by reviewing progress in the response to IRRT mission recommendations or suggestions. An IRRT follow-up mission may also include further reviews in specific topic areas.

This section provides the guidelines for the IRRT follow-up service. If a follow-up mission includes additional review activities the IRRT Guidelines continue to be applicable.

A.VII.2. PURPOSE OF THE FOLLOW-UP IRRT GUIDELINES

This section has been prepared to provide a common basis for IRRT follow-up missions. It is addressed to the team members of IRRT follow-up missions but it will also provide guidance to a host nuclear regulatory body receiving a follow-up mission.

A.VII.3. OBJECTIVES

The key objectives of an IRRT follow-up mission are to

- review progress in implementing improvements resulting from IRRT mission recommendations or suggestions; and
- provide further reviews in areas where significant changes have occurred since the mission or in areas, which were recognized as weaknesses during the IRRT mission.

A.VII.4. PROTOCOL

An IRRT follow-up review will only be initiated after the IAEA has been approached formally by a Member State at Governmental level. A follow up mission will normally take place 18 to 24 months after a mission. Exceptionally, a follow up mission can be arranged after a longer interval if a regulatory body undertakes substantial developments after a mission but more usually a repeat mission should be considered. A minimum of 9 months is normally required to prepare a follow-up mission.

The review of a national regulatory body will only be performed by a group of expert regulatory officials with both broad knowledge and long experience in the field, selected by the IAEA and supported by IAEA staff.

The report of the follow-up will be provided to the recipient and will be de-restricted 90 days after the IAEA transmittal letter unless the Member State requests that it remains restricted. The decision to implement any recommendations of the report will lie entirely with the relevant authorities of the country concerned.

A.VII.5. METHODOLOGY

A.VII.5.1. Preparation

On receipt of a request for an IRRT follow-up review a team leader will be assigned who will arrange for the:

- establishment of liaison contacts with the regulatory body and;
- recruitment and briefing of external experts for the team.

A preparatory meeting with the organization(s) involved may be necessary and should be completed approximately 6 months before the follow-up mission. At the same time, the host organization should nominate a counterpart in each review area who will be the primary contact with the team during the review. If a preparatory meeting is necessary it should be attended by the team leader and should be held at the regulatory body's headquarters to allow senior management and other organizations involved to participate. The meeting should consider the:

- specific purpose of the IRRT follow-up mission;
- regulatory body's preparation for the follow-up review, including a list of the documentation required during the review;
- preparation of the advance reference material (see AVII.6) and;
- logistic support required (see AVII.7).

A.VII.5.2. Team composition

The team will comprise a leader, who is always an IAEA staff member, and between 1 and 3 additional experts. For continuity the leader and some members should have participated in the original mission. For additional review there may be benefit in recruiting new team members with appropriate expertise. Normally the experts will work in pairs. No one from the host country will be included in the team. In some circumstances the inclusion of an observer may be proposed by the IAEA for consideration by the host country.

A.VII.5.3. IRRT team leader

The team leader will retain overall responsibility for:

- official IAEA liaison with the government/regulatory body;
- selecting the team members;
- co-ordination of the IRRT follow-up;
- participating in the entry and exit meetings representing the IAEA;
- supervising the review, including conducting daily team meetings, ensuring that schedules are met, informing government officials, resolving issues requiring decision and preparing for the exit meeting;
- co-ordinating the preparation of all Technical Notes
- helping the regulatory body to prepare public information needed during the mission and;
- producing the IRRT Follow-up Report.

The team leader will take the lead in reviewing progress against the action plan but will not normally participate directly in any of the detailed areas of review.

A.VII.5.4. The review

A.VII.5.4.1. Review of response to mission findings

The review of responses to recommendations and suggestions will be carried out following the normal IRRT approach. That is information required to reach a judgement will be gathered by

- a review of written material;
- interviews with personnel; and
- direct observation of organization, practices and activities.

The principal written material for this activity will be the action plan drawn up by the recipient. However, additional written material will be necessary to demonstrate the measures implemented and the progress made. The reviewers will be looking for evidence to support the self-assessment of progress recorded in the action plan and will provide further advice as appropriate.

A.VII.5.4.2. Review of additional topics

The review of specific topics will be completed according to the IRRT Guidelines.

A.VII.5.5. Reporting

During the course of the follow-up review team members will write detailed Technical Notes on their observations and conclusions. For the review of progress against the IRRT mission findings team members will record observations against each of the mission findings. The observations to be used are:

- actions completed;
- actions in progress;
- further review necessary.

Additional advice may be provided using recommendations or suggestions. Any good practices identified should be recorded for the benefit of other member States.

For areas that are subject to further review the results should be reported in the same way as for an IRRT mission.

On completion of the review, the team leader will prepare the IRRT Follow-up Report on the basis of the Technical Notes. This is an official IAEA document that summarizes the team's main observations and conclusions. Before the text is finalized, the regulatory body that has been reviewed will be given the opportunity of offering comments on accuracy and clarity. The published report will be submitted through official channels to the Member State concerned. The IAEA restricts initial distribution to the authorities concerned, the contributors to the report and responsible IAEA staff. Any further distribution will be at the discretion of the Member State (see A.VII.4).

A.VII.5.6. Schedule

An IRRT follow-up mission will normally last one week. If it is agreed that there should be a substantial review element to a particular mission there may be a need to extend the mission into a second week.

A programme for the week should be agreed in advance of the mission. All follow-up missions should have formal opening and exit meetings. The first half-day of the follow-up mission would normally involve presentation of information contained in the Advance Reference Material.

A.VII.6. ADVANCE REFERENCE MATERIAL

The advance reference material from the original IRRT mission should be made available to the follow-up team. In preparation for the follow-up mission the host should prepare a document that outlines any significant changes to the advance reference material provided for the original mission.

As mentioned in section AVII.5.1 the advance reference material for review of progress in responding to IRRT findings is the action plan and supporting evidence. For specific topics advance reference material should be prepared specifically.

All advance reference material should be provided to the team leader at least three months before the mission.

A.VII.7. SUPPORT FACILITIES

Prior to the IRRT follow-up review the IAEA will make arrangements with the Member State being visited to ensure the provision of necessary support facilities. All reviews are conducted in English and the Member State should provide any necessary interpretation facilities to enable the reviewers to do their work. At all times, there should be at least one meeting room at the disposal of the reviewers, of sufficient size to enable them to work and to hold discussions in reasonable privacy. Additionally, full secretarial services, including typing in English and copying facilities, should be made available by the Member State throughout the whole period of the review. If this is not possible a request to the IAEA should be made to provide secretarial support.

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