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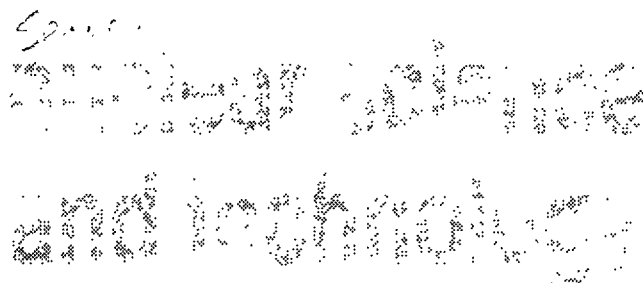
nuclear science and technology

Establishing an effective nuclear safety regulatory regime Part 1 — Objectives and requirements

Report

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European Commission



Establishing an effective nuclear safety regulatory regime

Part 1 — Objectives and requirements

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SUMMARY

The Report is concerned with the regulation of nuclear safety. This Document (Part 1 of the Report) draws upon experience in Western European countries, internationally recognised good practices in nuclear safety, and the Safety Fundamentals identified by the Nuclear Safety Standards Advisory Group (NUSSAG) of the International Atomic Energy Agency (IAEA). It examines the objectives of an effective nuclear safety regulatory regime, the requirements that it should meet, and the arrangements for their achievement. Developed by a Task Force of the Regulatory Assistance Management Group of the CEC, it is intended as a source of guidance to those at the senior governmental and regulatory level in countries operating nuclear power programmes, particularly where such arrangements are currently being introduced or strengthened.

The legislative and administrative provisions for implementing the regulatory process are examined. Criteria upon which an effective regulative regime should be based, including the clear separation of regulatory and operating responsibilities, are summarised. The concept of the 'regulatory organisation' is discussed and its terms of reference and responsibilities reviewed, together with the supportive arrangements necessary for it to carry out its licensing, assessment, inspection and enforcement activities effectively.

The functions of the regulatory organisation are reviewed, including the need to develop regulatory policy and guidance, establish rules, codes of practice and assessment criteria, and ensure the provision of adequate emergency response arrangements. Guidance is provided on its organisational structure and staffing, the provision of adequate resources needed for it to function effectively, and access to expert technical and nuclear safety policy advice.

The various stages in the licensing process, from initial design to completion of decommissioning, are examined. The concept of licensing and the purpose of the nuclear licence are discussed. Guidance is given on the attachment of conditions and constraints

to the licence in the interests of safety, and on additional controls that may need to be imposed from time to time for regulating the safe operation of an installation.

The role of regulatory assessment of the operator's safety submissions in the initial licensing process and throughout the life of a nuclear installation is reviewed. Assessment objectives and procedures are outlined, together with guidance on the information that should be provided to the regulatory organisation so that it can satisfy itself that its safety requirements have been met.

Inspection is an important element in verifying compliance with regulatory requirements, including licence conditions. Inspection arrangements, including the deployment of inspectors and the development of inspection programmes and guide-lines, are discussed. The duties of regulatory inspectors are reviewed, together with procedures for providing a graded response to any non-compliance of regulatory requirements, investigating safety related incidents, and implementing compliance and enforcement arrangements.

Provisions for maintaining regulatory effectiveness over the longer term are considered. The importance of establishing effective liaison arrangements between the regulatory organisation and other relevant bodies, including the operating organisation, the media and the public is emphasised. The need for a structured programme of on-going staff training, and for participation in the work of relevant international and inter-governmental organisations, is also stressed.

For completeness, the Report summarises the responsibilities of the operating organisation for complying with licensing requirements and meeting its operational safety commitments.

ESTABLISHING AN EFFECTIVE NUCLEAR SAFETY REGULATORY REGIME

PART 1 - OBJECTIVES AND REQUIREMENTS

FOREWORD

Recent years have seen an increasing emphasis at the inter-governmental and international level on identifying the nuclear safety objectives and principles that should provide the foundation of national arrangements for the safe regulation of nuclear installations. The importance of ensuring a legally based, independent, technically strong regulatory authority for the effective implementation of these safety arrangements has been internationally recognised. Within the framework of the programmes of the European Community (EC) for economic assistance to Central and Eastern European States (PHARE) and to the ex-USSR States (TACIS), priority has been assigned to assistance in nuclear safety. Support to nuclear safety authorities is a fundamental component of the assistance programme.

The technical framework for the implementation of the EC assistance in the field of nuclear safety regulation under the PHARE and TACIS programmes is the CONCERT Group. This Group consists of the nuclear safety authorities represented in the CEC Working Group on "Safety of Thermal Reactors: Methodology, Criteria, Codes and Standards" (EC Member States, Sweden and Finland) and representatives of those nuclear safety authorities of Central and Eastern European States and ex-USSR States that accepted the CEC's invitation to become Group members. In June 1991 the CONCERT Group initiated a programme of information exchange, supported by practical assistance, relating to the objectives, requirements and arrangements for establishing a national nuclear safety regulatory regime. The programme centred around the required legislative and administrative framework, the regulatory provisions, the safety related responsibilities, safety standards and licensing arrangements.

In recognition of the regulatory assistance needed (as identified by the CONCERT Group), Western European members established a Regulatory Assistance Management Group (RAMG) as an advisory group

to the CEC for the effective implementation of regulatory assistance programmes to regulatory authorities in Central and Eastern European States and the ex-USSR States, and to advise the Commission on any requests received for assistance from their regulatory organisations. The RAMG has proposed for its general method of work that any requests for assistance should be viewed against a deeper understanding of the requesting country's needs, and a knowledge of the country's legal bases, structures, state of development and methods of working. It has also established guide-lines for use in its exploratory missions for ascertaining such information.

A Task Force was appointed by the RAMG to develop guidance on the establishment of an effective nuclear safety regulatory regime. Part 1 of this guidance, dealing with fundamental objectives and requirements, is the subject of this Report. In developing its guidance, the Task Force has drawn upon the practical experience accumulated over several decades in the assurance of nuclear safety in Europe; it has also taken into account the safety objectives and supporting basic safety principles identified by the Nuclear Safety Standards Advisory Group (NUSSAG) established by the International Atomic Energy Agency.

The guidance provided in Part 1 is intended for those at the senior governmental and regulatory level in countries, including those in the former Soviet Union and Central and Eastern Europe, where arrangements for regulating nuclear safety are currently being introduced, revised or strengthened. It should also serve as a reference upon which RAMG members can draw when carrying out practical assistance missions. In addition, the Report should serve as a source of information for a wider, non-specialist audience, including those at the socio-political level and interested members of the general public, for furthering their understanding of how a nuclear regulatory regime should function.

It is planned to publish additional guidance being developed currently by the Task Force. This will complement the guidance provided in Part 1 by addressing the more practical arrangements that need to be established in order to provide for effective nuclear safety regulation.

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The following nuclear safety authority representatives participated in the work of the Task Force established by the Regulatory Assistance Management Group.

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1 INTRODUCTION

BACKGROUND

101. There is no such thing as absolute safety and no human activity, however beneficial, is entirely free from risk.¹ Normal socio-economic pressures dictate that the benefits received as a result of an industrial activity should outweigh the associated detriment, although the population group bearing the risk detriment resulting from a particular activity is not necessarily the same as that receiving the benefit. As with many industrial activities, installations within the nuclear fuel cycle may present a risk to plant workers, to those who live within the vicinity and, in exceptional circumstances, to society as a whole, if the process is not adequately controlled. Effective measures must, therefore, be implemented in accordance with established criteria to limit the potential for harm from all reasonably foreseeable circumstances that may arise during the routine operation of the plant or in the event of a plant accident.

102. Many first generation nuclear power plants and their supporting installations within the nuclear fuel cycle were designed and built some 30 or more years ago, employing techniques and materials that, in some cases, were relatively novel. Even so, the potential harm that could result from an accident was recognised and conservative designs incorporating best practices, and involving large safety margins, were employed. Since then, there has been a steady development in safety concepts and technology, with major advances and improvements in materials, control and instrumentation, testing and inspection techniques, and in computational methods. The more recently designed and built nuclear power plants have been able to benefit from these safety developments. Many older plant have also benefited through

¹For the purposes of this Report, 'risk' is defined as the probability of a specified harmful effect occurring within a specified period of time.

judicious modifications and upgrading of their safety provisions. Recent years have seen an increasing awareness of what the public expects in terms of safety, and the evolvement and application of a more formalised nuclear safety culture.

103. 'Nuclear safety' refers to the collective arrangements for the prevention of accidents and the limitation of their effects with respect to the design, construction, operation and decommissioning of nuclear installations. The objective of these arrangements is to ensure the protection of all persons, property and the environment against any hazards, disruption or damage as a result of the construction, operation and decommissioning of nuclear installations, including any plant malfunction or accident.²

104. 'Radiological safety' (more commonly referred to as 'radiological protection') is concerned with the protection of individuals, society as a whole, and the environment, from the harmful effects of exposure to ionising radiation, including exposures that may occur as the result of human activities.

105. Although the terms 'nuclear safety' and 'radiological safety' are sometimes considered to refer to separate safety related disciplines, there is an inherent link between the two concepts. Without the additional health risks posed by the presence of ionising radiation, the safety problems associated with the nuclear fuel cycle would differ little from those encountered in many conventional industrial processes. Safety assessment decisions would then be based solely upon the conventional risk posed by the plant and there would be no need for the assessment to be more stringent than for any other (non-nuclear) plant having similar potential chemical engineering hazards (e.g., structural failures, explosions, release of toxic materials, etc.).

²For the purposes of this report:
'operation' includes the maintenance of the installation;
'decommissioning' covers the activities within the period from final shut-down of the installation, through to its dismantling and release of the site for unrestricted use.

106. For the purposes of this Report, 'nuclear safety' is deemed to embrace the composite safety provisions for preventing or providing an effective defence against any potential radiological consequences that might result from the normal operation of the plant or in the event of a plant malfunction or accident.

107. Safe operation of a nuclear installation remains, at all times, the responsibility of the relevant operating organisation. It involves many factors, the more important of which include operating the plant within defined safety parameters, careful maintenance (including an effective programme of preventative maintenance), and implementing a scheduled programme of component inspections throughout the life of the plant. All of this should be supported by relevant research and development programmes, including those designed to monitor and predict any changes in material properties. Procedures for the safe operation of the plant should be fully documented and maintained. They should be supported by arrangements for recording and assessing the results of operational experience so that this can be drawn upon to effect further improvements in the overall safety of the plant and its operation. A comprehensive safety auditing and quality assurance programme should be implemented to ensure that these procedures and arrangements continue to be effective.

108. To provide for an effective control on safety in the development and use of nuclear power, countries with nuclear power programmes normally establish regimes for regulating their nuclear installations. The regulatory arrangements established in support of such regimes, and particularly those relating to safety assessment, licensing and inspection, generally reflect the guidance developed in these areas at the international level, including that published by the International Atomic Energy Agency (IAEA). It is the task of the nuclear regulator to ensure that nuclear safety is first assured through careful assessment of the initial design concept and intent, followed by stringent monitoring of the plant design, construction and commissioning, before licensed operation of the installation is permitted to commence. Through a concerted programme of assessment and inspection, this process of regulatory control continues throughout the life of an installation and until completion of

decommissioning. Thus, through the combined application of effective operator control and regulatory vigilance, safe operation should be established and maintained on both a year-by-year as well as a day-by-day basis.

PURPOSE AND SCOPE

109. The purpose of this Report is to provide guidance on the requirements that need to be satisfied in establishing and maintaining an effective nuclear safety regulatory regime. These requirements are aimed at achieving identified safety objectives, and are based upon the application of established safety principles and practical supporting criteria. The guidance draws on procedures and arrangements that have been developed and implemented by nuclear regulators within Western European countries. It also includes internationally recognised 'good practices' in the field of nuclear safety.

110. This document (Part 1 of the Report) sets out the nuclear safety objectives and supporting principles on which an effective nuclear safety regulatory regime should be based. It provides guidance on the supporting legislative requirements, the framework and operation of the regulatory organisation, and the provisions for licensing, safety assessment, inspection and regulatory enforcement. The organisational interface requirements essential for implementing the regulatory regime and ensuring that it functions effectively are reviewed, as are the provisions of the operating organisation for satisfying its regulatory obligations and maintaining an effective level of nuclear safety. Provisions for maintaining regulatory effectiveness are also reviewed.

111. To complement the guidance set out in Part 1, the more practical requirements to be taken into account when establishing and implementing the regulatory arrangements will be the subject of further parts to this Report. However, the Report, as a whole, is not intended to be a source of guidance on detailed safety arrangements, for which the reader is referred to the relevant subject areas within the IAEA Safety Series, and in particular, the NUSS Codes and Guides.

PRESENTATION

112. In presenting the Report, the Task Force recognises that the specific legislative and administrative provisions and supporting arrangements for establishing an effective nuclear regulatory regime can differ significantly between countries. In some countries, for example, responsibility for the different elements that make up the regulatory process, such as licensing, safety assessment, inspection and enforcement, has been vested within a single organisation. In others, the responsibility has been apportioned between several organisations. The particular arrangements adopted will tend to be dictated by established national practice. Those of one country should not be judged as being either more, or less, safety effective or advantageous just because they differ from those of another. The essential criterion is whether the arrangements adopted provide the basis for an effective regulatory regime to be achieved in practice.

113. For the purposes of this Report, the responsibilities for pre-licensing and operational safety assessment, licensing procedures, inspection, and the enforcement of regulatory arrangements, are considered to be carried out within a single organisation, referred to as the 'regulatory organisation'. This should allow the reader to concentrate upon the underlying principles for establishing and maintaining an effective nuclear safety regulatory regime, and how these might best be implemented within the constraints of his own particular national practices.

114. The operating organisation is the body responsible for the operation of a nuclear installation (see footnote 2). For the purposes of this Report, the operating organisation includes those organisations that carry out the functions of design, engineering and construction of the installation. When a licence is issued to the operating organisation authorising it to construct or operate a nuclear installation, the operating organisation also becomes the licensee. Thus, where the Report refers to licensed nuclear installations, the terms 'operating organisation' and 'licensee' are considered to be synonymous unless otherwise stated.

TERMINOLOGY

The terminology used in this Report is similar to that used in the IAEA Nuclear Safety Series. In particular, the reader is referred to the definitions provided in the Safety Standards - Codes on the Safety of Nuclear power plants - IAEA Safety Series No.50 (Rev.1).

2. NUCLEAR SAFETY OBJECTIVES

201. Nuclear installations should be sited, designed, constructed, commissioned, operated and decommissioned in accordance with strict requirements and regulations that have been developed to protect plant personnel, the public and the environment from harm. Any hazards arising from these activities should be strictly controlled. An effective nuclear safety regulatory regime should ensure that this objective is achieved.

FUNDAMENTAL OBJECTIVES

202. The safety objectives and supporting principles that, jointly, provide the foundations for such a regulatory regime, and upon which this Report is based, have been discussed at the national, international and intergovernmental level over a number of years (Refs.1, 2). The internationally agreed Basic Safety Objectives and their supporting Fundamental Safety Principles are summarised in the IAEA NUSSAG report "The Safety of Nuclear Installations - Safety Fundamentals" (Ref.3). These objectives and principles are concerned with limiting the risk to workers, and society as a whole, from the effects of exposure to ionising radiations, either as a direct consequence of workplace activities within the nuclear fuel cycle, or indirectly through the impact of such activities upon the environment. The three Basic Safety Objectives that an effective nuclear safety regulatory regime must meet are presented in this Section. The Fundamental Safety Principles that support these objectives, and that should provide the foundation for an effective nuclear safety regulatory regime, are summarised in Appendix 1.³

203. A number of the Fundamental Safety Principles have direct relevance to the regulatory organisation. They provide the basis

³To avoid confusion when defining the safety objectives and principles, the identical NUSSAG wording has been used.

for the generic guidance set out in this Report, which amplifies them and indicates how they can be applied in practice. Although national practices will determine how any particular country implements the guidance, no nuclear safety regulatory regime can be considered fully effective unless it can be demonstrated that all of the relevant Fundamental Safety Principles have been satisfied. The national regulatory arrangements should, therefore, be examined to ensure that, as a minimum, the requirements of the Basic Safety Objectives and of the relevant Fundamental Safety Principles will be met.

204. Those Fundamental Safety Principles considered to be of particular relevance to the guidance presented in each of the following Sections of this Report are identified at the beginning of the particular Section.

NUCLEAR SAFETY

205. The General Nuclear Safety Objective:

To protect individuals, society and the environment from harm by establishing and maintaining in nuclear installations effective defences against radiological hazards.

206. Individuals, society and the environment need to be protected from the harmful effects of exposure to ionising radiation resulting from the use of nuclear energy. The potential for exposure to ionising radiation, either directly due to its penetration through the containment, from direct contact with radioactive materials, or from the intake of radioactive materials into the body by ingestion or inhalation, is inherent in the majority of nuclear fuel cycle processes.

207. Compliance with the General Nuclear Safety Objective requires that nuclear installations are designed, constructed, commissioned, operated and eventually decommissioned in such a manner as to keep all potential sources of radiation exposure under strict technical and administrative control.

208. The General Nuclear Safety Objective is supported by two complementary safety objectives, one relating to radiological safety and the other to technical safety aspects. They are interdependent, in that the technical safety aspects, in conjunction with the administrative and procedural measures for their effective implementation, ensure the appropriate defence against hazards from ionising radiation.

RADIOLOGICAL SAFETY

209. The Radiological Safety Objective:

To ensure that in all operational states radiation exposure within the installation or due to any planned release of radioactive material from the installation is kept below prescribed limits and as low as reasonably achievable, and to ensure mitigation of the radiological consequences due to accidents.

210. The concepts for providing protection against the harmful effects of ionising radiation are now well established. At both the national and international level, legislation and guidance relating to radiological safety generally reflect the recommendations of the International Commission for Radiological Protection (ICRP) (Refs.4, 5).⁴ Its most recent recommendations on basic radiation protection principles are set out in ICRP Publication No.60 (Ref.6) and cover both normal and abnormal situations. The recommendations have been summarised by several organisations having national responsibility for radiological protection (e.g., Ref.7).

211. Where the source of radiation exposure is under control, ICRP recommends that the practice giving rise to the exposure must be justified, the protection must be optimised to ensure that exposures are as low as reasonably achievable (the ALARA concept), and the exposure of individuals should not exceed prescribed dose limits. When establishing radiological protection arrangements for workers at nuclear installations or the public, including dose limits, the relevant national authority should ensure that these arrangements will enable the ICRP recommendations to be satisfied.

⁴For example: Basic Safety Standards for Radiation Protection (1982 Edition); IAEA Safety Series No. 9, IAEA, Vienna (1982). Euratom Basic Safety Standards; Directives of the Commission of the European Communities, 1980-84. (These publications are currently under review to implement the ICRP 60 recommendations.)

212. At those installations where radioactive liquid and gaseous wastes resulting from the particular fuel cycle process may need to be discharged to the air or into local waterways, all such discharges should be justified and the requirements should be subject to formal assessment and authorisation by the relevant authorities and strictly controlled. The authorisation should ensure that radiological protection criteria will be met, taking into account the quantity and radionuclide content of the discharges, their movement and dilution along the environmental pathways, potential reconcentration and re-entry into the foodchain, and any abnormal dietary habits of the potentially exposed population. Any inter-governmental or international requirements relating to the discharge of radioactive wastes should also be taken into account.

213. An effective defence should also be maintained against the accidental release of radioactive materials. Where the source of radiation exposure is not under control - albeit temporarily - as in the event of a nuclear accident, ICRP recognises that it may only be possible to limit exposure by some form of intervention action, the nature, extent and timing of which will depend on the prevailing circumstances and, particularly, upon the potential hazard the situation poses to plant workers, the public and the environment. Formal emergency response plans should, therefore, be developed before a nuclear installation is commissioned or commences operation. These should encompass both the on-site and off-site arrangements for ensuring that remedial actions appropriate to the nature of the accident situation can be implemented within the requisite time to prevent or mitigate any possible adverse effects.

TECHNICAL SAFETY

214. The Technical Safety Objective:

To take all reasonably practicable measures to prevent accidents in nuclear installations and to mitigate their consequences should they occur; to ensure with a high level of confidence that, for all possible accidents taken into account in the design of the installation including those of very low probability, the radiological consequences, if any, would be minor and below prescribed limits; and to ensure that the likelihood of accidents with serious radiological consequences is extremely small.

215. In order to satisfy the Technical Safety Objective, not only must the conventional as well as the radiological hazards pertaining to the normal operation of a plant be taken into account when assessing the safety of installations operating within the nuclear fuel cycle, but also the potential consequences of their combined effect as the result of any plant malfunction or accident.

216. Thus, to meet the nuclear safety objectives as a whole, it is necessary both to limit the radiation exposure incurred as the result of normal operation, and to prevent, with a high degree of confidence, the likelihood of any plant malfunction or accident that could lead to a loss of control over the source of exposure. The design of the installation should incorporate conservative safety margins, backed by protection systems that limit, control or shut down operations if the operational safety boundaries are breached. Together with strict adherence to plant operating procedures, these arrangements should ensure that the probability of an uncontrolled release of radioactive material from the installation will be very low.

217. Despite these arrangements, the possibility of a plant failure or accident that might result in the release of radioactive material into the environment and the consequential exposure of plant personnel and the public, can never be entirely eliminated. The design safety assessment of the installation

should demonstrate that the potential radiological consequences of any accident, including those of low probability, is likely to be small. Never-the-less, emergency response arrangements should be established to mitigate the possible extent of any radiation exposures should an accident occur. It is essential for measures that may need to be implemented, both on and off the site, to mitigate such consequences be planned in advance, and in place and tested before the plant is allowed to operate.

3. LEGISLATIVE AND ADMINISTRATIVE FRAMEWORK

Relevant Fundamental Safety Principles: 1, 2, 3.

301. An effective level of nuclear safety cannot be achieved unless all organisations involved demonstrate a clear commitment to this objective, and it is supported at the national level by adequate legal provisions, implemented through an effective nuclear safety regulatory regime. Those countries that have implemented or intend to implement a nuclear power programme should ensure that effective legislative and administrative provisions are in place to provide for the safe regulation of the industry and for the clear assignment of safety related responsibilities. Responsibility for ensuring that the appropriate legislative framework is established, including any necessary supporting legislation and statutory provisions for implementing the regulatory process, will normally rest with national Government and Parliament. Guidance on the criteria that should govern the legislative and administrative provisions is provided in this Section.

NATIONAL ARRANGEMENTS

302. Although constitutional differences between countries may result in different approaches to the establishment of national regulatory arrangements, there are a number of basic criteria for ensuring effective regulatory control that should be common to all national provisions, as set out below.

303. **Identification of Responsibility:** The governmental department or organisation responsible at the national level for ensuring that the legislative and administrative provisions relating to the safe use of nuclear energy are properly implemented, including the establishment of an effective regulatory organisation, should be clearly identified.

304. **Separation of Responsibilities:** The nuclear regulatory responsibilities should be confined within a single, identifiable,

organisation, the regulatory organisation. This organisation should be effectively independent of any organisation having responsibility for the promotion or utilisation of nuclear energy, and should have separate reporting lines of responsibility to Government and/or Parliament.

305. There should also be a clear separation of responsibilities between the regulatory organisation and the operating organisation.

306. **Responsibility for Safety:** The legislative arrangements should assign the prime responsibility for the safety of a nuclear installation to the relevant operating organisation

307. **Regulatory Responsibility:** The objective of the regulatory organisation is the safety of nuclear installations. It should be assigned responsibility for the assessment, licensing and inspection of all nuclear installations within the nuclear fuel cycle and for enforcing the relevant regulatory arrangements. Hence, the regulatory and operating organisations are each responsible for different facets of nuclear safety within the overall national legislative framework.

308. **Regulatory Terms of Reference:** The scope of the authority and powers delegated to the regulatory organisation to enable it to fulfil its responsibilities should be prescribed within the legislative and administrative provisions and should form the basis of the organisation's terms of reference. These should clearly indicate to whom the regulatory organisation reports at the governmental / parliamentary level on matters of nuclear safety, and provide for direct and rapid access whenever the regulatory organisation considers this to be necessary in the interests of safety. The regulatory organisation should be precluded from undertaking any duties or responsibilities that might conflict with, or jeopardise, its responsibilities in relation to the safety of nuclear installations.

309. **Provision for Resources:** The legislative / administrative arrangements should include provisions for ensuring that the regulatory organisation has adequate resources, including

facilities, suitably qualified staff and appropriate funding arrangements, to enable it at all times to fulfil its statutory responsibilities in an effective manner.

310. Regulatory Enforcement Penalties: The prime objective of nuclear regulation is the enhancement of safety, rather than the punishment of regulatory violations. Where penalties are required for non-compliance with regulatory requirements, they should be real, effective and enforceable at law. Such penalties should be directed at the operating organisation, rather than individuals. However, the legislation should not preclude individuals who are guilty of severe misdemeanours, such as deliberate safety violations (as compared with human error faults), from prosecution.

311. Socio-Economic Factors: Should social, economic or other factors need to be balanced against any nuclear or radiological safety related decision (ie, where national considerations determine that these factors may need to override the safety requirements of the regulatory organisation), the final decision should only be made at the more senior political / governmental level.

312. Other Safety Related Legislation: When establishing the legislative and administrative framework for the safe regulation of nuclear energy, the relevance of any existing national safety related legislation should also be taken into consideration to ensure that there is no clash of interests in its application.

CONSULTATION

313. Consultation on Proposed New Installations: Any decision to site and operate a nuclear installation should be preceded by a structured consideration of its potential societal impact, and of the specific nuclear safety issues relating to both normal operation and the provision of emergency response arrangements. To ensure that these aspects are fully considered, the legislative and administrative arrangements adopted by some countries require the licence applicant to consult the relevant governmental

organisations and bodies having responsibilities for health, safety and environmental issues. These organisations and bodies should, in turn, consult with and advise the regulatory organisation on any relevant safety related concern they may have with regard to the proposed installation, so that this may be taken into consideration when the regulatory organisation formally advises on whether the proposed installation should be licensed. This requirement to provide safety related advice to the regulatory organisation should extend throughout the life of the installation and its decommissioning.

314. Consultation and Statement on Environmental Impact: Both national requirements and international commitments may require the licence applicant or the relevant governmental organisation to consult, and to provide an assessment and formal statement, on the potential environmental impact from the operation and decommissioning of the proposed installation, including the generation, management and disposal of any radioactive waste. Although the consultative provisions discussed above should enable some of these issues to be resolved, those responsible at the governmental level for deciding whether to grant permission for the siting of the installation are likely to have to take into account a broader range of public, political, economic, technical and other specialist opinions, before making a formal decision.

315. Public Inquiries: In the majority of industrial countries there is a significant level of public concern with regard to the safety of nuclear installations. Any new construction proposal is likely to generate considerable critical response, particularly if the proposed site is in proximity to an area of high population density, or if the area is considered to be of significant amenity or environmental importance. In some countries, the initial consultative process enables the proposals to be considered more openly through the forum of a public inquiry. Depending upon the particular national practice, this arrangement may be an integral part of the normal consultative process, or only implemented in response to a formal request by concerned parties.

316. Summaries of the legislative and administrative arrangements relating to the regulation of nuclear energy in OECD Member countries are given in Refs.8, 9 and 10. A detailed study of the legislation adopted by one country (Sweden) is given in Ref.11.

4. THE REGULATORY ORGANISATION

Relevant Fundamental Safety Principles: 1, 3, 4, 6, 8.

401. The regulatory organisation is the body responsible within the national legislative and administrative framework for the licensing and inspection of nuclear installations, and for the enforcement of the regulatory requirements. Its primary duty is the implementation of an effective regulatory regime for the safe siting, design, construction, commissioning, operation, maintenance and decommissioning of nuclear installations within the national boundaries. The regulatory organisation should be established in accordance with the criteria set out in Section 3, and particularly paras. 303-310. It should be structured and organised so as to provide the essential elements for ensuring effective regulatory control. The criteria upon which an effective regulatory regime should be based are summarised in paras. 402-409 below. Guidance on the general arrangements for their implementation is given in the remainder of this Section.

RESPONSIBILITIES AND REQUIREMENTS

402. **Establishment of the Regulatory Organisation:** To the extent possible, the regulatory organisation should be established in advance of the construction of the first nuclear installation. The size of the regulatory organisation and the level of resources allocated to it should, at all times, take into account the size, structure, organisation and potential development of the national nuclear programme.

403. **Regulatory Responsibility:** Within the legislative and administrative framework established by national government for the regulation of nuclear safety, the regulatory organisation should have responsibilities for the licensing process. In support of this function it should implement effective arrangements for the assessment of safety analysis submissions and for the inspection of nuclear installations in pursuance of regulatory compliance and enforcement. No other responsibilities

should be permitted to jeopardise or conflict with the regulatory organisation's responsibility for the regulation of nuclear safety.

404. Regulatory Independence: It is a paramount prerequisite that the regulatory organisation is effectively independent of those organisations or bodies concerned with the promotion of nuclear activities. The control of the activities of the regulatory organisation by government and parliament should be clearly defined, together with the inter-relationships with other relevant governmental and national organisations. Although the regulatory organisation may be part of the governmental structure, it should be functionally independent so that its decisions may be taken without undue pressure. This arrangement provides for the essential public credibility of the regulator. Furthermore, the regulatory organisation should not be required to assume other responsibilities in addition to matters of nuclear safety interest, as this may significantly diminish its authority and effectiveness.

405. Authority for Nuclear Safety: The statutory authority vested in the regulatory organisation should be clearly defined, as should the extent to which such authority is devolved to its professional regulatory staff. The regulatory organisation has considerable discretionary authority delegated to it in matters of nuclear safety and is responsible for ensuring that its functions are carried out in an effective and credible manner.

406. No other regulatory organisation should be able to override the authority of the nuclear regulatory organisation in relation to nuclear safety.

407. Professional Competence: The regulatory organisation should be responsible for maintaining a high level of professional competence, commensurate with its safety assurance role. It should ensure that it has sufficient numbers of adequately qualified, trained and experienced regulatory staff, preferably with a background in the nuclear or other relevant industry. They should have a clear understanding of the organisation's regulatory role and objectives, and how these are expected to be met in

practice. They should also have a clear understanding of the legal criteria and authority upon which their activities are based, the discretionary powers delegated to them, and how these should govern their assessment, licensing, inspection, and enforcement activities. To broaden its approach in its regulation of nuclear safety, the regulatory organisation should establish arrangements for effective liaison with other relevant national institutions and regulatory authorities, nuclear regulatory authorities in other countries, and with relevant international and inter-governmental organisations.

408. Public Accountability: It is essential for the regulatory organisation to establish and maintain public confidence in the effectiveness of the nuclear safety regulatory regime and in its supporting provisions for ensuring the protection of individuals, society and the environment. To this end, the regulatory organisation should adopt a policy of public accountability, setting out its regulatory objectives, policies, and standards (including the criteria against which it assesses the safety of licence applications), and the effectiveness with which they are implemented. This should be done in such a way that the responsibilities of the regulatory organisation, and the manner in which they are met, can be readily understood by a non-specialist audience. The regulatory organisation should also ensure that its regulatory decisions, and the background against which they are taken, are properly documented. The reasoning in support of major policy decisions, including those relating to the granting of nuclear site licences, should be explained and made available to all organisations or persons who may have an interest, including members of the public.

REGULATORY FUNCTIONS

409. Although the size, structure and responsibilities of the regulatory organisation may differ between countries, depending upon the particular legislative and administrative provisions adopted, there are a number of regulatory functions that should be common to any effective nuclear regulatory regime. A number of these functions are concerned with carrying out the regulatory

organisation's statutory responsibilities; additional functions provide for the establishment of the necessary support arrangements. The following paragraphs cover the need for policy guidance, definitions of safety requirements, and the establishment of emergency response arrangements. Guidance on the implementation of the licensing, assessment, inspection, compliance and enforcement functions is provided separately in Sections 5, 6, 7 and 8, respectively.

410. Policy and Guidance: Within the overall framework of licensing it will be necessary to develop regulatory policy, together with guidance on its implementation, for a number of specific subject areas, including:

- statutory requirements governing the granting of nuclear site licences, including the specification of licence conditions with which operators must comply;
- siting policies for proposed new installations;
- criteria for application in the safety assessment and licensing process;
- radioactive waste management strategy;
- liaison with other national and international organisations;

The diversity of the tasks within this area will demand a range of professional skills and experience covering technical, legal and administrative disciplines.

411. Defining Safety Requirements: The regulatory organisation should be responsible for defining the safety requirements with which the operating organisation must comply. It should establish assessment procedures and monitoring arrangements, including on-site inspections, to verify that the operating organisation is meeting its regulatory commitments and that its policies are aimed at maintaining high levels of safety. These safety levels should

be subject to appropriate checks, controls and on-going reassessment by the regulatory organisation.

412. Developing Rules, Codes and Guidance: To enable the operating organisation to identify its regulatory commitments, and to provide a basis upon which to assess the operator's regulatory and safety related response, the regulatory organisation should establish appropriate safety objectives and assessment criteria. To ensure that these objectives and criteria can be properly interpreted and effectively implemented, they should be supported through the development of rules, codes of practice, procedures and guidance. As an input to this development, the regulatory organisation should take into account appropriate national standards, as well as relevant international standards (e.g., Refs.12, 13), together with recognised good nuclear safety practices, particularly those relating to similar types of plant and equipment. In approving the application of such rules, codes of practice or guidance, the regulatory organisation should exercise care that their adoption is not construed as relieving the operating organisation of its safety responsibilities.

413. Establishing Emergency Response Arrangements: The regulatory organisation should require the operating organisation/licensee to make suitable arrangements for responding to abnormal and accident situations (Ref.14). These should include the provision of site accident management procedures and supporting arrangements for regaining control of the plant and returning it to a safe condition, and for implementing remedial actions aimed at terminating any release of radioactive material and mitigating its on-site and off-site consequences. Arrangements for the introduction of off-site measures for the protection of the public should normally rest with the public authorities, at both the local and national level (Ref.15).

414. Developing Emergency Response Plans: Emergency response plans for mitigating the radiological risk to the public should be developed in advance by the relevant authorities, including the regulatory organisation, and should be coordinated with those of the operating organisation to ensure an effective integrated response. All organisations and persons who may be required to

respond in accordance with the plan in the event of an accident should be made aware of their responsibilities and of the actions they should take. Those members of the public who may be affected by the response should also be aware of the arrangements that have been made for their protection. The plans should in place before the installation is commissioned and should be regularly tested by appropriate exercises throughout its lifetime (Ref.16, 17).

ORGANISATIONAL ARRANGEMENTS

415. The structure of the regulatory organisation should provide for clear lines of control, responsibility and reporting, with effective coordination and well defined interface arrangements, both internally and with the operating organisation.

416. **Size of the Regulatory Organisation:** The actual size and structure of the regulatory organisation, and the regulatory approach adopted, will tend to be dictated by, inter alia, the particular constitutional and legal framework of the country, the specific responsibilities assigned to the organisation, the size of the nuclear power programme, the number of utilities, and the extent to which sub-contracting arrangements are used.

417. In the early stages of a nuclear power programme the limited number of installations and of suitably qualified staff may place constraints on the size of the regulatory organisation. However, as the number of installations increases, the size and subdivisions within the functional areas should be reviewed and expanded accordingly.

418. **Structure of the Regulatory Organisation:** The structure of the regulatory organisation in a country with a highly centralised governmental system may differ significantly from one in a federal system. In a federal system, each constituent state or county may wish to develop and implement its own state law, in addition to the federal law and legislative arrangements. The regulation of nuclear safety and of nuclear installations under a federal system may require the extensive direct involvement of regulators, inspectors or assessors located in several agencies or

governmental organisations, including those in the particular state or county within which the specific nuclear installation is to be located. Similarly, a regulatory organisation that is incorporated as part of a larger governmental organisation, and upon whose facilities and services it is expected to draw support for some of its less specialised functions (such as the provision of legal advice, administrative support, etc.), or for its budget, will differ from that of a more autonomous organisation.

419. The regulatory organisational arrangements applying in a number of OECD Member countries are reviewed in Refs. 18 - 22.

420. **Provision of Resources:** The legislative arrangements should provide for sufficient resources to be made available to establish and maintain an efficient, competent and independent regulatory organisation. It is important that the level of resources made available enable the regulatory organisation to carry out its duties, particularly with regard to site inspection, without having to rely upon the services or draw upon the resources of the operating organisation.

421. Adequate provisions for financing the regulatory organisation should be made, for example, through fees levied on the operators of nuclear installations. To carry out its work, the regulatory organisation should have available:

- sufficient and suitably qualified staff;
- adequately equipped office accommodation in suitably located buildings (Headquarters, Regional or Site-based) that will allow regulatory staff to carry out their duties effectively;
- effective communication arrangements (telephone, facsimile, telex, radio-telephone, computer links, transport, etc.);
- adequate technical and administrative support (including secretarial services, computer access, personal computers, calculators, word-processing facilities, document reproduction and storage, photographic, video and audio

recording, access to technical information, library facilities, etc.).

422. **Staffing Arrangements:** The regulatory organisation should ensure that all functions required of its staff can be adequately performed and directed, and that it is able to act independently of all bodies or organisations over which it has, or may have, regulatory responsibility. It should also ensure that the expert resources available to the organisation are focused on the statutory tasks to be accomplished and that the duties of all staff are clearly defined and documented.

423. **Establishing Staffing Policy:** The regulatory organisation should establish a staffing policy based on a graded structure of professional and technical expertise and commensurate at all times with the size of the regulatory programme. The policy should indicate the required numbers of professional, technical and support staff, and the functions to which they will be assigned (e.g., assessment, inspection, preparation of regulations and guides, legal matters, administrative support, etc.). The need to provide for Headquarters, regional and resident site inspection should also be taken into account. The staff structure should provide avenues for promotion between the grades; the responsibilities of each grade should be clearly defined, as should the job description, terms of reference, required qualifications and experience for each individual post.

424. The professional competence of regulatory staff should also be kept under review. They should participate, as appropriate, in on-going programmes of training aimed at maintaining an adequate level of regulatory expertise, and in keeping abreast of national and international developments in the field of nuclear safety.

425. **Staff Remuneration:** To provide for mutual respect and a professional dialogue between regulators and licensees, regulatory staff should not only be suitably experienced, qualified and trained, but their level of reward, including financial remuneration, should not compare unfavourably with that received by staff at a similar level of responsibility in the operating organisation. Without such provisions, the regulatory

organisation is unlikely to be able to attract the high calibre staff essential for effectively implementing its regulatory responsibilities or to retain those with experience, a factor that will be of increasing importance as the organisation increases in size.

426. Provision of Expert Safety Advice: Although the regulatory organisation should have the sole responsibility for recommending whether an installation may be licensed, and for implementing the regulatory arrangements, this should not preclude it from seeking external expert advice on nuclear safety issues. The governmental organisation to which the regulatory organisation reports, together with other relevant national organisations, may also require access to such advice. Where specific analyses or assessments require specialist skills that are not available within the regulatory organisation, provision should be made for drawing upon specialist advice, either through the services of suitably qualified external consultants or by establishing appropriate advisory committees.

427. Advisory Committees: The composition of any particular advisory committee will be dictated by its purpose and the level of advice (in terms of its relative importance to major safety issues) that the committee is expected to provide. The essential criteria are that members, which may include foreign experts, should be chosen for the particular expertise that they will be able to contribute; that all disciplines essential for the provision of sound, equitable and discerning advice are represented; and that there is a minimum number of members who are independent of the regulatory and the operating organisations. Advisory committees should not have regulatory or enforcement powers; rather, their role should be confined to the provision of expert and unbiased policy advice.

428. Technical Advisory Committees: Technical advisory committees may need to be established to provide in-depth advice on a range of technical and fundamental safety issues, such as the plant operating procedures being proposed by the operating organisation, pressure vessel integrity, radioactive waste management, computerised plant control, etc. Depending upon the type of

advice being sought and the time span over which it is required, such committees may need to be appointed on either a permanent or ad hoc advisory basis.

429. **Senior Advisory Committee:** Where a committee is established to provide high level advice both to the regulatory organisation and to government on the broader issues relating to national nuclear safety policy (such as changes to nuclear law, national energy arrangements, etc.), the members should be appointed by the governmental body or minister to whom the committee will report. Committee members should be able to make their views known, independent of their organisation. Although it is not normal practice for the regulatory organisation to be a member of such a committee, arrangements should be made for it to maintain a close liaison with the committee, for example, by having a senior regulatory staff member attend meetings on an observer basis. Senior advisory committees are normally established on a long-term, rather than ad hoc basis; however, membership will change with time and will need to reflect current nuclear safety philosophy.

430. Examples of the provision of expert safety advice are given in Refs. 19, 20, 21 and 22.

5. LICENSING

Relevant Fundamental Safety Principles: 16, 25.

501. It is normal practice for the control over nuclear installations and, therefore, over nuclear safety, to be implemented through the application of a licensing system. The licence is usually granted only to a legally constituted operating organisation (the Licensee) and represents the formal authorisation for the construction or operation of the installation to proceed. National practice will dictate whether licences relating to nuclear installations are issued by the regulatory organisation or by some other responsible national body. In the latter case, a licence should only be issued on the safety advice of the regulatory organisation. In either case, the practice in most countries is for the regulatory organisation to be responsible for ensuring that the licensing process and the operation of any licensed nuclear installation is in compliance with any relevant statutory requirements. Its assessment and inspection functions support this process.

NUCLEAR LICENCE

502. **Purpose:** Although each country may have its own particular definition of the term 'nuclear licence', it can be generally described as the authorisation issued by the regulatory organisation to the operating organisation (the licensee) to carry out specific activities in relation a nuclear installation. The licence may have conditions attached to it in the interests of safety (see para. 508).⁵ The essential purpose of the nuclear licence, and of any conditions that it may impose in the interest of safety, is, inter alia, to:

⁵For the purposes of this Report, the term 'licence' refers to the licence and its attached conditions.

- authorise the operating organisation (the licensee) to carry out a specified activity or set of activities associated with the siting, design, construction, commissioning, operation or decommissioning of a nuclear installation;
- stipulate any requirements and conditions of the regulatory organisation that govern the performance of these activities; and
- place any appropriate time restrictions on the validity of the authorisation.

503. **Content:** The organisation responsible for licensing should ensure that any nuclear licence that it issues:

- complies with the relevant national legislation;
- accurately specifies the activities to be licensed and the place where they are to be carried out;
- clearly indicates any constraints regarding the activities to be licensed (e.g., specific requirements, conditions or time limitations).

504. A licence comprises a formal authorisation for the activities of the particular installation for which it is issued, a description / identification of the site at which it will be located, and a concise statement of the type and purpose of the installation. Additional documents may be attached to the licence as required.

LICENSING PROCESS

505. **Licensing Stages:** The licensing process covers the different stages in the regulatory control of a nuclear installation. The guidance provided in this Report is based on the assumption that a single licence (including any attached conditions) will be issued for the installation, prior to the commencement of construction.

However, it is also possible to issue separate licences at various stages of the process. Irrespective of whether responsibility for the licensing of nuclear installations rests with the regulatory organisation or with a separate licensing body, the licensing process, from the initial design concept through to the final decommissioning and deregulation of the installation, can be broadly divided into the following stages:

- assessing the safety analyses and safety report submitted by the operating organisation in support of its application for the initial licensing of a particular installation, and determining whether or not the application should be approved;
- preparing the licence and identifying any specific conditions with which the licensee will need to comply in the interests of safety;
- issuing the licence to enable construction of the installation to proceed, together with any conditions with which the licensee must comply;
- assessing any additional or up-dated safety reports that the operating organisation may be required to submit at successive stages in the construction, commissioning and initial operation of the installation, and determining whether permission should be given to proceed to the next stage;
- updating the licence and its associated conditions, as appropriate, to reflect the regulatory requirements;
- suspending activities under the licence should the regulatory organisation consider this to be necessary in the interests of safety;
- updating the licence or the imposed conditions to take account of any modifications to the installation or of any additional safety information that becomes available;

- modifying the licence and the imposed conditions on completion of operation of the installation to ensure that the plant is maintained in a safe state, or to enable decommissioning to take place; and
- revoking the licence on completion of satisfactory decommissioning of the installation.

506. To complete the licensing process it is also necessary to:

- monitor the licensee to ensure compliance with the licence and with the imposed conditions;
- implement any necessary enforcement actions against non-compliance with the licence or the imposed conditions;

507. **Operator's Arrangements:** There should also be sufficient flexibility within the overall licensing framework to enable the operating organisation to propose the arrangements best suited to its particular operations, provided that they will meet any requirements imposed under the licence and any other safety requirements of the regulatory body.

LICENCE CONDITIONS

508. **Objectives:** In support of the licensing and regulatory process, the regulatory arrangements should provide for conditions and constraints to be imposed on the licensee in the interests of safety at any stage in the siting, design, construction, commissioning, operation, maintenance and eventual decommissioning of the particular installation for which a licence has been granted. Their objective should be to ensure that all reasonably practicable steps are taken by the licensee to protect workers on the site, members of the public and the environment from any risk arising from the operation of the installation. National arrangements will determine whether these conditions and constraints should be incorporated as an integral part of the licence, attached as an addendum to it, or issued as a separate regulatory requirement in support of the licensing or regulatory

function. However, for convenience, and for the purposes of this report, they are considered as being attached to the formal nuclear licence and will be referred to, generically, as 'licence conditions'.

509. The licence conditions will govern the manner in which the installation may be operated and should be so worded as to allow the detailed level of compliance required by the licensing body or the regulatory organisation to reflect, and be appropriate to, the current stage of construction, commissioning, operation or decommissioning of the installation, as appropriate.

510. **Key Safety Related Conditions:** Although the manner in which the licence conditions are prescribed, and their extent and detail, is a matter for individual regulatory organisations, the conditions should address the key areas relating to the safety of the plant, including:

- plant construction, commissioning and operation;
- plant operating limits;
- operating rules and procedures;
- testing and maintenance procedures;
- modification procedures;
- operation and control of the plant by competent persons;
- radiological protection;
- radioactive waste management;
- quality assurance;
- nuclear safety committees;
- safety documentation, including a Safety Report;

- reporting of incidents;
- arrangements for dealing with accidents or emergencies;
- staff training; and
- arrangements for reviewing and up-dating operating procedures and safety related documentation.

511. **Separation of Licence Conditions:** The formal licence to construct or operate a nuclear installation (see paras. 502-504) is likely to require fewer changes during the lifetime of the installation than the conditions attached to it, many of which may be of a technical nature and subject to periodic up-dating. Separating the conditions in the form of an attachment or appendage to the licence, rather than as an integral part of it, can prove an advantage, particularly where the procedures for approving proposed changes to the formal licence are likely to be more lengthy and taken at a higher level than those relating to changes in the licence conditions. In general, the more extensive and detailed the licence conditions, the greater the advantage in separating them from the formal licence.

512. **Several Installations on a Single Site:** Where several nuclear installations are located on a single site, there may be a further advantage in licensing the site as a whole, rather than on the basis of individual installations. This may simplify the overall licensing arrangements by, for example, enabling those activities that may be common to all installations on the site (such as radiological protection and emergency response arrangements) to be treated as an entity. Conditions that are specific to individual installations on the site, such as plant operating rules, can be grouped separately within the licence for application to the particular installation to which they apply. Alternatively, there may be situations where separate licences are preferable, so that different conditions can be applied to each individual plant. In such cases, care must be taken to ensure that plant that is common to the installation as a whole can be adequately controlled.

MAINTAINING EFFECTIVE LICENSING ARRANGEMENTS

513. **Revision or Modification of Licence Conditions:** The achievement of a high level of nuclear safety must continue to be a live issue throughout all stages in the life of a nuclear installation. In support of this, the regulatory arrangements should provide for the licence conditions to be revised or modified as circumstances and safety related experience dictate, and as the results of technological progress or of nuclear safety research and development become available. Any such revisions or modifications, including those that may be requested by the licensee, should always be subject to the formal agreement of the regulatory organisation. By incorporating provisions into the licensing arrangements for amending, adding or revoking the licence and/or conditions at any time that it considers necessary in the interests of safety, the regulatory organisation should be able to maintain a flexible but rigorous control over a licensee's safety related activities.

514. **Provision for Controls:** Provision may need to be made for exercising other forms of control in regulating for the safe operation of an installation. In particular:

(i) **Agreement to Carry Out a Safety Related Activity:**

Where a particular safety related activity is not already subject to licence conditions, a licensee may need to be precluded from carrying out the activity until he has satisfied the regulatory organisation that it is safe to do so and has received its formal agreement that the activity may proceed.

(ii) **Submission for Approval of Proposed Arrangements:**

Where issues of particular safety significance are involved, the regulatory organisation may require the licensee to submit in writing, and for its formal approval, his proposed arrangements for meeting the relevant condition of the licence, or carrying out the relevant activity. Following such approval, the licensee would be precluded from changing the arrangements or procedures without a resubmission to the regulatory organisation.

(iii) **Instruction to Take Safety Related Action:**

The regulatory organisation may consider it necessary to intervene where matters of particular safety concern are identified, and to instruct the licensee to implement appropriate remedial measures. Any such intervention should be based on an assessment of the seriousness of the identified situation and of the urgency for remedial action. For example:

Urgent Safety Related Actions: Where an identified situation is considered to pose an immediate safety risk and require urgent remedial action, the licensee should be instructed forthwith to take the appropriate measures for returning the installation to a safe state. This may include shutting down the plant and maintaining it in a safe condition until the regulatory organisation is satisfied that it is safe to restart, and has given its formal consent to the licensee.

Non-Urgent Safety Related Actions: Where a situation is identified that, although not posing an immediate risk to safety, does require remedial action to be taken without undue delay, the licensee should be instructed to implement the agreed remedial measures within a time scale that reflects the seriousness of the situation.

Long-Term Safety Related Requirements: Where problems are identified that, although not of immediate safety importance, may have significance in the longer term (for example, progressive embrittlement of pressure circuit welds), the regulatory organisation should place a formal requirement on the licensee to submit proposals for remedying the situation within a specified time (eg, all remedial work to be completed within 2 years). The proposed time scale should be commensurate with the seriousness of the problem, the need to complete any rectification work before it can pose a significant risk to the safety of the installation, and the extent of the work involved.

(iv) **Ensuring Qualified and Experienced Plant Operators:** The regulatory organisation should require the operating organisation to ensure that, where safety related requirements dictate, specific tasks are only carried out by operators having specific qualifications and experience.

PRESCRIPTIVE AND NON-PRESCRIPTIVE ARRANGEMENTS

515. **Prescriptive Regulation:** In the prescriptive approach to the regulation of nuclear safety, the regulatory organisation specifies all of the safety related requirements that a licensee must meet, usually in the form of detailed statutory regulations and supportive provisions. Although, compared with a non-prescriptive regime, a highly prescriptive approach to regulation may simplify the regulatory inspection process and be less demanding in terms of the qualifications and experience required of its regulatory inspection staff, it can also prove counter-productive. For example, because it places the emphasis upon detailed written regulations and provisions to cover all aspects of safety, the result may be to reduce the effective dialogue between those responsible for regulatory inspection and the licensee. It may also limit a licensee's flexibility to meet the statutory requirements placed upon him in the most efficient and effective manner, thereby resulting in significant additional operating costs. Similarly, the licensee may be deterred from seeking additional safety benefits, in that having fully complied with a specific safety related regulation, he may have no further legal obligation to attempt an even greater improvement in the level of safety, even though it may have been practicable to achieve, and would have been a requirement, had the concept of ALARA been applied.

516. It should also be recognised that the more prescriptive the regulatory approach, the greater the effort that will be needed by the regulatory organisation to define and disseminate unambiguous requirements that will not become the subject of interpretation and confusion for the licensee. Moreover, the development of a highly prescriptive approach can place a heavy demand on regulatory resources. It is likely to be more cost/resource

effective, therefore, when applied in a country that is planning or operating a relatively large nuclear power programme, where there is likely to be a correspondingly large regulatory staff, and where the regulations can be applied generically to a majority of the installations to be licensed.

517. **Non-Prescriptive Regulation:** In contrast to the prescriptive approach of specifying in detail what a licensee should do in every particular circumstance, the licence conditions can be used to define areas where special attention will need to be paid in the interests of safety. Adopting this approach allows a licensee to develop his own arrangements, depending upon, and specific to, the particular circumstances of his operations. Thus, although he remains responsible for the initiation and application of detailed safety standards and safe procedures for his installation, he is able to exercise his responsibility for safety without being unduly constrained by specifically prescribed requirements. The licence conditions, whether issued as an integral part of the licence or as supportive safety related requirements, can, therefore, be used to provide a basis for overall safety control of the installation in relation to its potential impact upon workers on the site, the public, and the environment.

518. In either the prescriptive or the non-prescriptive approach to licensing, any safety related conditions issued in support of the nuclear licence do not, per se, ensure safety, nor do they relieve the licensee of his responsibility for safety, including the safety of his plant.

519. Further guidance on nuclear licences and on the manner in which safety related conditions are issued in support of the licensing and regulation of nuclear installations are given in Refs.18, 20 and 23.

6. ASSESSMENT

Relevant Fundamental Safety Principles: 5, 7, 9, 10, 11, 12, 13,
15, 16, 22, 23, 24, 25.

601. Safety assessment in relation to the licensing and regulatory control of nuclear installations encompasses the systematic critical examination of the safety analysis carried out by the operating organisation and of the Safety Report submitted in support of the licence application. This safety case should apply to those structures, systems and components that have a bearing either directly or indirectly on the safety of the installation. It should cover the various ways they might fail to operate as designed, or their integrity might be affected, and the resultant consequences. The purpose of safety assessment is to identify any underlying design or operational weaknesses.

602. Before a licence is granted for the construction or operation of a nuclear installation, the regulatory organisation will need to assess the acceptability of the licence applicant's written formal proposals, using either its own assessment staff or its nominated external consultants specialising in particular fields of technology. It needs to be satisfied that at all stages throughout the life of the proposed installation, and during its decommissioning, the safety criteria of the regulatory organisation will be met, that the installation will not present an unacceptable risk to persons on the site or to the public, and that it will not result in an unacceptable environmental impact.

REGULATORY ASSESSMENT RESPONSIBILITIES

603. **Commencement of Assessment:** The more detailed procedures for licensing a nuclear installation will vary from country to country. However, good practice dictates that the review and assessment of the site characteristics and of the design of the installation, together with the collection and collation of siting and environmental data, should be commenced well in advance of the date upon which the licence is required to come into force.

604. **Assessment Areas:** The general area of safety assessment can be sub-divided to cover both generic and site-specific tasks relating to:

- the safety assessment of new installations;
- periodic reassessment of the safety case;
- plant modifications at existing installations;
- assessment of plant operating and maintenance proposals;
- the safety assessment of ageing plant;
- the decommissioning safety case; and
- assessment and periodic reassessment of the emergency response arrangements.

605. **Assessment Arrangements:** In practice, and particularly in the case of a large assessment programme, the arrangements for carrying out assessments tend to be dealt with on a discipline oriented basis, with further sub-divisions covering, for example, fault analysis, seismology, thermal hydraulics, reactor physics, electrical engineering, mechanical engineering (including pressure vessel design), civil and construction engineering, chemical engineering, instrumentation and control engineering, radiological protection, human factors, and quality assurance. This, in turn, will require those working in these various sub-divisions to have adequate in-depth experience and specialist knowledge of the particular discipline to which their assessment work relates.

606. When carrying out a safety assessment for a particular installation, and to guard against incompatibilities occurring across plant interfaces, the results of the different analyses and their related findings should be assessed to ensure that, together, they present a fully integrated system of safety at the plant level. The results of all reviews, analyses and assessments should be documented in detail to facilitate independent audit of the scope, depth and conclusions of the examination.

ASSESSMENT PROCEDURE

607. **Design Assessment:** The regulatory organisation should carry out a thorough assessment of the licence applicant's submissions to determine whether the siting proposals, design of the installation and the proposed operating limits and procedures meet the regulatory organisation's safety objectives and criteria. To do so it will need to acquire a thorough understanding of the design of the installation and the manner in which the plant, as an entity, is expected to behave, particularly in relation to:

- the underlying safety concepts upon which it is based;
- the quality assurance provisions that will support the installation throughout its design, construction, commissioning, operation and eventual decommissioning;
- the operating principles and control parameters proposed by the licence applicant.
- the provisions made for the minimisation, safe handling, accumulation, discharge or disposal of any radioactive wastes arising throughout the life of the installation, or as a result of its decommissioning.

608. **Design Assessment Procedure:** The design assessment procedure should proceed from a broad-based survey of the installation as a whole, to a more detailed review of individual plant units and an in-depth assessment of how individual systems, structures and components will perform under normal operation, anticipated operational occurrences and accident conditions. It should be ascertained that the design is based on proven technologies (including those proven by experiment) and that it incorporates the principle of 'defence in depth', with the release of radioactive material being restrained by several levels of protection and multiple barriers. Emphasis should be placed on those items of particular relevance to maintaining safety during normal operation and anticipated operational occurrences, and on regaining safe plant conditions following an accident, taking into account the capabilities and limitations of human performance.

The proposed radioactive waste management arrangements should also be considered, including the need to meet any international commitments in relation to discharges or disposal.

609. **Provision of Relevant Information:** To support its assessment process, the regulatory organisation should establish and maintain a system for obtaining from a licence applicant all documentation, including safety reports, that it considers necessary for assessing the safety, technical feasibility, accuracy and compliance with any statutory requirements, of the applicants proposals. Through a systematic and rigorous process of examination, supported where appropriate by independent design checks, by analytical methods and calculations, and by inspections, the regulatory organisation should satisfy itself that its requirements have been met, and in particular, that:

- the licence applicant has provided all the information that the regulatory assessors or their consultants deem necessary for carrying out their review and assessment;
- the information presented in the reports is accurate and complies with the requirements of any applicable rules and regulations;
- the engineering solutions proposed, and particularly any novel solutions, are feasible in the light of current technology, and capable of achieving the design safety objectives.

610. Where the regulatory organisation considers that a submission does not fully satisfy its safety objectives, the licence applicant should be required to either rework its safety justification, or make appropriate modifications, and re-submit the proposals for further assessment.

611. **Impact on Licence Conditions:** Following the regulatory organisation's initial design safety analysis and assessment, the first formal licensing action may well be its approval of the design safety concept and the issue of a construction licence. Proceeding to subsequent stages in the construction, commissioning

and initial operation of the installation may be subject to relevant upgradings or changes to the nuclear licence, or to the safety related conditions with which the licensee must comply. These may be required in order that any revised state of the plant or results of more detailed and up-dated plant safety assessments can be taken into account.

612. Assessment Throughout Installation Lifetime: In addition to the initial review and assessment of a licence applicant's proposals, the regulatory organisation should develop a systematic programme of review and assessment appropriate to, and applicable at each stage in the development and life of an installation, from design and construction, through to final decommissioning. As part of this programme, the regulatory organisation should establish a schedule for the formal submission by the licence applicant/licensee of supporting documentation (including relevant safety analyses and up-dated Safety Reports) at each stage in the licensing of the installation.

613. Assessment Prior to Resumption of Operation: The regulatory organisation should also establish formal arrangements (including specifying the supporting safety documentation to be submitted by the licensee) for assessing whether an installation may be permitted to resume normal operation following a major plant shut-down, such as that due to annual maintenance, plant modification, core reloading, etc.

614. Quality Assurance: Where appropriate, during the construction or any modification of the plant, the licensee should be required to conduct quality assurance audits of its manufacturers, suppliers and sub-contractors to verify and provide evidence to the regulatory organisation of their qualification for nuclear related work. The prime purpose of these arrangements is to ensure that the quality and performance required by the regulatory organisation are achieved by the licensee at all stages in the life of the nuclear installation. In this respect, they should complement the regulatory organisation's own review and assessment of the licensee's activities.

615. Further guidance on assessment, and examples of assessment arrangements, are given in Refs. 19, 20, 24, 25, 26 and 27.

7. INSPECTION

Relevant Fundamental Safety Principles: 1, 3, 16.

701. Inspection is the means by which the regulatory organisation satisfies itself that a licensee is complying with the licence conditions, and with any criteria relating to the safe operation of the plant as set out in the licensee's safety submission, including the formal Safety Report. Effective inspection arrangements should provide for the systematic verification of plant and operational safety, the identification of any failure to meet regulatory requirements, and the initiation of appropriate enforcement action against the licensee to remedy the situation.

INSPECTION ARRANGEMENTS

702. **Organisation:** For any particular country, the manner in which activities within the inspection area are organised will depend, largely, upon the size of the nuclear programme, the geographical location of the nuclear installations and any inspection and enforcement procedures already established for non-nuclear plant. Task-related sub-divisions within the functional area of inspection will tend to be dictated by the size of the nuclear power programme and the range of installations to be licensed. Where, at any one time, the regulatory organisation is responsible for the inspection of installations under construction, in operation, and being decommissioned, there may also be an advantage in further sub-dividing on this basis. Any sub-division should aim at making the best use of the specialist expertise available within the regulatory organisation. However, it is essential for the regulatory organisation to maintain a consistent approach when implementing its inspection arrangements; care should be exercised, therefore, that this is not jeopardised by any sub-division of these arrangements or of inspection duties.

703. **'Regional' and 'Resident' Inspection:** When establishing its inspection arrangements, the regulatory organisation will need to decide whether inspectors should be centrally based, (eg, at the

regulatory organisation's headquarters), or whether the distances, geographical locations, or national sub-divisions (eg, into states, counties, etc.) dictate the establishment of regional inspection groups. Any requirement for "resident" inspectors at particular installations or groups of installations must also be determined. Decisions relating to these requirements should take into account specific circumstances, established national practice and the inherent advantages and disadvantages of the different inspection arrangements. The provision of adequate communication arrangements between the regulatory organisation's headquarters and its inspectors is of paramount importance. Moreover, for those inspectors who are based at regional offices or at particular installations, it is essential that effective links with the headquarters organisation for the provision of technical support are maintained on a permanent basis.

704. Where the regulatory arrangements require an inspector to act as a focal point for any discussion between the regulatory organisation and the licensee, the inspector should ensure that he is kept aware of all regulatory inspection activities relating to the installation, including any necessary inspection of manufacturers, suppliers and sub-contractors.

705. **Inspection Programme:** The regulatory organisation should establish arrangements for the formal inspection of all licensed nuclear installations by suitably qualified and trained inspectors and for the enforcement of any licence conditions or regulatory requirements with which the licensee must comply. In support of these arrangements, it should develop a programme to assure itself that:

- all nuclear installations are constructed and operated in conformity with the designs and safety procedures approved by the regulatory organisation;
- all of an installation's safety related structures, components and systems are of the required quality;
- those who will operate the installation are competent to do so in a safe manner;

- the installation is operated within the limits agreed with the regulatory organisation and in accordance with the conditions specified in the licence;
- any deficiencies that may be of safety significance are corrected by the licensee without undue delay and notified to the regulatory organisation; and
- any necessary enforcement action is, primarily, directed at the licensee as a corporate organisation.

706. **Types of Inspection Visits:** The programme of inspection should include both announced and unannounced inspection visits. It should continue throughout all stages of the licensing process, from the commencement of construction to completion of decommissioning. There should also be built-in allowances for reactive inspections in response to particular situations such as post-maintenance start-up and plant incidents. When determining a specific plant inspection programme the operational experience of the particular plant should be taken into consideration. Although the depth of attention paid to any specific item should be determined by its relative importance to safety, it should be recognised that there is not necessarily any sharp dividing line between safety and non-safety related equipment and processes.

707. **Frequency of Inspection:** The time scale over which a complete cycle of regulatory inspections aimed at assessing compliance with licence conditions is carried out should be as short as is reasonably practicable. The actual frequency of inspection for any particular type of installation should be determined by the policy of the regulatory organisation and the resources available to it. The frequency of routine inspections accorded any particular plant item or procedure should reflect its relevant safety significance. Compliance with key safety parameters, such as plant operating limits, should be verified at each inspection visit and include the inspection of relevant operating records.

708. **Access to Site:** It is essential that designated inspectors have freedom of access to all plant, equipment, documentation

(including drawings, operating logs, radiological protection records, etc.) and personnel on the licensed site. The licensee and his staff must be aware of the need to meet these requirements. Never-the-less, the regulatory organisation should recognise that the licensee's management, particularly at plant level, is the primary channel through which it should acquire formal information. An inspector should use his regulatory powers with discretion; unnecessary interference with plant operations or the work of plant staff should be avoided. Except when the urgent pursuance of his regulatory duties makes it impracticable, an inspector should be required to comply at all times with any site safety rules and requirements.

709. Inspection Guidelines: To ensure that the programmed inspections are carried out in a systematic and consistent manner, the regulatory organisation should develop inspection guide-lines. These should be aimed at assessing the current safety status of the plant and the manner in which it is being operated, identifying any matters of safety significance (including the potential for any impact upon plant workers, the public or the environment) and gauging the effectiveness with which the licensee manages the safety of his plant. The guide-lines should provide sufficient flexibility for inspectors to take the initiative in identifying and addressing any new matters of concern as they arise.

710. Post-Inspection Actions: Informal discussions on plant conditions held during the course of an inspection visit should be summarised in a formal discussion between the inspector and an appropriate representative of the licensee's plant management before completion of the visit. Following an inspection, and as part of its regulatory inspection arrangements the regulatory organisation should:

- establish a structured procedure for the evaluation and systematic follow-up of all inspection findings, both normal and those indicating any non-compliance with licence conditions;

- formalise the results of each inspection as soon as practicable after its completion by means of a protocol, letter or report, with copies, as appropriate, to the licensee;
- evaluate and, where appropriate, assess the inspection report, identifying any underlying causes and generic issues for subsequent follow-up action;
- ensure that the relevant information is fed back to the licensee without delay for the initiation of any necessary corrective measures; and
- arrange for inspection and assessment staff associated with various installations or projects to meet periodically to exchange views and discuss the findings and issues raised in their reports.

THE NUCLEAR INSTALLATION INSPECTOR

711. **Regulatory Inspectors:** The role of the regulatory inspector demands a high level of technical expertise and in-depth experience relating to a range of subject areas. It also demands a high level of personal integrity, coupled with the ability to discuss technical and safety related issues with senior plant management on a basis of professional mutual respect.

712. **Use of Designated Regulatory Inspectors:** Depending upon national arrangements, inspection may be carried out by a pool of regulatory staff, or by designating particular inspectors to be responsible for one or more specific installations, or by some combination of these arrangements. Where resources permit, it is generally more effective, from a regulatory viewpoint, to have one or more designated inspectors responsible for each particular installation. This not only enables the designated inspector to acquire an in-depth knowledge of the installation for which he is responsible, but also to establish the necessary rapport with management and staff that will enable him to determine whether it is being managed and operated in a safety conscious manner.

713. **Independence of the Regulatory Inspector:** Whatever the inspection arrangements, it is essential that regulatory staff, and particularly those allocated to inspection, maintain their independence by adopting a professional detachment with regard to plant performance and operational problems when carrying out their duties. This independence by the regulatory organisation must be recognisable at all times. There should be no significant reliance upon the operating organisation/licensee to provide the facilities or services necessary for the effective conduct of an inspector's work. Never-the-less, to enable the regulatory inspection functions to be carried out in an effective and efficient manner, to the extent possible and consistent with good inspection practice, there should be close co-operation with the licensee.

714. **Rotation of Inspector's Duties:** To ensure that an inspector's professional detachment is not jeopardised, and to enable him to broaden his experience, there should be a limit on the time that an inspector is assigned to any particular installation, preferably not more than a few years. To the extent practicable, the experience of regulatory staff should be broadened by rotating their duties between inspection and other regulatory functions, including those carried out at the regulatory organisation's headquarters. Where an inspector has been recruited from the operating organisation or a licensee, it is preferable that he should not be given immediate inspection responsibility for any installation at which he has recently been employed, and in any case, not until he has completed his induction training and sufficiently assimilated regulatory practices to enable him to effectively maintain his independence.

715. **Staffing:** In principle, the extent of any national nuclear regulatory inspection programme should be dictated by the need to verify that nuclear installations continue to be operated in a safe manner. Sufficient staff should, therefore, be assigned by the regulatory organisation to inspection duties to ensure that the on-going inspection programme can not only be maintained, but that there will be a sufficient margin for dealing with any contingencies that may arise. Should the regulatory organisation decide to utilise the services of consultants to assist with its

inspection programme, it should recognise that their use does not diminish its own responsibility.

716. Resident Inspectors: Where 'resident' inspectors are attached to installations, the regulatory organisation should ensure that they do not become isolated, preferably by allocating more than one inspector to an installation to provide for mutual support. All inspection staff, including resident inspectors, should participate in reviews and audits at installations other than those to which they are normally assigned, in order to strengthen their inspection capability and broaden their regulatory perspective.

717. Local Inspection Office: In those cases where inspectors are resident at a nuclear installation there may be a major benefit in establishing a local office for their exclusive use, where reasoned discussion and decision making can take place in an environment away from the day to day site pressures. The office should be located outside the boundary of the relevant site, preferably within a convenient distance for ready access to the site. It should be adequately equipped with modern communications facilities, including telephone, facsimile and computer terminal links with the regulatory organisation's headquarters.

718. Maintaining Effective Inspection Arrangements: It is essential that inspection staff have a broadly based, comprehensive understanding of the safety issues underlying the policy and decisions of the regulatory organisation. To this end, arrangements should be made for them to have regular contact with the regulatory headquarters safety assessment staff in a working environment away from the day to day site pressures. This is especially important for inspectors who are resident at a particular site, or attached to a regional office. They should also have access to specialists, either within the regulatory organisation or outside consultants, who can provide in-depth advice in particular areas of technology. In some cases, specialists may also need to participate with the inspector in the on-site inspection and in the subsequent evaluation of inspection findings. All of these considerations and requirements will need

to be taken into account when establishing the regulatory inspection arrangements.

719. Further guidance on inspection, and examples of inspection arrangements, is given in Refs.18, 19, 20 and 28.

8. REGULATORY COMPLIANCE AND ENFORCEMENT

Relevant Fundamental Safety Principles: 3, 21.

801. Responsibility for the reporting of any non-compliance with regulatory requirements rests, in the first instance, with the licensee. Enforcement is the legal action initiated by the regulatory organisation against the licensee with the intention of correcting and, as appropriate, penalising non-compliance with the regulatory requirements. The legislative arrangements referred to in Section 3 should provide for adequate powers to effectively enforce the licence conditions and to require the licensee to carry out any other actions that the regulatory organisation considers necessary in the interests of safety. These provisions should be in addition to the dynamic system of licence controls for enabling the licence conditions to be revised or modified as circumstances and safety experience dictate, as discussed in Section 5.

COMPLIANCE AND ENFORCEMENT ARRANGEMENTS

802. **Responsibility for Reporting Safety Violations:** It should be a legal responsibility for the licensee to report to the regulatory organisation, in accordance with pre-established procedures and arrangements, safety related incidents, non-compliance with licence conditions, or other breaches of regulatory requirements of which he is aware. The licensee should also be responsible for taking prompt and appropriate action to remedy the situation and return the installation to a safe state. Such action should be initiated without waiting for any formal directive from the regulatory organisation. However, the licensee remains responsible for implementing any further measures the regulatory organisation may consider necessary in the interests of safety.

803. **Establishing Response Procedures:** To ensure that safety violations or breaches of licence conditions can be dealt with effectively and with minimum delay, the regulatory organisation

should establish criteria and internal procedures for responding to identified deficiencies in plant operations, safety documentation or safety management. These procedures should include identification of the supervisory level at which formal regulatory response should be initiated with the licensee, and the range and nature of the enforcement actions that may be applied, especially those involving curtailment of activities, plant shut-down, monetary fines, or other punitive actions, in the event of non-compliance.

804. The response by the regulator should normally proceed from discussions with plant management or written requests for explanations, through succeeding stages such as directives, restrictions on operations or amendment of licence conditions, culminating as a final resort in legal action, suspension of operation and financial penalties. Commensurate with the safety importance of the identified deficiency, the objective should be to achieve mutual agreement, at the lowest possible authoritative level, on the action to be taken to remedy the situation.

805. **Graded Enforcement Action:** The severity of the enforcement action taken by the regulatory organisation should be so graded as to reflect the safety significance of the particular breach of licence conditions, or the failure to meet particular regulatory requirements, and should take into account the licensee's previous safety record. The enforcement action may include placing appropriate constraints upon the licensee, for example, by limiting or restricting particular plant operations or by making effective use of the regulatory organisation's powers for authorising the restart of the plant following shut-down.

806. **Initiation of Legal Action:** In the event of any safety violation, the regulatory authority will need to decide whether to instigate legal proceedings against the licensee, including prosecution through the courts. The nature and extent of any legal action taken will depend upon the seriousness of the violation and on the particular national legislative provisions. These provisions should enable a licensee to be prosecuted through the courts in response to any deliberate and significant breach of licence conditions, operating rules, operating safety limits, or

non-compliance with regulatory requirements. In general, any penalty imposed by the court should be directed at the licensee / operating organisation as a body, rather than at individuals within the organisation, except when such individuals are guilty of deliberate and major misdemeanours or criminal actions. It should be recognised that the need to take legal action, irrespective of any penalty imposed, indicates a failure in the pursuance of an effective nuclear safety policy. However, the penalty does not, in itself, resolve the root cause of the failure. This must be examined separately and positive measures implemented to ensure that there will be no recurrence.

807. Authority of the Regulatory Inspector: It is important that the degree of authority vested in the regulatory inspector be fully understood, both by the regulator and the licensee. Some countries have found it an advantage to provide the inspector with the authority to direct a licensee to take immediate corrective actions (including curtailment of the particular activity should this be considered necessary) if, in the inspector's judgement, there is imminent and significant risk to the health and safety of persons on the site or of the public, or to the environment. Other countries require such enforcement decisions to be taken at a more senior level within the regulatory organisation. In this latter case, the promptness with which the relevant information is received, and the regulatory response is determined and transmitted to the licensee, should reflect the urgency of the situation and enable actions to be implemented in adequate time to prevent any further significant deterioration in safety.

RESPONDING TO SAFETY RELATED INCIDENTS

808. Incident Spectrum: Safety analyses and operating experience indicate that there is a continuous spectrum of safety related incidents that may occur at nuclear installations. This can range from minor events or abnormal occurrences that have no direct influence on the safety of the plant, nor present any significant radiological hazard to site personnel or the public, to serious accidents that involve the release of radioactive materials to the environment. As with breaches of regulatory requirements, the

response required of the licensee should be graded to reflect the degree of severity of the particular incident, as should the reporting and recording arrangements that the licensee is required to make.

809. Response of the Regulatory Organisation: The response of the regulatory organisation should also reflect the seriousness of the incident. If it is of a more minor nature, the incident may only come to the attention of the regulatory organisation during a site inspection visit; provided the licensee has already taken appropriate remedial action and rectified the situation, no further action may be necessary. Where the situation has not been rectified, the regulatory inspector should bring it to the attention of the site management without delay and, if possible, the remedial action and time-table for its implementation should be agreed. In the case of more serious incidents, the regulatory organisation may need to issue instructions, or even direct the licensee, to take immediate remedial action, which may include suspending operation. In the extreme case of an accident involving, or having the potential for, the release of radioactive materials, it may be necessary to implement the emergency response arrangements.

810. Investigation by the Regulatory Organisation: The regulatory organisation should also determine at what level of incident it needs to carry out a detailed investigation. Should an investigation be considered necessary, the regulatory organisation will need to decide whether it is sufficient for this to be done by a single inspector or if the seriousness and extent of the consequences of the incident are such that a broader based investigation is more appropriate. The analysis of the incident, and of the consequences of any remedial actions proposed by the licensee, may also require regulatory assessment effort. In the extreme, the conclusions of the regulatory organisation may be that legal action should be taken against the licensee. Examples of response actions by the regulatory organisation and the licensee to different incident levels are given in the following paragraphs.

IMPLEMENTING COMPLIANCE AND ENFORCEMENT ARRANGEMENTS

811. **Significant Safety Related Incidents:** During the life of a nuclear installation, safety related incidents may occur that, in the judgement of the regulatory organisation, could result in a significant hazard to persons on the site, to the public, or to the environment. Their occurrence may be brought to the attention of the regulatory organisation as the result of inspection of the installation, or by the licensee or other person. Where such breaches of safety are identified in the course of inspection, the inspector should immediately bring the matter to the attention of the site manager (as the most senior representative of the licensee) and report the situation to the regulatory organisation headquarters.

812. Should time permit, the regulatory organisation should issue a written warning to the licensee, specifying the nature and regulatory basis of the alleged breach and, if appropriate remedial action has not already been implemented, directing the licensee to do so, specifying the period within which the action must be completed. If the seriousness of the incident demands a more urgent response, the regulatory organisation, either directly through its headquarters organisation, or through the inspector, should immediately direct the licensee to curtail the relevant activities associated with the occurrence and ensure that the plant is put into a safe state.

813. A similar approach should apply where an occurrence is drawn to the attention of the regulatory organisation, other than as the result of inspection. In this case, there may be an urgent need to send regulatory staff, including the responsible inspector, to the installation in order to appraise the situation and determine any necessary remedial measures, before specifying further safety related actions to be taken by the licensee.

814. **Return to Normal Operation:** With the plant in a safe condition, the licensee should submit the remedial measures it proposes to implement, and the time scale for their completion, to the regulatory organisation for its agreement. Following its assessment and agreement to the proposals, the regulatory

organisation should stipulate the conditions to be satisfied before the installation will be permitted to return to normal operation. Should the regulatory organisation consider it appropriate to provide guidance to the licensee on the nature of the remedial action it would wish to see undertaken, it must make it clear that the adoption of such guidance does not in any way diminish the responsibility of the licensee for any remedial action taken or for the safe operation of his installation.

815. Notification to Cease Operation: In the case of a serious plant accident, particularly if it results in, or could have resulted in, a significant uncontrolled release of radioactive material into the environment, the regulatory organisation should decide whether, in the interests of safety, the licensee should be directed to permanently cease operation. A similar approach should be considered in response to persistent serious breaches of licence conditions. When notifying the licensee of any such decision, it should be made clear that the operating organisation will continue to retain full responsibility for the safety of the installation, including any consequences of its radiological impact upon site personnel, the public and the environment, until the installation has been safely dismantled and decommissioned, and the regulatory authority has revoked the licence.

816. Maintaining Adequate Records: Formal records of all significant safety related incidents and accidents should be maintained by the regulatory organisation, together with any directives issued to the licensee, and any response or remedial actions taken. The licensee should also be required to maintain appropriate records. Where the seriousness of any incident or accident may result in legal proceedings being taken against the licensee by the regulatory organisation, the recording of actions related to their instigation should be separate from those relating to the reinstatement of plant safety. Should the consequences of a major plant incident or accident result in subsequent compensation claims from those who consider they have been harmed or have suffered financial loss, including members of the public, the availability of detailed and accurate records relating to the occurrence will be of particular importance.

817. Further guidance on compliance and enforcement arrangements, is given in Refs.8, 9, 18 and 28.

9. REGULATORY LIAISON

901. Although the prime responsibility for the monitoring and enforcement of nuclear safety rests with the regulatory organisation, if it is to carry out its duties effectively it will need to maintain a close liaison with other relevant governmental organisations, national advisory bodies, and the operating organisation/licensee. It should also keep abreast of nuclear safety developments world-wide by establishing effective links with relevant international and inter-governmental organisations. The main liaison requirements are considered in this Section.

LIAISON WITH GOVERNMENTAL ORGANISATIONS

902. In most countries, national responsibilities for environmental protection, occupational and public health and safety, safe transport, agriculture and foodstuffs, water resources, electrical power supplies, civil protection, etc. are located within specific governmental organisations. A number of these will have responsibilities at national, regional and local levels that relate directly or indirectly to nuclear safety matters; for example, radiological protection, pressure vessel integrity, emergency services, planning and control of land utilisation, transport of hazardous materials, etc. To ensure that the particular responsibilities, legislative requirements and advice of these governmental organisations are taken into account in the overall nuclear safety arrangements, it is essential that an effective liaison is established and maintained between them and the regulatory organisation.

903. The liaison arrangements should be established at an early stage in the planning of the first nuclear installation and should continue in force, as appropriate, until all installations have been successfully decommissioned. In practice, they should facilitate cooperation between the regulatory organisation and other concerned governmental organisations at the national, regional and local levels. Any relevant responsibilities of these organisations, including those of a statutory nature, should be

taken into account by the regulatory organisation when assessing the licensee's proposals for the safe operation of his installation. In particular, this should cover their role and responsibilities in responding to an accident, including the provision of emergency services and the introduction of remedial measures for the protection of the public in the event of a release of radioactive materials into the environment.

904. Examples of liaison between the regulatory organisation and other governmental organisations are given in Refs.18, 19, 20, 21 and 22.

LIAISON WITH THE OPERATING ORGANISATION

905. During all stages of the licensing process, from the initial pre-licensing discussions through to completion of decommissioning and final de-licensing of the installation, a close liaison between the regulatory and operating organisations is an essential element in the safe regulation of a nuclear installation. At the preliminary stage of the licensing process the operating organisation should provide the regulatory organisation with all relevant information (including that obtained from the design, engineering, and other support organisations) upon which to base a decision as to whether or not the proposed installation can be licensed (see Section 6). Similarly, for each stage in the licensing process, the operating organisation (which will include, where appropriate, the licensee) should be aware of the regulatory requirements that will have to be satisfied before permission is granted to proceed to the next stage. This exchange of information, and hence the regulatory process itself, is enhanced when the regulatory authority and the operating organisation are able to interact in an atmosphere of mutual confidence and respect.

906. The regulatory organisation should ensure that arrangements for providing an effective liaison between the two organisations, both at the headquarters and plant level, are jointly developed and in place at the earliest possible stage. Without diminishing the independence of the two organisations or detracting from their

responsibilities, these arrangements should provide for both formal and informal channels of communication at appropriate levels of seniority within their respective headquarters and site organisational structures, throughout the installation lifetime.

907. During the licensing period, and particularly the initial stages, there should be frequent contacts between the regulatory and operational organisation (and, where appropriate, the supporting organisations contracted to the operating organisation) in order to develop a mutual in-depth understanding of each others working arrangements and the most effective way of meeting the regulatory requirements. Regular meetings between senior members of the operating organisation/licensee and of the regulatory organisation should be held across the life of the installation to consider plant safety status issues, including those identified in the course of inspections. The operating organisation should be encouraged to regard the regulatory organisation as a valued source of constructive criticism and technical guidance. This can best be achieved by the regulatory organisation demonstrating consistently high standards in its assessment of safety and the development of nuclear regulatory criteria.

908. Examples of liaison between the regulatory organisation and the operating organisation/licensee are given in Refs.19, 20, 21 and 22.

LIAISON WITH EXPERT SAFETY ADVISERS

909. As part of the arrangements for the provision of expert safety advice, as discussed in Section 4, a formal liaison should be established with the relevant advisory committees at an appropriately senior level within the regulatory organisation. This should ensure that issues raised by the advisory committees, or requests for information, are dealt with authoritatively. It should also ensure that any relevant safety related advice or opinion provided by the advisory committees is considered and disseminated to the appropriate persons within the regulatory organisation without undue delay. Examples of liaison with expert safety advisers are given in Refs.18, 19, 20 and 22.

LIAISON WITH THE PUBLIC

910. It is essential that at all times the regulatory organisation is seen to retain its independence, including independence from the promotional aspects of nuclear energy, if it is to maintain public confidence in its regulatory activities. The development of both formal and informal lines of communication for the provision of regulatory information and advice to the public is, therefore, an important element in promoting and maintaining public confidence in the work of the regulatory organisation.

911. Formal channels of liaison with the public can be established in a number of ways, including:

- publication of information brochures on the role and organisation of the regulatory organisation;
- representation on relevant national, regional or local advisory committees;
- participation in public enquiries;
- provision of information or advice in response to requests by members of the public through their representation at local, regional or national government level; and
- publication of an annual report setting out in a manner that can be readily understood by the public, the activities and achievements of the regulatory organisation during the particular year, in relation to its regulatory objectives and criteria.

912. Informal liaison with the public can also provide an effective way of presenting the regulation of nuclear safety to a wider audience, including those at the socio-political level, informed members of the public, senior schools, universities, local business and social organisations. This can be achieved, for example, by responding to requests to provide lectures and informal talks, or to participate in relevant discussions. Within the regulatory organisation, a formal channel should be

established for liaising with the public in response to such requests and for identifying appropriate speakers. Examples of liaison with the public are given in Refs.11, 18, 19 and 20.

LIAISON WITH THE MEDIA

913. Because of the size of the audience it can address at local, national or international level, the speed with which it can respond to events and the influence it can bring to bear upon public opinion, the media (press, radio or television) must be recognised as an important intermediary between the regulatory organisation and the public. It is essential, therefore, that all information provided to the media is factual, unambiguous and presented in a manner that can be readily understood by those without specialist knowledge. Provisions for effective liaison between the regulatory organisation and the media, at both the formal and informal level, are essential.

914. Within the regulatory organisation there should be structured arrangements for dealing with all media related activities including the presentation of regulatory information for dissemination to the public and for responding to information requests. To avoid unnecessary public concern, arrangements should also exist for dealing with unfounded rumours; the development of informal contacts with media representatives can be of particular value in dealing with this type of situation. Those regulatory staff, including inspectors, who could be approached by members of the media in the course of their duties should receive appropriate training to enable them to respond more effectively.

915. To minimise the likelihood of public statements by the regulatory organisation being misquoted or misconstrued, any formal provision of information to the media should be provided in the form of a written "press statement". This should set out briefly, and in non-technical language, the subject of the statement, sufficient background information to put the subject into context, a summary of the subject matter to which the press statement relates, any further actions that will result, and references to where more in-depth information may be found. If

appropriate, the statement should also indicate the time that the information may be released for publication. Depending upon national arrangements and the particular circumstances, press statements may be provided to the media in the course of routine or ad-hoc press conferences or by direct distribution to the relevant media outlets (press, radio and television). In the latter case, the urgency for releasing the information should dictate the particular method used (e.g. telephone, facsimile, telex, courier, etc.) to transmit the statement to the media.

916. Press statements are of particular importance following any incident or accident at a nuclear installation, not only as a means of providing reassurance to the public but also for issuing authoritative and updated information on the situation, the remedial measures being implemented, and any action to be taken by the public.

917. When information is presented at a press briefing, and particularly in the post-accident situation, simple illustrative diagrams or models that are readily photographed can assist the understanding of a complex subject. Throughout the life of the regulatory organisation a library of media related illustrative material should be developed and maintained.

918. An example of liaison between the regulatory organisation and the media is given in Ref.19.

INTERNATIONAL LIAISON

919. The effective safe regulation of nuclear energy is of international concern. Ensuring that the most up-to-date safety principles and criteria will be satisfied is fundamental to the regulatory organisation's assessment, licensing and inspection responsibilities. It demands a multi-disciplined approach and cannot be achieved in isolation. Participation in conferences, seminars and the work of those international and inter-governmental organisations having responsibilities for promoting the safe operation and regulation of nuclear energy is an essential mechanism for keeping the regulatory organisation

abreast of developments in other nuclear countries. It also enables the regulatory organisation to have an influence on standards, recommendations, procedures and guide-lines relevant to nuclear safety that are being developed at the international level. Without participation in these international activities, the regulatory organisation cannot expect to maintain its essential role in the development and implementation of an effective nuclear safety practice in its own country.

920. International liaison activities of the regulatory organisation can be divided into three groups:

(i) Activities that centre around the major international organisations such as the IAEA, the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD-NEA) and the Commission of the European Communities;

(ii) Direct co-operative arrangements with nuclear regulatory organisations in other countries under formal or informal information exchange agreements on specified safety related subjects, including the exchange of technical and radiological data following a nuclear accident, and the provision of post-accident assistance; and

(iii) Informal, ad hoc, exchanges of information, and of regulatory staff, between regulatory organisations in different countries.

921. A summary of bilateral and multilateral agreements in the field of nuclear safety has been published by the IAEA (Ref.29).

922. The activities referred to in para. 920 (i) above include participation in the arrangements developed by the IAEA and the OECD-NEA with regard to the Incident Reporting System (IRS) for the reporting and dissemination of safety related information relating to incidents at nuclear installations, and the International Nuclear Event Scale (INES) for classifying incidents in relation to their safety significance (Refs.30, 31). Depending upon national arrangements, the regulatory organisation may wish to act as the focal point for implementing these activities, or to

ensure that they are carried out by other relevant bodies, such as the operating organisation.

923. In addition to the arrangements discussed in paras. 920 and 922 above, the regulatory organisation should be able to advise on any Government to Government bi-lateral or multi-lateral agreements to which its country is party for the formal post-accident exchange of information. This applies in particular to those agreements established in response to the IAEA Conventions on Early Notification and Mutual Emergency Assistance following a nuclear accident (Ref.31).

10. REGULATORY RESPONSE OF THE OPERATOR

Relevant Fundamental Safety Principles: 2, 4, 5, 6, 7, 8, 13, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25.

1001. The prime responsibility for the safety of a nuclear installation, including any impact it may have upon workers, the public and the environment, rests with the operating organisation. An essential element of this responsibility is compliance throughout the lifetime of the installation with the licence conditions and with any other requirements that the regulatory organisation may consider necessary in the interests of safety. Determining the effectiveness with which these responsibilities are discharged should be an essential part of the regulatory organisation's on-going programme of assessment and inspection. The criteria that should govern the response of the operating organisation for meeting its regulatory commitments are summarised in this Section.

ORGANISATIONAL AND SAFETY RELATED CRITERIA

1002. **Safety Policy:** The operating organisation is responsible for establishing an effective safety policy that places highest priority on safety matters, and for ensuring that it is fully implemented.

1003. **Responsibility and Authority:** The lines of responsibility for meeting the operating organisation's safety commitments' including its regulatory requirements, should be clearly defined and the levels of authority to which decisions of safety relevance must be referred should be clearly specified.

1004. **Professionally Staffed Installations:** To ensure that the operating organisation can properly fulfil its responsibilities for safety, it should maintain departments of professional staff with design, engineering and operational expertise.

1005. **Independent Nuclear and Radiological Safety Advice:** The operating organisation should maintain a centralised health and safety department, independent from operations. This should be staffed and supported by safety professionals and have the capability for carrying out peer reviews of the operator's safety proposals.

1006. **Access to Management Board:** On matters of urgent safety importance, the directors of each of the safety related departments should have direct access at a senior level to the operating organisation's board of management.

RESPONSIBILITIES

1007. **Responding to Licensing Requirements:** As part of the licensing procedure, the licence applicant (the operating organisation) is responsible for:

- providing all information appropriate to the siting, design, construction, commissioning, operation, maintenance and decommissioning the installation, together with the relevant supporting safety cases and assessments, as the regulatory organisation may specify or request;
- establishing proper arrangements with vendors or contractors to ensure that any required information is made available to the regulatory organisation in a timely manner;
- keeping the regulatory organisation informed of any new information, or of alterations to any previously submitted information, that may be relevant to the licensing process; and
- ensuring that the format and contents of documents submitted in support of the licensing process satisfy any requirements established by the regulatory organisation.

1008. **Meeting Operational Safety Commitments:** To meet its responsibilities for the safe operation of a nuclear installation, including its commissioning and decommissioning, the operating organisation should:

- assure itself, and satisfy the regulatory organisation, on the quality of the installation as designed, constructed and commissioned, and that the relevant safety criteria have been met;
- establish operating rules and procedures that reflect the design intent and safety justification of the installation, and that are aimed at the safe control of the installation under all conditions;
- ensure that the installation is operated and maintained by sufficient numbers of suitably trained and authorised staff, and in accordance with the operating rules and procedures;
- establish arrangements for ensuring that there is no unacceptable degradation in the quality of safety throughout the life of the installation;
- establish procedures for analysing the results of operating experience in order to improve the level of operational safety;
- prepare a decommissioning programme in advance of the foreseen end of life of the installation, describing the activities to be carried out during each stage of its decommissioning, together with a safety justification for each of the activities;
- maintain effective control over fissile and other radioactive materials used or generated within the nuclear installation;

- establish documented accident management and emergency response procedures for initiating rapid action to terminate safety significant incidents and accidents, for limiting any off-site release of radioactive materials, and for initiating measures for the protection of plant personnel and the public;
- establish procedures for recording safety significant incidents and accidents and for reporting them to the regulatory organisation;
- establish an adequate level of physical protection for controlling access to the site, and accounting for all persons both on the site and in areas of safety significance within the installation (Ref.32); and
- monitor, audit and review all safety related matters on a regular basis to satisfy itself, and demonstrate to the regulatory organisation, that the safety obligations, including compliance with licence conditions or any other statutory requirements, are being met.

1009. It must be stressed that compliance with the requirements of the licensing body or the regulatory organisation, including any conditions attached to, or imposed in support of, the licence, does not relieve the licensee of his fundamental responsibility to protect site personnel, the public and the environment from harm.

1010. **Support Organisations:** Other bodies may also have legal, technical or financial responsibilities with respect to the operating organisation, any of which may have a bearing on safety. For example, designers, manufacturers and constructors are required to meet quality standards and specifications. Although the operating organisation may delegate its authority to carry out various functions on its behalf, it cannot delegate its safety responsibilities. In such cases, the prime responsibility for safety remains with the operating organisation, which must satisfy itself as to the competence and safety standards of those to whom it contracts work. Further guidance on meeting the regulatory obligations of the operating organisation is given in Ref.33.

11. MAINTAINING REGULATORY EFFECTIVENESS

1101. The previous sections have set out the requirements for establishing an effective nuclear safety regulatory regime. Maintaining the effectiveness of such a regime in the longer term can only be achieved through constant review and critical appraisal of the overall regulatory objectives, and of the regulatory organisation's assessment, licensing and inspection arrangements through which they are implemented. To this end, the regulatory organisation should apply the principles of quality assurance to its own activities to ensure that its regulatory decisions, and the background against which they were taken, remain valid and are properly documented. These arrangements should be supported by a comprehensive programme of training aimed at developing all staff in their regulatory capabilities and keeping them abreast of international developments.

STAFFING

1102. In practice, the effectiveness with which the regulatory organisation continues to carry out its responsibilities will depend, to a large extent, upon the calibre and performance of its staff. As indicated in Section 4, it is essential that regulatory staff continue to command the professional respect of those they are required to regulate. Not only should they be suitably qualified, experienced and trained for the particular regulatory duties they are required to undertake, their level of remuneration should be maintained at least comparable with that received by their opposite numbers in the operating / licensee's organisation. Staff turnover, particularly the loss of qualified staff to other nuclear energy organisations, should be carefully monitored, as this will provide an indication as to whether the regulatory organisation is maintaining an adequate level of job satisfaction - including financial reward - to attract or retain suitably qualified regulatory staff.

1103. Delays in the operating organisation's or licensee's programme due to the need for regulatory inspection, assessment or the granting of approval before the programme may proceed, can prove expensive and frustrating, particularly if they are the result of an unacceptably slow regulatory process. It is particularly important, therefore, for the regulatory organisation to maintain sufficient numbers of staff, having the relevant qualifications, experience and training, to meet the demands placed upon it at all stages in the regulatory programme. To this end, the criteria upon which the size and structure of the regulatory organisation were originally determined should be reviewed periodically to ensure that they remain valid.

TRAINING

1104. It is essential for all members of the regulatory organisation, at all levels, to understand the organisation's regulatory role, legal responsibilities, and objectives, and how these are expected to be achieved in practice. The effectiveness with which this will be accomplished will depend not only upon the calibre, experience and qualifications of the staff recruited, but also on the extent to which their professional competence is enhanced by further appropriate training within the regulatory organisation.

1105. **Training Programme:** At an early stage in the life of the regulatory organisation, an experienced staff member should be given the responsibility for developing and implementing a structured training programme based on a formal training policy agreed at the most senior management level. To the extent practicable, senior and experienced members of the regulatory staff should participate in the training programme, and particularly in the training of newly recruited staff in their regulatory duties and responsibilities. This should also ensure that senior management not only pass on their experience, but are also kept informed of the effectiveness of the training programme, and of any particular training requirements that may arise. A training record should be maintained for each staff member, indicating the date and nature of the training provided.

1106. **Induction Training:** The basic qualifications and experience demanded of staff joining the regulatory organisation should normally be dictated by the nature of the posts for which they are initially recruited. To provide newly recruited staff with a proper perspective and understanding of their role as regulators, the regulatory organisation should ensure that they participate in a structured programme of induction training. This should be completed within the first several months of joining the organisation and be sufficiently flexible to take account of an individual's previous background and experience. Where staff are recruited from the operating organisation, and particularly from a licensed nuclear installation, to the extent practicable, their induction training (and especially their on-site training) should not be carried out at installations with which they were previously associated.

1107. **Development Training:** Throughout their period of employment, staff should be given the opportunity to retrain, as necessary. The basic training should also be supplemented by further development training appropriate to individual duties, needs and responsibilities. Any requirement for retraining or development training should be identified by supervisory staff as part of a periodic staff review and performance appraisal. Staff should also be encouraged to take advantage of the available training provisions. These should include a structured range of management training courses and be aimed both at broadening an individual's regulatory expertise and increasing his managerial skills, thereby enabling him to cover a range of responsibilities within any particular grade, and to improve his eligibility for promotion to the more senior regulatory posts.

1108. **Content of Structured Training Courses:** Typical subject matter that could be included in a structured programme of induction and development training for regulatory organisation staff might include, as appropriate:

Regulatory Related Courses:

- basic introductory course on the role, responsibilities and working procedures of the regulatory organisation;

- nuclear regulatory legislation and other relevant legislative and administrative provisions and requirements;
- law enforcement in relation to nuclear installations;
- communication skills and information technology;
- attachment at, and/or study of, a relevant nuclear installation;
- simulator training (to provide an understanding of plant behaviour and shift operator duties);
- in-plant inspection training by accompanying an experienced inspector;
- participation in site inspection visits and preparation of visit reports;
- on-site radiological protection training;
- witnessing a site emergency exercise and participating in its assessment.
- training attachments to other relevant (non-nuclear) regulatory organisations and to nuclear regulatory organisations in other countries.

Professionally Related Courses:

- basic radiological protection;
- nuclear engineering;
- nuclear safety;
- risk assessment;
- safety assessment criteria and techniques.

1109. **Feedback of Review and Training Results:** The on-going review and appraisal of the regulatory organisation's objectives and the arrangements by which they are met, and of the results of the supporting training programme, should enable any significant deficiencies to be identified and remedied; for example, by the provision of additional or specific training, or in some cases, the revision of particular task related procedures. The process provides an essential "feedback loop" for ensuring that the regulatory organisation not only maintains its expertise in the regulation of nuclear safety, but also develops it to the fullest possible extent.

1110. **Maintaining Professional Expertise:** In addition to any structured programme of development training, provision should be made for regulatory staff to keep abreast of current thought, research and development within their own particular professional field. The regulatory organisation should provide for access to relevant journals, encourage active participation in the work of professional institutions and societies, and support attendance at specialist seminars and conferences. Where it is necessary to gain a rapid, in-depth, appreciation of a specific subject or problem, short attachments to an appropriate university department or other specialist organisation should be considered.

1111. **Participation in International Safety Developments:** Active participation at the international level in relevant seminars, symposia and conventions, and as observers or experts in working groups, provides an important role in developing and broadening the experience of regulatory staff. The regulatory organisation should maintain a list of such meetings so that staff can be nominated to attend those that would be of benefit both to the organisation as a whole, as well as to the particular nominee.

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APPENDIX 1

FUNDAMENTAL SAFETY PRINCIPLES

The Fundamental Safety Principles that support the Basic Nuclear Safety, Radiological Safety and Technical Safety Objectives, as developed by the IAEA Nuclear Safety Standards Advisory Group (NUSSAG) and summarised in the IAEA NUSSAG Report "The Safety of Nuclear Installations - Safety Fundamentals", are set out below.

1. The government shall establish a legislative and statutory framework for the regulation of nuclear installations. There shall be a clear separation of responsibilities between the regulatory body and the operating organisation.

2. The prime responsibility for safety shall be assigned to the operating organisation.

3. The regulatory organisation shall be effectively independent from the organisation or body charged with the promotion or utilisation of nuclear energy. It shall have licensing, inspection and enforcement responsibilities and shall have adequate authority, competency and resources to fulfil its assigned responsibilities. No other responsibility shall jeopardise or conflict with its safety responsibility.

4. Organizations engaged in activities important to safety shall establish policies that give safety matters highest priority, and ensure that these policies are implemented within a managerial structure having clear divisions of responsibility and lines of communication.

5. Organizations engaged in activities important to safety shall establish and implement appropriate quality assurance programmes which extend throughout the life of the installation, from siting and design through to decommissioning.

6. Organizations engaged in activities important to safety shall ensure that there are sufficient numbers of adequately trained and authorised staff working in accordance with approved and validated procedures.

7. The capabilities and limitations of human performance shall be taken into account at all stages in the life of the installation.

8. Emergency plans for accident situations shall be prepared and appropriately exercised by all organizations concerned. The capability to implement approved emergency plans shall be in place before an installation commences operation.

9. The site selection shall take into account relevant features which might affect the safety of the installation, or be affected by the installation, and the feasibility of carrying out emergency plans. All aspects shall be evaluated for the projected lifetime of the installation, and re-evaluated as necessary to ensure the continued safety acceptability of site related factors.

10. The design shall ensure that the nuclear installation is suited for reliable, stable and easily manageable operation. The prime goal shall be the prevention of accidents.

11. The design shall include the proper application of the defence in depth principle so that there are several levels of protection and multiple barriers to prevent releases of radioactive materials, and ensure that failures or combinations of failures that might lead to significant radiological consequences are of very low probability.

12. Technologies incorporated in a design shall be proven by experience or testing or both.

13. The systematic consideration of the man-machine interface and human factors shall be included in all stages of design and the associated development of operational requirements.

14. The exposure to radiation of site personnel and releases of radioactive materials to the environment shall be made by design as low as reasonably achievable.

15. A comprehensive safety assessment and independent verification shall be carried out to confirm that the design of the installation will fulfil the safety objectives and requirements, before the operating organisation completes its submission to the regulatory body.

16. Specific approval by the regulatory body shall be required before the start of normal operation based upon an appropriate safety analysis and a commissioning programme. The commissioning programme shall provide evidence that the installation as constructed is consistent with design and safety requirements. Operational procedures shall be validated to the extent practicable as part of the commissioning programme with the participation of the future operating staff.

17. A set of operational limits and conditions derived from the safety analysis, tests and subsequent operational experience shall be defined to identify safe boundaries for operation. The safety analysis, operating limits and procedures shall be revised as necessary if the plant is modified.

18. Operation, inspection, testing and maintenance and supporting functions shall be conducted by sufficient numbers of adequately trained and authorised personnel in accordance with approved procedures.

19. Engineering and technical support, competent in all disciplines important for safety, shall be available throughout the lifetime of the installation.

20. The operating organisation shall establish documented and approved procedures as a basis for operator response to anticipated operational occurrences and accidents.

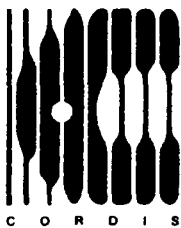
21. The operating organisation shall report incidents significant to safety to the regulatory body. Both the operating organisation and the regulatory body shall establish complementary programmes to analyse operating experience to ensure that lessons are learned and acted upon. Such experience shall be shared with relevant national and international bodies.

22. The generation of radioactive waste, both in activity and volume, shall be kept to the minimum practicable by appropriate design measures and operating practices. Waste treatment and interim storage shall be strictly controlled in a manner consistent with the requirements for safe final disposal.

23. The design of an installation and the decommissioning programme shall take into account the need to limit exposures during decommissioning to as low as is reasonably achievable. Prior to the initiation of decommissioning activities, the decommissioning programme shall be approved by the regulatory body.

24. The operating organisation shall verify by analysis, surveillance, testing and inspection that the physical state of the installation and its operation continue in accordance with operational limits, safety requirements and the safety analysis.

25. Systematic safety reassessments of the installation in accordance with the regulatory requirements, shall be performed throughout its operational lifetime, taking into account operating experience and significant new safety information from all relevant sources.



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This report is concerned with the regulation of nuclear safety. This document (Part 1 of the report) draws upon experience in West European countries, internationally recognized good practices in nuclear safety, and the safety fundamentals identified by the Nuclear Safety Standards Advisory Group (Nussag) of the International Atomic Energy Agency (IAEA). It examines the objectives of an effective nuclear safety regulatory regime, the requirements that it should meet, and the arrangements for their achievement. Developed by a task force of the Regulatory Assistance Management Group of the European Commission, it is intended as a source of guidance to those at the senior governmental and regulatory level in countries operating nuclear power programmes, particularly where such arrangements are currently being introduced or strengthened.

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