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Guidelines for IAEA International Regulatory Review Teams (IRRTs)

INTERNATIONAL ATOMIC ENERGY AGENCY IAEA

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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 power plants 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 Nuclear Safety Standards (NUSS) publication entitled Code on the Safety of Nuclear Power Plants: Governmental Organization, Safety Series No. 50-C-G (Rev. 1) (1988), provides a general consensus reference for the practices necessary for a national organization to fulfil the regulatory purposes and discharge the regulatory functions. The Code also defines the terms used in these Guidelines.

The guidance given in the Code 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 Series publications, including the NUSS Code on Governmental Organization 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.

EDITORIAL NOTE

In preparing this material for the press, staff of the International Atomic Energy Agency have mounted and paginated the original manuscripts and given some attention to presentation.

The views expressed do not necessarily reflect those of the governments of the Member States or organizations under whose auspices the manuscripts were produced.

The use in this book of particular designations of countries or territories does not imply any judgement by the publisher, the IAEA, as to the legal status of such countries or territories, of their authorities and institutions or of the delimitation of their boundaries.

The mention of specific companies or of their products or brand names does not imply any endorsement or recommendation on the part of the IAEA.

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Part I
IRRT MISSIONS

I-1. INTRODUCTION

101. 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.

102. 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.

103. 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 judgement on a national regulatory body.

104. What can be achieved, however, is for an International Regulatory Review Team (IRRT) to compare, insofar as this is possible, the regulatory practices in a country with existing international consensus guidelines and equivalent good practices elsewhere. The IRRT can, and should, be judgemental in evaluating the regulatory body with respect to these guidelines 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 power plant (NPP) site 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.

105. International guidelines referred to in this document are the IAEA's Safety Series and related publications.

I-2. PURPOSE OF THE GUIDELINES

106. This document has been prepared to provide a basic structure and 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 will also provide guidance to a host nuclear regulatory body receiving a mission.

107. 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;
- licensing process and requirements on the applicant(s)/licensee(s);

- review and assessment procedures;
- inspection and enforcement practices; and
- emergency preparedness.

This is not an exhaustive list and the NUSS Code on Governmental Organization is the basic reference that should be used. 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.

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

I-3. OBJECTIVES

109. The IRRT is intended to be a peer review conducted by a team of international experts with direct experience applicable in the areas of evaluation. Judgements 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 existing international consensus guidelines and an exchange of experiences and equivalent good practices aimed at strengthening the organization and the procedures and practices being followed.

110. This document is intended to be used by IRRT teams in reviewing the activities of a regulatory body as applicable to the regulation of NPPs. The mission will, however, take note of any other activities of the regulatory body when drawing up the review report. The document does not specifically deal with the functions of a regulatory body responsible for other types of nuclear facilities or related nuclear activities, but it is intended that the concepts presented in the document could be applied where appropriate.

111. 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 review of their nuclear regulatory practices with respect to international guidelines;
- Providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance falls short of internationally accepted practices;
- 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.

I-4. PROTOCOL

112. An IRRT review will only be initiated after the IAEA has been approached formally by a Member State at governmental level, in view of the fact that an IRRT review would need to consider the legal framework and regulatory regime in the country to be visited.

113. The review of a national 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.

114. The report of the expert group will be confidential to the country visited unless the country specifically states otherwise. The decision to implement any recommendations of the report will lie entirely with the relevant authorities of the country concerned.

I-5. METHODOLOGY

I-5.1. Preparation

115. On receipt of a request for an IRRT review, the team leader designated by the IAEA will arrange for:

- the establishment of liaison contacts with the regulatory body;
- a preparatory meeting with the organization(s) involved; and
- the recruitment and briefing of external experts for the team.

116. At the same time, the host organization should nominate a counterpart in each review area who will be the primary contact with the expert(s) in that area during the review.

117. The preparatory meeting, usually attended by the team leader, should be held at the regulatory body's headquarters to allow senior management and other organizations involved to participate. The meeting will consider:

- the main features of the IRRT programme;
- the regulatory body's preparation for the review, including a list of the documentation required during the review;
- preparation of the advance information package (see Section I-6); and
- logistic support required (see Section I-7).

I-5.2. Team composition

118. The team will comprise a leader, who is always an IAEA staff member, and four to six experts in the field of NPP regulation. 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 may be proposed by the IAEA for consideration by the host country.

119. IRRT members are selected by the IAEA so as to ensure that a variety of national approaches to regulatory organization and implementation is represented. Each of the experts invariably has, in addition to a particular area of expertise, knowledge of other national approaches and other relevant areas. Coupling this knowledge with the IAEA Nuclear Safety Standards allows the best international practices to be identified.

I-5.3. IRRT team leader

120. The team leader will retain overall responsibility for:

- Official IAEA liaison with the government/regulatory body;
- Co-ordination of the IRRT;

- 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;
- Responding to the media as appropriate and agreeing with the government/regulatory body on any joint press release(s); and
- Producing the final IRRT Report.

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

I-5.4. The review

121. The IRRT team uses three methods to acquire the information needed to develop their recommendations as set out in the experts' Technical Notes (see Section I-5.5.1). These are:

- a review of written material;
- interviews with personnel; and
- direct observation of organization, practices and activities both at the main regulatory headquarters and at an NPP site.

122. Experts are expected to cover each topic to the extent necessary to be able to make an informed judgement. 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.

I-5.4.1. Documents

123. The basis for the review of the regulatory body will consist of the IRRT experts' reviews of (a) national legislation, (b) regulatory organization and procedures, and (c) regulations and guides. The experts will assess these against the NUSS Code on Governmental Organization [1], the report of the International Nuclear Safety Advisory Group on Safety Culture [2], and additional NUSS Codes and Guides as appropriate.

124. The many documents that are necessary for the execution of the regulatory body's duties can usually be grouped into three categories:

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

125. Among these documents, the written material of general interest to the whole team that should be provided prior to the review is listed in Section I-6, while the documents

specific to a given area that are to be reviewed only by the expert responsible are included in the corresponding section of the supplementary guidance in Part II.

I-5.4.2. Interviews

126. After consideration of the relevant written material, the interviews with personnel can then be used:

- To obtain additional information not covered by the documentation;
- To review issues arising out of the documentation review;
- To form a judgement of the arrangements, duties and responsibilities of the regulatory body;
- To determine whether the regulatory and administrative arrangements meet established international guidelines and consensus;
- To elicit individual opinions;
- To form a judgement of the knowledge base, training and resources of the organization; and
- To examine the relationship between the regulatory body and the licensee, in particular how the regulatory body regulates and assesses the way the licensee operates the installation from a nuclear safety viewpoint.

127. The interviews will also provide an opportunity for important information to be exchanged between experts and their counterparts. An interview should be a give and take discussion and not an interrogation of the counterparts by the experts. Properly conducted, these interviews are a most important part of the IRRT review.

I-5.4.3. Direct observation

128. Direct observation of regulatory work activities should be an important aspect of the review process. 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 and morale of the regulatory staff;
- The commitment to safety objectives;
- The effectiveness of the regulatory staff in influencing and enhancing the levels of nuclear safety; and
- The formal traceability of safety assessments and the decision making process.

129. On the basis of the interviews and observations, the experts can then if necessary modify their preliminary views, which were based only on the formal arrangements, to form a judgement of performance and effectiveness. It may be that more than one iteration through document review, interview and observation will be necessary in order to form a judgement.

I-5.5. Reporting

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

- Identify where national practices differ from those described in NUSS Codes or Guides, with account taken, as appropriate, of the Analysis of Replies to an IAEA Questionnaire on Regulatory Practices in Member States with Nuclear Power Programmes [3];
- Make comparisons and offer proposals for change;
- Remember that any changes to national practices are at the discretion of the authorities of the Member State concerned; and
- Consider how effectively laws, procedures, etc., are implemented in practice.

The comparisons may result in recommendations or suggestions or the identification of good practices in accordance with the following definitions:

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, and 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.

131. Each working day of the review, the team leader will call a brief co-ordination meeting where each expert should summarize findings for the day, including perceived strengths and weaknesses, succinctly, in order to allow all the review areas to be discussed at the same meeting. This should create the opportunity for team members to consolidate their views.

I-5.5.1. Technical Notes

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

presentations at the exit meeting. One or more copies of the Technical Notes are given to the senior regulatory management prior to the exit meeting.

133. 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).

134. Guidelines for drafting Technical Notes are presented in Part III.

I-5.5.2. The IRRT Report

135. On completion of the review, the team leader will prepare the IRRT Report on the basis of the Technical Notes. This is an official IAEA document that summarizes the team's main observations and conclusions from comparisons with proven international practices, including all recommendations, suggestions and good practices. Before the text is finalized, the regulatory body which has been reviewed will be given the opportunity of offering comments. 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.

I-5.6. Schedule

136. A typical two week IRRT programme would be scheduled as follows:

Pre-mission	*Prebriefing at IAEA or other suitable venue and/or by correspondence.*
Day 0	*Arrival: Briefing meeting.*
Days 1-2	*Entry and Introductions: Presentation by national regulatory body to cover its role and responsibility and the legal and administrative systems of the Member State. This should also address the objectives of the regulatory body, how these are achieved and how they are seen to compare with international standards.*
Days 3-5	*Interviews by mission experts of their regulatory body counterparts, probably to be divided into specialist areas, e.g. Organization, Regulations and Guides; Licensing Process; Requirements on the Licensee/Applicant; Assessment and Review; Inspection Procedures; Enforcement; Emergency Preparedness.* *[Note: prior to the mission, and on the basis of their expertise, specific areas for review will be allocated to IRRT members].*
Days 6-7	*Weekend: programme at the discretion of the Team Leader.*
Days 8-9	*Visit nuclear site and discuss regulatory regime with licensee/operator.* *Tour site.* *Discuss regulatory regime, inspection procedures and enforcement with regulatory site inspector(s).*
Day 10	*'Flexible' day for travel or for further discussions either at the NPP site or at regulatory headquarters (detailed arrangements to be agreed prior to the mission).*

Day 11	*Private day for IRRT team members and IAEA staff to finalize their Technical Notes prepared during the review and to prepare for the exit meeting discussions with the regulatory body.*
Day 12	*Exit meeting: IRRT experts will meet with the senior management of the regulatory body to discuss their findings, compare these with internationally accepted practices and, where applicable, discuss proposals for possible improvements. The experts will also provide the regulatory body with copies of their Technical Notes, for information.*
Post-mission	*Team leader to prepare a final Report on the basis of the Technical Notes and circulate it to team members for final consideration. It then progresses through IAEA channels before the submission of the final, confidential Report to the Member State.*

I-6. ADVANCE REFERENCE MATERIAL

137. Typical documents, to be submitted (in English, translated if necessary) prior to the IRRT review and discussed at the preparatory meeting, are listed in the following. 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 safety and radiation protection.

(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;
- 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 NPP licence; and
- List of applicable codes and standards.

I-7. SUPPORT FACILITIES

138. Prior to the IRRT review, as part of the discussions at the preparatory meeting, 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.

I-8. FOLLOW-UP

139. 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, and encouraging the de-classification of the report for general distribution. There may also be a follow-up review mission if the IAEA and the regulatory body consider it appropriate.

140. After several missions have been undertaken, an analysis of the various findings should be carried out by the IAEA. If it is possible to produce a report on this analysis without identifying the particular Member State(s), this may be done to provide guidance for future missions.

Part II
SUPPLEMENTARY GUIDANCE

201. This supplementary guidance is intended to assist members of an IRRT team to identify and acquire the information they need to develop and produce satisfactory Technical Notes. The reference document on which the reviews should be based is the IAEA Nuclear Safety Standards (NUSS) Code on the Safety of Nuclear Power Plants: Governmental Organization [1]. Other relevant NUSS Guides and IAEA documents are identified under 'Additional reference(s)' in each review section, as appropriate.

202. In addition, the IAEA-TECDOC Analysis of Replies to an IAEA Questionnaire on Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants [4] has highlighted variations in national practices in a number of areas. These should be taken into consideration by the experts in preparation for the review.

203. The IRRT members should consider and report on each section of the Code to the extent possible within the constraints of the review. Prior to the review, each expert will be allocated one or more of the major areas to report on in the Technical Notes. The breadth of the NUSS Code and Guides on Governmental Organization, the limited time for the review, and the fact that some topics in each of the major areas may need more detailed attention mean that the IAEA staff and the reviewers will have to use their judgement to determine priorities.

204. Each review area is subdivided into 'Additional reference(s)', 'Objectives', 'Documentation' and 'Review points/specimen questions'. The 'Documentation' lists the relevant preliminary background information that the IAEA will have requested from the Member State prior to the mission and further documentary information (which may not be required in English translation) that should be made available during the course of the mission. The 'Review points/specimen questions' are drawn from the IAEA-TECDOCs Analysis of Replies to an IAEA Questionnaire on Regulatory Practices in Member States with Nuclear Power Programmes [3] and Analysis of Replies to an IAEA Questionnaire on Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants [4], and also from Safety Culture [2] and from a draft report on the 1989/1990 regulatory peer group discussions as they relate to operational plant. The 'Review points/specimen questions' are intended only to act as pointers; they should not be taken as all-encompassing or definitive, and must not be considered as a constraint on the reviewer, who should use judgement regarding their usefulness/applicability in any particular Member State.

205. This guidance is intended to promote thought rather than to be prescriptive and should be used to encourage self-examination on the part of the regulatory body and its staff; the 'Review points/specimen questions' should not be used as a Yes/No checklist.

206. Supplementary IRRT guidelines have been developed in the following areas:

- Governmental Organization and Nuclear Safety Legislation
- Role and Responsibility of the Regulatory Body
- Organization of the Regulatory Body
- Regulations and Guides
- Licensing Process

- Requirements on the Applicants/Licensees
- Review and Assessment during the Licensing Process
- Regulatory Inspection and Enforcement
- Emergency Preparedness.

II-1. GOVERNMENTAL ORGANIZATION AND NUCLEAR SAFETY LEGISLATION

207. This is the fundamental basis on which the nuclear safety regime of the Member State rests. Governments need to discharge their responsibilities to regulate the safety of nuclear plant in order to protect site personnel, the public and the environment from undue radiological risk. The Member State therefore needs to have an adequate and supportive governmental organization and statutory legislation. The legislation should provide for a regulatory body, which must have sufficient staff, funding and legal powers to perform its duties and the freedom to do so without undue interference. The government should also encourage international exchanges aimed at improving safety and seek to minimize any impediments to such exchanges.

208. In order to allow time for a comprehensive consideration of these fundamental issues the background information, necessary to enable reviewers to begin to formulate comments on this area, will need to be provided in advance by the Member State.

II-1.1. Additional reference

[2] INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Safety Culture, Safety Series No. 75-INSAG-4, IAEA, Vienna (1991).

II-1.2. Objectives

209. The government or state legislature of the Member State should establish an organizational system and nuclear safety legislation within which the nuclear regulatory body can exist and operate effectively, has adequate legal powers and sufficient funds for its activities, and can pursue its regulatory task without undue interference.

210. The government should ensure an adequate hierarchy of authority, responsibility and reportability to enable the nuclear regulatory body to fulfil its safety functions. In particular, the regulatory body should be separated in the governmental organization from the bodies responsible for developing, promoting or operating nuclear installations.

211. The government should provide a legal basis for ensuring that nuclear installations within the Member State function, at all stages of their life, without undue radiological risk to site personnel, the public and the environment.

212. State's legislation should ensure that adequate financial indemnification is available in the event of a nuclear accident.

II-1.3. Documentation

- Primary legislation, decrees, laws, etc. issued by the government;
- Secondary legislation, subsidiary/lower tier laws (where these exist);
- Tertiary legislation, other relevant legislation, legal requirements, licences, etc., issued by the regulatory body;
- Description of the constitutional and legal system of the Member State;
- Description of all the government Ministries or Departments involved in nuclear regulation, together with their responsibilities and how they interrelate;
- Description of the pattern(s) of industrial practice in the Member State; and
- Description of the extent of procurement from or involvement with foreign vendors/operators or regulators.

II-1.4. Review points/specimen questions

(a) What are the numbers and types of facilities and/or activities that the Member State is operating or planning to operate in the following areas:
  (i) Nuclear power plants;
  (ii) Research reactors, experimental reactors and critical assemblies;
  (iii) Fuel processing and manufacturing plants;
  (iv) Fuel reprocessing plants;
  (v) Radioactive waste management facilities;
  (vi) Transportation of radioactive materials;
  (vii) Any other facility associated with civil nuclear energy;
  (viii) Radiation sources for use in medical, industrial and research facilities;
  (ix) Other facilities involving ionizing radiation that are being operated or are planned?

(b) What are the principal laws, ordinances, decrees or other legal provisions used to regulate the national nuclear power programmes? (Note: these provisions should include nuclear safety, radiation and environmental protection, emergency planning, waste management and decommissioning). Is this body of legislation satisfactory and does it emphasize safety as a prerequisite for the use of nuclear power?

(c) Describe how the current legislation requires the establishment of a regulatory body or bodies with responsibilities for full governmental regulation of all aspects of nuclear power programmes relating to nuclear safety and radiation and environmental protection.

(d) Provide a diagram showing the governmental organization(s) for the regulation of nuclear power, making clear the reporting lines of the various bodies within the legislative framework. It would be helpful to distinguish between direct lines of control and lines which show where advice is given and/or received.

(e) Has the budget for the regulatory body kept pace with inflation and the growth of the industry? Is funding sufficient to allow the employment of staff of adequate competence?

(f) Does the current legislation require licensing of all nuclear facilities, such as those described in (a)?

(g) Does the current legislation require the regulatory body to issue safety regulations? If not the regulatory body, then who does?

(h) Are there any undue impediments to the necessary amendment of regulations?

(i) Does the current legislation require the preparation of periodic reports on the safety of licensed nuclear facilities, and if so, by whom? If yes, to whom are these reports addressed?

(j) Does the current legislation require public participation in the licensing process? If yes, what form of public participation is required?

(k) Are there any other requirements that are defined in current legislation?

(l) How often do contacts take place between the regulatory body and the applicant(s)/licensee(s)? At what level are the contacts and what are their purposes? Do they address the licensee's experience, performance and problems? Is there an appropriate formality and professionalism between the officers of the regulatory body and the applicant/licensee? Do the applicant(s)/licensee(s) respond appropriately to initiatives of the regulatory body?

(m) Are there any instances of governmental interference in technical matters of safety relevance?

(n) Are there any plans to implement new legislation in the near future?

II-2. ROLE AND RESPONSIBILITY OF THE REGULATORY BODY

213. The primary objective of the regulatory body is to ensure that site personnel, the public and the environment are protected from possible adverse effects arising from NPPs. To fulfil this objective the regulatory body needs:

- To establish a system to define acceptable levels of safety; to monitor the licensees to ensure that they fulfil their safety responsibilities; to reassess safety levels and ensure that the licensees continuously strive to improve safety; and to impose controls to ensure the achievement of improved safety.
- To have a clearly defined legal status and independence from both the promoters of nuclear energy and the applicant(s)/licensee(s). It also needs to have the legal authority to enable it to perform its responsibilities and functions effectively.
- To establish clear regulatory objectives, and to understand how these are achieved and how they compare with international standards and good practices. The regulatory body will also need to establish a system for effective interaction, liaison and co-operation with other regulatory bodies and with international bodies and organizations.
- To promote an effective safety culture within its own organization as well as within those of its licensees.

II-2.1. Additional reference

[2] INTERNATIONAL NUCLEAR SAFETY ADVISORY GROUP, Safety Culture, Safety Series No. 75-INSAG-4, IAEA, Vienna (1991).

II-2.2. Objectives

214. All staff of the regulatory body should clearly understand the legal authority underpinning their activities, and how this governs their activities in assessment, licensing, inspection, enforcement, planning, etc.

215. In exercising their authority in matters of nuclear safety, all staff of the regulatory body should understand their organization's regulatory role and objectives, how these are achieved and how they compare with international standards and good practices.

216. The regulatory body should establish any necessary arrangements for co-ordination with other regulatory organizations responsible for health, safety and environmental issues to ensure an integrated approach to nuclear safety.

II-2.3. Documentation

- Description of the regulatory body's legal status and responsibilities as defined by law and its objectives;
- Description of how the regulatory body liaises with and relates to each of the government ministries or departments involved with nuclear regulation; and
- Description of how the regulatory body liaises with and relates to other regulatory organizations responsible for health, safety and environmental issues.

II-2.4. Review points/specimen questions

(a) What are the statutory responsibilities of the regulatory body?
(b) What are the statutory responsibilities of licensees?
(c) Is the statutory responsibility of the regulatory body institutionally separate from that of the applicant(s)/licensee(s)? If not, what is the relationship?
(d) Is the regulatory body independent of the organization responsible for the promotion of nuclear power? If not, explain the relationship.
(e) If the regulatory body comprises more than one organization (e.g. national and state bodies), what is the relationship between these bodies having responsibility for nuclear safety, radiation and environmental protection?
(f) How does the regulatory body liaise or consult with the governmental or other bodies having responsibility for each of the following:
    (i) emergency planning;
    (ii) water resources;
    (iii) land use planning;
    (iv) radiation protection of workers;
    (v) radiation surveillance of the environment;
    (vi) public health; and
    (vii) any other areas as appropriate?
(g) Does the regulatory body possess the following legal authorities for regulatory licensing, inspection and enforcement?
    (i) to establish and issue binding requirements, standards and regulations which, among other things, serve as the basis for inspection;
    (ii) to enter at any time for inspection purposes the premises of any NPP or related vendor establishment;
    (iii) to require preparation of, access to within a reasonable time, and supply of such reports and documents from applicant(s)/licensee(s) and their vendors as are essential for the performance of its inspection responsibilities;
    (iv) to require the co-operation and support of each of the various governmental bodies and consultants possessing inspection related competence or qualifications;
    (v) to communicate inspection information, findings, recommendations and conclusions;
    (vi) to require licensees to promptly inform the regulatory body of conditions, events or developments which could affect the safe operation of the NPP;
    (vii) to require licensees to comply within a reasonable period of time with all decisions and enforcement actions of the regulatory body; and
    (viii) to require the licensee to shut down the plant immediately for safety reasons and under what conditions?
(h) If any answers under (g) are yes, identify the principal laws, ordinances, decrees or other legal provisions that confer the authority.
(i) What are the responsibilities of the regulatory body for inspection and enforcement? Specify the distribution of inspection responsibilities between the regulatory body and the licensee. For example, does the regulatory body only ensure that the licensee performs its own inspection programmes properly, or do both the regulatory body and the licensee have separate inspection programmes?
(j) What are the regulatory body's responsibilities for informing the government and the public of regulatory activities and issues? How are these responsibilities discharged?

(k) What are the regulatory body's international contacts in the fields of nuclear safety and radiation and environmental protection in relation to:
   (i) exchange of information;
   (ii) notification of incidents or abnormal occurrences; and
   (iii) mutual assistance in the event of a nuclear accident?

(l) Are these contacts based upon formal exchange agreements or are they on an ad hoc basis?

(m) At what levels are international contacts made?

(n) Does the regulatory body actively participate in the activities of international organizations?

(o) Are the regulatory body's safety objectives clearly stated and readily understandable? Do they strike a good balance between being too general and too prescriptive, and between innovation and reliance on proven techniques?

(p) How free is the exchange of safety information with other countries?

(q) Does the country participate in the IAEA Incident Reporting System and other relevant international activities (including the various safety review team programmes such as the OSART, ASSET and INSARR programmes[1])?

[1] OSART: Operational Safety Review Team.
ASSET: Assessment of Safety Significant Events Team.
INSARR: Integrated Safety Assessment of Research Reactors.

II-3. ORGANIZATION OF THE REGULATORY BODY

217. The structure and organization of a regulatory body will differ between Member States depending on many factors, including its assigned responsibilities, the constitutional and legal system of the Member State, the national patterns of industrial practice, the number of licensees, the size of its existing and contemplated nuclear programme and the extent of procurement from foreign vendors.

218. No single regulatory model is universally accepted; nonetheless, the regulatory body must be structured and organized in a manner which will enable it to be capable of fulfilling its functions effectively and efficiently. This should include strong lines of authority, clear lines of reporting, and few and simple interfaces, and should be supported by clear definitions and documentation of duties.

II-3.1. Additional reference

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Qualification and Training of Staff of the Regulatory Body for Nuclear Power Plants: A Safety Guide, 50-SG-G1, IAEA, Vienna (1979).

II-3.2. Objectives

219. The structure and organization of the regulatory body should be such as to ensure that all the functions required of the regulatory staff can be adequately performed and directed, and that the regulatory body can act independently of all bodies or organizations over which it has, or is about to have, regulatory responsibility.

220. The regulatory body should have a technical and professional staff capable of carrying out the regulatory functions appropriate to the level(s) necessary for the national programmes covering nuclear installations. Staff employed by the regulatory body should be suitably experienced, qualified, trained and recompensed such that they are respected and so as to permit a professional dialogue between the staff of the applicant(s)/licensee(s) and the regulatory body staff.

221. To supplement its own staff in areas where it is not entirely self-sufficient, the regulatory body may engage consultants. The consultants should be independent of the applicant(s)/licensee(s) and vendors and should be experienced in the area in which they are consulted. The regulatory body must, however, have sufficient staff to independently assess the work being performed for it and the use of consultants should not in any way relieve the regulatory body of its responsibility for making decisions.

222. The government or the regulatory body may set up a formal structure for obtaining expert opinion and assistance by creating advisory committees composed of independent experts. The terms of reference of such committees and the means by which their advice is sought and given should be formalized. The regulatory body needs a suitable structure and staffing to deal with advice from such committees.

II-3.3. Documentation

- Description of the structure and organizational tree of the regulatory body;
- Description of the structure of the staff, identifying their qualifications, experience and training;
- Description of the staff career structure, the 'grading' of each post and how this compares with other, similar, organizations in the Member State;
- Details of consultants used and in what capacity; and
- Description of how the regulatory body uses advisory bodies, including scientific bodies, and what use is made of any advice given, identifying any formal relationship between the regulatory body, other safety authorities (where appropriate) and the advisory body.

II-3.4. Review points/specimen questions

(a) Request a diagram showing the structure of the regulatory body. Where the regulatory body comprises more than one organization, request a diagram for each. The organizational chart(s) should show the management structure, the fields of activity covered by the regulatory body and the numbers of staff involved in each area.

(b) Where the regulatory body comprises a headquarters organization and supporting outstations, what is the relationship between each and how are responsibilities shared?

(c) What were the principal reasons and criteria used to determine the size and structure of the regulatory body? Is the size of the nuclear industry a factor?

(d) What is the present number of technical/professional staff employed? Specify the numbers of staff under the functions of (i) preparation of regulations and guides; (ii) review and assessment; (iii) inspection and enforcement; and (iv) legal matters; and identify whether these staff are based at Headquarters or a regional office or are permanently based on a site, or whether they are external inspectors or consultants.

(e) What qualifications are required for staff engaged in the various functions of the regulatory body listed in (d)?

(f) What grades of technical/professional staff are employed? What levels of responsibility are attached to each grade?

(g) From where are staff recruited? Are there any posts or functions where previous experience in the nuclear industry is of particular importance?

(h) What importance is attached to previous experience and does this determine the grade of the officer?

(i) Are technical/professional staff recruited from the organizations responsible for the design, manufacture and operation of nuclear facilities? What proportion of staff have practical operating or design experience?

(j) Is there an education and training programme for technical/professional staff in the regulatory body?

(k) Does the regulatory body receive advice from advisory committees?

(l) Are advisory committees a legal requirement?

(m) Are these advisory committees standing or ad hoc committees?

(n) What is the scope of each advisory committee?

(o) What is the composition of each advisory committee, i.e. what technical background is required of Members?

(p) Who appoints the advisory committees?

(q) Are members appointed individually or are they appointed to represent organizations?
(r) Do the advisory committees have written guidelines to facilitate their discussions?
(s) If the answer to (r) is yes, specify the scope of such guidelines. If the answer to (r) is no, specify the basis on which recommendations are made.
(t) To whom do the advisory committees give advice?
(u) How binding upon the regulatory body is the advice given?
(v) Are reports of the advisory committees published?
(w) Are comments on regulatory requirements sought from competent bodies? Are such comments taken into account frequently enough to encourage future comments?
(x) Is there a predictable and logical process for dealing with issues that require consideration of both safety and economic factors?
(y) Is there a record of project delays or loss of production due to a lack of clarity in regulatory requirements or lack of timely regulatory decisions?
(z) Does the regulatory body routinely publish reports on important safety problems or summary reviews of plant performance?
(aa) Is the regulatory body funded adequately and what is the source and allocation process for funding the regulatory body?
(bb) Is there a manual describing the functions to be performed by the regulatory body at all levels? Are the individual responsibilities of all staff defined?
(cc) Is there an internal quality assurance programme in operation within the regulatory body?
(dd) Is there an adequate filing system in use to access documents, databases and other information sources?

II-4. REGULATIONS AND GUIDES

223. The regulatory body needs to establish a clear framework of requirements with which applicant(s)/licensee(s) should comply and to provide guidance amplifying how regulatory obligations may be fulfilled. Detailed regulations and guides are not obligatory for all situations. The regulatory body may consider it appropriate to develop them in step with the development of the national nuclear programme. The Member State may make use of IAEA Safety Series publications, i.e. Fundamentals, Codes, Guides and Practices.

224. The regulatory body should endeavour to ensure that regulations, codes, guides etc. explicitly address safety as the main reason for their production.

II-4.1. Additional reference

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations and Guides for Nuclear Power Plants: A Safety Guide, Safety Series No. 50-SG-G9, IAEA, Vienna (1984).

II-4.2. Objectives

225. The regulatory body should establish a clear policy regarding the approach taken to producing regulations and guides. This policy should be developed to suit both the licensing system and the system of government in the Member State.

226. The regulatory body should ensure that an applicant/licensee is made aware of regulations and guides that are applicable. The applicant(s)/licensee(s) and other interested parties should have the opportunity to comment during the production of regulations and guides.

II-4.3. Documentation

- List of guides, codes or technical standards produced by the regulatory body that are required to be used or complied with by the applicant(s)/licensee(s);
- List of guides, codes or technical standards not produced by the regulatory body that are required to be used or complied with by the applicant(s)/licensee(s); and
- Description of the process of production of codes, guides or technical standards in the Member State.

II-4.4. Review points/specimen questions

(a) Does the regulatory body produce safety principles, criteria, guides or other standards?
(b) If the answer to (a) is yes, specify their present status and for whom are they intended.
(c) If the regulatory body does not produce its own principles for nuclear safety and radiation safety, criteria, etc., what safety standards does it use?
(d) If the regulatory body does not produce its own technical standards, how are the technical standards which are used submitted/proposed and accepted?
(e) What is the hierarchy of regulations and guides that are to be used by the applicant(s)/licensee(s)? Does nationally produced documentation take precedence over, replace, endorse or amplify IAEA Codes and Guides?

(f) What system of consultation with independent bodies and/or applicant(s)/licensee(s) is in place to obtain feedback on codes or guides produced by the regulatory body? Is this voluntary or required by legislation?

(g) What system of internal scrutiny and assessment has the regulatory body established to confirm the adequacy of any code or guide prior to its implementation?

II-5. LICENSING PROCESS

227. Whilst responsibility for safety rests with each applicant/licensee, control over nuclear safety by the regulatory body, at all stages of the life of nuclear installations, is exercised primarily through governmental licence(s). Hence, a primary task of the regulatory body is to consider whether to approve (or not) applications for new licences, renewals or amendments to existing licences. The licence itself should be an official document authorizing an activity or activities relevant to nuclear safety, identifying limiting requirements and conditions on those activities and, where appropriate, placing time constraints.

228. Licensing needs to be kept as a live issue throughout all stages of the life of a nuclear installation. The licence may be changed or modified as circumstances dictate but always by and under the control of the regulatory body.

II-5.1. Additional reference

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Licences for Nuclear Power Plants: Content, Format and Legal Considerations: A Safety Guide, Safety Series No. 50-SG-G8, IAEA, Vienna (1982).

II-5.2. Objectives

229. The regulatory body should ensure that any licence issued is:

(a) in compliance with the relevant national legislation;
(b) accurately specifies the activity or activities to be licensed; and
(c) clearly identifies any constraints regarding the activities, i.e. requirements, conditions or time limits.

230. The regulatory body should ensure that it has received, and assessed, adequate documentary evidence from each applicant/licensee regarding the nuclear safety of the activity or activities to be licensed before the licence is issued.

231. Any change to a nuclear licence should be controlled by the regulatory body to ensure that the change receives appropriate levels of consideration and assessment before being implemented.

II-5.3. Documentation

- Description of the requirements placed on an organization to whom a licence can be granted;
- Description of the general licensing philosophy of the regulatory body, e.g. prescriptive or non-prescriptive; and
- Description of the particular function(s) of a licence in the Member State, how it is granted and who grants it; identify whether one or more licences is or are required for a nuclear installation, which stages of the licensing process they cover and whether they are time or event limited.

II-5.4. Review points/specimen questions

(a) Which part or parts of the government organization grant licences and what are the principal prerequisites for granting a licence?
(b) Is the licensing process single stage or multistage? What are the stages and what information is each applicant/licensee required to submit at each stage?
(c) What is the typical time-scale from the official receipt of the licence application for a particular facility to the granting of the licence?
(d) Is there any time allowed in the licensing process for public consultation, hearings or inquiries, and if so, what is a typical time? How are the findings of any public inquiry/hearing likely to affect the licensing process?
(e) Are there any other special features which have a bearing on the licensing process?
(f) What are the main requirements of a licence for each type of facility or activity described in II-1.4(a)?
(g) Is a licence specific to one facility or can it apply to a site with more than one facility?
(h) Do licences have restrictions, duties on the licensee or time limits and, if so, what are they? If not, explain the reasons for not having such limits?
(i) Do licences require licensees to shut down plants at regular intervals for inspection and maintenance? If yes, what is a typical interval? If no, how are these activities performed?
(j) Do licences require selected plant personnel to be licensed and, if so, by whom? If not, what procedures are used to ensure that plant personnel have adequate qualifications, training and experience?
(k) Can a licence be challenged in the courts? If so, who has the right to challenge it?
(l) Does the licensee have the right to appeal against conditions in the licence? If yes, to whom may one appeal and how are differences of view resolved?
(m) How does the regulatory body control any proposed changes to a licence? What system is in place to ensure that such a change receives appropriate consideration and assessment before being implemented?

II-6. REQUIREMENTS ON THE APPLICANTS/LICENSEES

232. The primary responsibility for ensuring safety at all stages of the life of a nuclear installation lies with each applicant/licensee. Requirements placed by the regulatory body do not relieve an applicant/licensee of any obligations. An applicant/licensee shall demonstrate to the regulatory body that the responsibility has been and will continue to be fulfilled. To this end an applicant/licensee must submit or make available to the regulatory body a wide variety of information and demonstrate compliance with licence conditions.

II-6.1. Additional references

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Information to be Submitted in Support of Licensing Applications for Nuclear Power Plants; A Safety Guide, Safety Series No. 50-SG-G2, IAEA, Vienna (1979).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Code on the Safety of Nuclear Power Plants: Operation, Safety Series No. 50-C-O (Rev. 1), IAEA, Vienna (1988).

[10] INTERNATIONAL ATOMIC ENERGY AGENCY, Code on the Safety of Nuclear Power Plants: Quality Assurance, Safety Series No. 50-C-QA (Rev. 1), IAEA, Vienna (1988).

II-6.2. Objectives

233. The regulatory body should have a clear policy on how nuclear safety requirements are placed on an applicant/licensee and in what areas. It should be clearly established how an applicant/licensee can satisfy the regulatory body that all obligations and responsibilities have been fulfilled.

234. The regulatory body should establish and agree with an applicant/licensee the format and content of documentation to be provided in support of any submissions required under the terms of the licence.

235. A programme and schedule for the submission, review and assessment of the safety documentation should be established and agreed between the regulatory body and each applicant/licensee.

236. The regulatory body should ensure that an applicant/licensee establishes a safety review system such as a safety review committee, independent of production pressures.

237. The regulatory body should ensure that an applicant/licensee has established a quality assurance programme for all appropriate stages of the NPP's life.

238. The regulatory body should ensure that an applicant/licensee takes into account the capabilities and limitations of human performance at all stages of the NPP's life.

239. The regulatory body should clearly identify requirements on an applicant/licensee for reporting on safety related matters.

II-6.3. Documentation

- Description of information required from each applicant/licensee by the regulatory body on siting, design, procurement, surveillance during construction, regulation of operations, control of modifications, maintenance, etc.; and
- Description of how an applicant/licensee fulfils the fundamental obligation to ensure nuclear safety, e.g. safety justifications and compliance with design standards.

II-6.4. Review points/specimen questions

(a) What organizational and administrative documentation or information is an applicant/licensee required to supply to the regulatory body before each stage of the licensing process? (e.g. organization functional descriptions, information on interfaces with other related organizations, organizational structure, support facilities, etc.)
(b) What safety documentation is an applicant/licensee required to supply to the regulatory body during the major stages of the licensing process?
(c) Does the required safety documentation include information on the management of spent fuel and radioactive waste? If so, what information is required at each stage?
(d) Does the required safety documentation include information on decommissioning? If so, what information is required at each stage?
(e) Has each applicant/licensee received any input in preparing and agreeing the documentation to be submitted and the programme for its submission?
(f) Have the regulatory body and each applicant/licensee agreed on the format, quality and standard of documentation to be presented?
(g) Does each applicant/licensee understand the requirements placed on it to produce documentation and is it capable of meeting these requirements? If documentation is produced by another body or organization, how is an applicant/licensee able to ensure its suitability?
(h) What auditing of applicant(s)/licensee(s) has the regulatory body carried out to determine the adequacy of any documentation being produced?
(i) Is an applicant/licensee required to have a quality assurance programme for all stages of the NPP life? How does the regulatory body ensure that this is adequate?
(j) How does the regulatory body obtain assurance that an applicant/licensee has established a satisfactory safety culture throughout its organization? How does it take into account, for all functions, the capabilities and limitations of human performance at all stages of the NPP life?
(k) What requirements are there on applicants/licensees for reporting on safety related matters? Is an applicant/licensee required to analyse and follow up safety related matters arising either at its own NPP or at other relevant installations elsewhere?

II-7. REVIEW AND ASSESSMENT DURING THE LICENSING PROCESS

240. It is the responsibility of the regulatory body to confirm that any proposed nuclear installation, at all stages of its life, presents no undue radiological risk to the site personnel, the public or the environment. To fulfil this requirement the regulatory body needs to acquire a complete understanding of the safety concepts, design and quality assurance programme of the installations, and the proposed operating principles of the applicant(s)/licensee(s). The regulatory body will also need to perform a thorough review of these issues to ensure that they comply with the regulatory body's own safety objectives.

241. Following suitable review, the regulatory body may require, modifications to be implemented where necessary.

242. The Member State may have established a legal procedure for reviewing licensing decisions at various levels. Notwithstanding this, the regulatory body needs to establish a system for reviewing, at the appropriate level, all of its licensing decisions.

II-7.1. Additional references

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Conduct of Regulatory Review and Assessment during the Licensing Process for Nuclear Power Plants: A Safety Guide, Safety Series No. 50-SG-G3, IAEA, Vienna (1980).
[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Commissioning Procedures for Nuclear Power Plants, A Safety Guide, Safety Series No. 50-SG-O4, IAEA, Vienna (1980).

II-7.2. Objectives

243. The regulatory body should establish and maintain a system to obtain, review and assess the safety documentation to support the proposals of an applicant/licensee to site, construct, commission, operate or decommission a nuclear installation. Proposals should be assessed for safety, technical feasibility, accuracy and compliance with legislation.

244. The regulatory body should establish a regime to ensure that review and assessment decisions are followed up by subsequent supervisory, inspection and enforcement activities to ensure that the decisions are implemented.

245. The regulatory body should establish an internal system for making licensing decisions. That system should not delay any urgent actions necessary to protect the site personnel, public or the environment from increased radiation risks.

II-7.3. Documentation

- Description of how, and on what basis, the regulatory body reviews and assesses licensing submissions (Note: review and assessment should be the bases for the regulatory body's decision making process and will be supplemented by subsequent supervisory, inspection and enforcement activities to ensure that these decisions are implemented);

- Description of how the plant safety case is used in judging modifications, the QA procedures and the applicants/licensees' operating procedures or technical specifications;
- Description of how the regulatory body can require corrective actions if it identifies deficiencies; and
- Description of how the legal system under which the regulatory body operates provides for the review of its decisions.

II-7.4. Review points/specimen questions

(a) Does the regulatory body carry out research and development to support its review and assessment programme? If not, who carries out such activities? Are the results also available to other organizations?

(b) Is there adequate funding for necessary safety research? Who provides the funding? Are the research results made openly available within the Member State and to other countries?

(c) Does the regulatory body carry out independent analyses (e.g. computer code calculations)?

(d) What programme of review and assessment is carried out by the regulatory body prior to the granting of a licence for the commencement of construction?

(e) What programme of review and assessment is carried out by the regulatory body during construction and commissioning of a nuclear facility?

(f) How does the regulatory body review submissions from the licensee for modifications during the operational phase of the plant? Does the regulatory body require periodic safety reviews during the operation of the plant? If so, what period of time is allowed between reviews?

(g) Has the regulatory body the right to use external consultants to assist it in its review and analysis of an applicant/licensee's submissions? Is it general practice to use external consultants?

(h) Does the regulatory body require probabilistic safety assessments? If so, who is responsible for carrying them out?

(i) How does the regulatory body monitor and review licensing decisions?

(j) Which bodies or organizations, if any, can call for the review of a licensing decision?

(k) What right of appeal does an applicant/licensee have against licensing decisions, and to whom is such an appeal addressed?

(l) What delay, if any, does an appeal cause in the implementation of a licensing decision?

II-8. REGULATORY INSPECTION AND ENFORCEMENT

246. The regulatory body should establish a regime for regulatory inspection and enforcement that complements its review and assessment activities. It needs to ensure that each applicant/licensee complies with national legislation and maintains the nuclear installation(s), throughout all stages of its life, in conformity with the design and safety procedures approved by the regulatory body.

247. A regulatory inspection regime needs to be established to satisfy the regulatory body that the licensee is fulfilling the conditions set out in the licence. The regulatory body will require correction of any non-compliances with the licence by application of the appropriate enforcement action(s).

II-8.1. Additional reference

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Inspection and Enforcement by the Regulatory Body for Nuclear Power Plants: A Safety Guide, Safety Series No. 50-SG-G4, IAEA, Vienna (1980).

II-8.2. Objectives

248. The regulatory body should establish a structured system for evaluating and systematically following up all inspection findings and an enforcement system to ensure that all aspects of legislation, including the licence, are fully complied with by each applicant/licensee, that this compliance is verifiable and that experience gained is fed back to the applicant/licensee.

249. The regulatory body should ensure that the responsible persons in an applicant/licensee's organizations are qualified to discharge their safety functions for all stages of the life of the nuclear installation(s).

250. The regulatory body should ensure that the required quality and performance are achieved by each applicant/licensee at all stages of the life of the nuclear installation(s).

251. The regulatory body should ensure that a licensee operates the installation within the envelope derived from the accepted operational safety analysis and complies with licence conditions. A licensee should correct any deficiencies without undue delay.

II-8.3. Documentation

- Description of how the regulatory body plans, carries out and documents its inspections;
- Description of the powers of enforcement available to the regulatory body, how much is delegated and to what level, and how this is used in practice; and
- Description of working relationship between site based and headquarters based regulatory body staff.

II-8.4. Review points/specimen questions

(a) What are the inspection functions of the regulatory body and how does it carry them out? What are the limits of the responsibilities of the regulatory body, e.g. are they limited to nuclear safety only or other aspects too?

(b) To what extent does the regulatory body make use of resident inspectors, designated site inspectors from headquarters, or other external inspection agencies, experts or consultants? Are these inspectors dedicated to one or more plants? How much time is spent at the plant?

(c) What types of inspection does the regulatory body conduct to verify that the licensee has adequately demonstrated that the installations complies with the design safety case at each of the stages of:

  (i) Preconstruction: does this cover site characteristics, production of codes/guides, etc., control of quality assurance and adequate record keeping?
  (ii) Construction: does this cover design, manufacture, and installation and testing of plant components?
  (iii) Pre-fuel-loading: does this cover initial receipt and storage of fuel, fuel loading activities, testing of fluid systems prior to criticality and initial criticality?
  (iv) Initial power raising;
  (v) Operation; and
  (vi) Decommissioning?

  Are there regulatory inspection programmes to which the inspector should adhere?

(d) Are special inspections (i.e. other than those in the routine programme) conducted as the result of a specific identified problem, concerns of the inspector, or a history of incidents or deficiencies?

(e) Do the same parts of the regulatory body conduct both the routine inspections and the special inspections? If not, identify the parts and explain the form the special inspections take.

(f) Does the regulatory body provide detailed written inspection procedures such as an inspection manual for use by the inspection staff? If not, how is guidance given?

(g) How do the regulatory inspectors prepare for inspections (such as by reviewing past reports, preparing detailed checklists, obtaining information from the licensee, etc.)?

(h) How do the regulatory inspectors check that all necessary licensee documentation exists, that the documentation complies with licence requirements, and that changes to the documents are properly controlled?

(i) To what extent does the regulatory body rely on the internal safety processes and arrangements of an applicant/licensee?

  - For each stage of plant life listed in (c), approximately what percentage of inspection time is spent in the direct observation of work activities in the plant? What is considered to be the relative importance of direct observation, as compared with the review of documentation?
  - What are the main objectives of interviews and consultations with the licensee's personnel? For each stage, how extensive are the interviews and consultations with the licensee's personnel, and how and by whom are they conducted?
  - Does the regulatory body, or do other organizations acting on its behalf, conduct physical tests and measurements as part of the inspection programme? If so, describe the types of tests conducted and specify the percentage of tests and measurements performed by the regulatory body, as compared with those made by the licensee.

- How does a regulatory inspector ensure that the tests and measurements conducted by a licensee are complete and accurate and comply with licence requirements?
- Does the regulatory body ever engage in the conduct of tests or measurements which require it to specify changes in the operational control of the plant or any of its major systems? If so, specify the conditions.
- What criteria do the inspectors apply to determine the number of samples to be selected for inspection in each inspection area? Is probabilistic analysis used in the selection?

(j) What are the form and content of the inspection reports prepared by the regulatory inspectors? To whom are the reports addressed, and to whom are they made available? How are unsatisfactory findings reported to a licensee and what responses are required?

(k) Describe the system used for storage, internal distribution and retrieval of specific information contained in the inspection reports.

(l) What kind of analysis is performed on regulatory inspection reports and by whom?

(m) Describe the basic arrangements and procedures for licensee reporting and classification of:

(i) abnormal occurrences,
(ii) accidents/emergencies, and
(iii) modifications to the plant.

The statement should describe how the regulatory inspection staff are made aware of the reports or requests, and should include any special requirements such as formal reporting and notification to third parties.

(n) What are the procedures for investigating accidents and for evaluating abnormal occurrences? To whom are the findings of such evaluations made available and in what way does the regulatory body make use of these findings?

(o) What legal powers of enforcement does the regulatory body have to ensure compliance with the licence or other regulations? What legal penalties apply?

(p) What methods of enforcement (e.g. warning letters, in order to curtail activities) are available to the regulatory body? Describe the basic criteria for each type of enforcement action.

(q) Describe the responses required and the periods of time normally allowed for licensee corrective actions with regard to written directives, warnings or notices of violations.

- What considerations are there in the regulatory body's decisions with regard to the times allowed for corrective actions? Are these dependent on the severity of the conditions or on the activities which require correction? If so, how?
- At levels in the regulatory body can decisions be made on the time allowed for corrective actions of various types? Who within the regulatory body has the authority to extend the allowed times?
- What regulations, if any, specify times for correction of specific deficient conditions or activities?

(r) Is the regulatory inspector ever empowered to take enforcement actions on the spot? If so, how and to what extent? Comments on actual experience would be useful. If the answer is no, describe the inspector's course of action to obtain an appropriate response from the regulatory body response to immediate safety concerns.

- In addition to requiring resolution of individual inspection report findings, does the regulatory body have a programme for evaluating all the findings at all plants to determine whether specific areas require more thorough regulatory inspection?

(s) Under what conditions does the regulatory body have the power to direct a plant to be shut down?

(t) Does the licensee have avenues of appeal against regulatory body decisions? If so, what are they and how are differences of views resolved?

(u) Does the regulatory body plan to adopt any new inspection methods in the near future? If so, what?

II-9. EMERGENCY PREPAREDNESS

252. Organizational practices in this area vary widely between countries. The role and responsibility of the regulatory body also vary to reflect the national situation. Any meaningful comparison with international standards will require an understanding of how the Member State organizes itself to cope with a nuclear emergency. The regulatory body should be involved but is generally only a part of this organization. Information on the national arrangements will be needed to enable the regulatory role to be put into context by the IRRT.

II-9.1. Additional reference

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Preparedness of Public Authorities for Emergencies at Nuclear Power Plants, A Safety Guide, Safety Series No. 50-SG-G6, IAEA, Vienna (1982).

II-9.2. Objectives

253. The regulatory body should have a role in the national arrangements for response to a nuclear emergency that is consistent with its expertise and authority, and should take part in appropriate emergency exercises.

254. The regulatory body should ensure that an adequate updated overall emergency plan exists and that emergency preparedness is maintained at each nuclear installation.

255. During an emergency situation the regulatory body should act in an advisory capacity to government and public authorities and should have the capacity to monitor the emergency as it progresses.

256. The regulatory body may act in an advisory capacity to government on the follow-up activities and should review the cause(s) of the emergency and the recovery actions taken by the licensee, and initiate appropriate regulatory actions.

II-9.3. Documentation

- Description of the national arrangements and organization for planning for and participating in the response to a nuclear emergency. The organizations and bodies involved should be identified, together with their responsibilities prior to and in the event of a nuclear emergency, and their points of contact; and
- Description of the regulatory body's role and responsibilities during the planning for or in the event of a nuclear emergency. If the regulatory body's response differs as part of a graded response to incidents of different scales, this should be highlighted.
- Description of how the regulatory body ensures that the overall emergency plan is updated and that emergency preparedness is maintained at each nuclear installation.

II-9.4. Review points/specimen questions

(a) What are the regulatory body's responsibilities for emergency planning?
(b) What role does the regulatory body have in relation to the national or state emergency plan?
(c) Does the regulatory body have its own emergency plan and how is it exercised?

(d) Does the regulatory body observe a licensee's emergency exercises?
(e) To what extent does the regulatory body participate in emergency exercises?
(f) How is the scenario for exercises determined?
(g) How frequent are the exercises of different levels and types observed by the regulatory body?
(h) What other bodies are involved in emergency planning? To what extent do they participate in exercises?
(i) What requirements does the regulatory body put on the licensee concerning emergency arrangements (training, exercises, hardware, etc.)?
(j) What information is supplied to the public on the emergency planning? Who is responsible for supplying this?
(k) What resources does the regulatory body have available for emergency preparedness purposes?

Part III
GUIDE TO DRAFTING TECHNICAL NOTES

III-1. INTRODUCTION

301. Writing the Technical Notes is one of the IRRT reviewer's most important tasks. The team members, having followed the IRRT Guidelines and supplementary guidance, will collect a vast amount of information that must be recorded. These facts, impressions and conclusions must be written clearly and concisely since, once the team leaves, all the regulatory body has to work from is the Technical Notes.

302. 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.

303. 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.

304. It should be emphasized that this Guide on drafting Technical Notes:

- is not intended to substitute for the IRRT guidelines and supplementary guidance; 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.

III-2. FORMAT

305. Each area of review should be designated by a number and a heading (bold and capitalized):

1. **GOVERNMENTAL ORGANIZATION AND NUCLEAR SAFETY LEGISLATION**
2. **ROLE AND RESPONSIBILITY OF THE REGULATORY BODY**
3. **ORGANIZATION OF THE REGULATORY BODY**
4. **REGULATIONS AND GUIDES**
5. **LICENSING PROCESS**
6. **REQUIREMENTS ON THE APPLICANTS/LICENSEES**
7. **REVIEW AND ASSESSMENT DURING THE LICENSING PROCESS**
8. **REGULATORY INSPECTION AND ENFORCEMENT**
9. **EMERGENCY PREPAREDNESS**

This should be followed by the name(s) (family name and initials of given names) of the reviewer(s). If there are several reviewers, their names should appear in alphabetical order, followed by the name(s) of observer(s) and marked as such, e.g.

Expert: J. Doe

or

Experts: J. Doe and A.N. Other (observer)

or

Experts: J. Doe and Q. Kingston-Recess and A.N. Other (observer).

306. 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.

307. The subareas should be designated by a two digit number and a bold subheading, e.g. in 2. ROLE AND RESPONSIBILITY OF THE REGULATORY BODY:

2.1. Legal status
2.2. Responsibilities
2.3. Functions

Further subdivisions, if necessary, should be structured under appropriate subheadings. The final structure for each subarea could be several paragraphs long, possibly together with recommendations, suggestions and good practices. These should be numbered and, if necessary, itemized.

308. For definitions of Recommendations, Suggestions and Good Practices, refer to Section I-5.5 of this document.

III-3. NUMBERING SYSTEM

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

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

311. A *'basis'* is a recapitulation of the concern giving 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).

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

313. 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 subarea 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 subarea number need not be included.

III-4. EXAMPLE OF LAYOUT

7. REVIEW AND ASSESSMENT DURING THE LICENSING PROCESS

Expert: J. Doe

- GENERAL IMPRESSION -

7.3. PROGRAMME FOR THE REVIEW AND ASSESSMENT

7.3.1. Schedule for the submission of documents

- DESCRIPTION -

7.3.1.1. Recommendations and suggestions

(1) BASIS - DETAIL OF BASIS -
(a) Recommendation: - DETAIL OF RECOMMENDATION (1)
(b) Recommendation: - DETAIL OF RECOMMENDATION (2)
(c) Suggestion: - DETAIL OF SUGGESTION.

(2) If there is another Basis and subsequent Recommendation(s) and/or Suggestion(s), etc.

Note: If a Good Practice is identified, then *7.3.1.2* would be inserted in a similar format; if no Good Practice is identified then the subclause would not be inserted.

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CONTRIBUTORS TO DRAFTING AND REVIEW

Addison, P. *(Scientific Secretary)*	International Atomic Energy Agency
Lequerica, I.	Consejo de Seguridad Nuclear, Spain
Reponen, H.	Centre for Radiation and Nuclear Safety, Finland
Taylor, M.	Atomic Energy Control Board, Canada
Wood, C.	Atomic Energy of Canada Ltd, Canada
Zuber, J.-F.	Federal Nuclear Safety Inspectorate, Switzerland

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