

Some Aspects of Producing Regulations and Guides for Controlling Safety in Nuclear and Radiation facilities

Mahmoud Ahamed Shafy Haraza

Head, Quality Assurance and Quality Control dept, Regulations Section

National Centre of Nuclear safety and Radiation control

Atomic energy authority , Egypt

ABSTRACT

Since Regulating nuclear and radiation safety is a national responsibility, keep the use of nuclear energy for welfare and prosperity of nation, and ensure that the use of nuclear energy is safe for man and the environment and does not promote the proliferation of nuclear weapons, Atomic energy act and related legal regulations and decrees are a must for each state wish to use a peaceful nuclear energy . After issuing the atomic energy act or any related legal system organizing the nuclear field activities, state should establish a national regulatory body (RB) which is responsible to control the nuclear and radiation safety of the facilities that work within the state. One task of national RB is responsible to develop regulations and guides that need to control the regulatory activities. The present paper gives some aspects of producing Regulations and Guides for Controlling Safety in Nuclear and Radiation facilities based on the international standards and guides issued by International Atomic Energy Agency and considered national practices.

1. INTRODUCTION

Under the National Atomic Energy Act and in fulfilling its statutory obligations , Radiation and Nuclear Safety Authority or whoever and may be known as regulatory body belongs to state, should establish, promote or adopt regulations and guides upon which its regulatory actions are based. It issues certain formal documents such as general instructions and regulations ,concerning the use of Nuclear and Radiation facilities in safe operation practices. They will be required for the regulatory processes by the laws and regulations of the country as well as the rules of the regulatory body. Other formal documentation will be provided in response to specific requests from the regulatory body or at the initiative of the operator or other parties involved. The regulatory body itself will also produce and disseminate many documents, some of which will form the basis for its decisions. The records of official meetings and hearings could also constitute a means of formally exchanging information.

Since Regulating nuclear and radiation safety is a national responsibility, many Member. States have decided to adopt the IAEA's safety standards for use in their national regulations.

Mohamed ElBaradei Director General of IAEA said a forward , in recent draft of IAEA Safety Guide dated in October 2007, The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. The IAEA standards provide a consistent, reliable means of ensuring the effective fulfillment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The states should ensure a high level of safety in the use of nuclear and radiation facilities and manage in a safe manner. National Regulatory body should invoke an effort to issue a national regulations and guides to achieve that goal.

2. Regulatory Body: Responsibility and Tasks

The National Radiation and Nuclear Safety Authority or National Regulatory Body for Radiation & Nuclear Safety (RB) is responsible for the supervision of safe use of nuclear energy. Regulatory body is defined as an authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating nuclear, radiation, radioactive waste and transport safety. In addition, be responsible for attending to the supervision of physical protection and emergency planning, and for the necessary control of the use of nuclear energy to prevent proliferation of nuclear weapons. In order to carry out these tasks, the NRB may in particular:

- (1) participate in the processing of licence applications pursuant to the national atomic act;
- (2) supervise the observance of licence conditions as well as set detailed requirements concerning the operations referred to in the licence;
- (3) issue detailed regulations and put forward the proposal for the general regulations;
- (4) supervise the observance of the regulations;
- (5) set qualification requirements for persons involved in the use of nuclear energy and control that the requirements are met;
- (6) provide expertise for other authorities;

- (7) carry out research and development activities necessary for supervision and participate in international co-operation in the field; and
- (8) put forward proposals and issue statements occasioned by supervision.

The National Radiation and Nuclear Safety Authority or National Regulatory body For Nuclear and Radiation safety may also be in charge of passing judgements on such licence applications pursuant to the National Atomic Energy Act as have been provided to be determined by this national Authority or Body and of supervising that indemnification regarding liability in case of a nuclear damage has been arranged as provided.

3. Regulatory body Functions

This National Nuclear and Radiation Regulatory body normally has main functions that include: Assessment, inspection, licencing & accreditation and enforcement. Other supplementary functions: national Accountant System for Safeguard Transportation for Radiation Material Emergency and Preparedness for Radiation Hazards Training and Qualification Research and Development Public Affairs – Awareness. All these function needs formal documents to control.

These activities should need issuing regulations to cover the assessment of the nuclear/ radiation facilities such as Nuclear Power reactor, or Nuclear research reactor or radiation protection whether in hospitals, or laboratories or Industries as well as radiation facility and waste management in the country.

The regulatory body should specify the purposes of the various regulatory documents necessary for it to perform its functions. The documents may be categorized as comprising: legislation; regulations, licences and other mandatory documents; guides and other advisory documents.

For Example the National regulatory body for assessing of Nuclear Power Plant may need to issue or adopt regulations and guides for controlling the following aspects:

- 1 Design of Structures, Components, Equipment, and Systems Reactor/facility
- 2 Reactor /facility Coolant System and Connected Systems
- 3 Engineered Safety Features
- 4 Instrumentation and Control Systems
- 5 Electric Power
- 6 Auxiliary Systems
- 7 Steam and Power Conversion System
- 8 Radioactive Waste Management
- 9 Radiation Protection
- 10 Conduct of Operations
- 11 Initial Test Program
- 12 Accident Analysis

- 13 Safety Limits (SLs)
- 14 Quality Management System
- 15 Human Factors Engineering
- 16 Severe Accident Analysis
- 17 Probabilistic Risk Assessment
- 18 Integrated Reliability Analysis (IRA)
- 19 Emergency Plan
- 20 Feedback

Thus a huge amount of regulations and guides shall be the first task of the regulatory body and other related authorities to issue and keep to upgrade whenever needs and according to the national and international legal state and the technology state the art. The regulations production is normally a dynamic process.

4. Production of Regulations and guides Criteria

The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated.

A systematic approach should be adopted for the production of regulations and guides, and the regulatory body's quality management should cover these activities.

Procedures should be developed which establish the general method for the development and review of regulations and guides, in accordance with the State's legal system. These procedures should cover the composition of working groups and the drafting and review procedure, including the required legal support. The procedure for formal approval and promulgation of the regulations and guides should be established in accordance with the legal system of the State concerned.

The establishment and periodic review of a system of regulations and guides tailored to the specific needs of a State entail a continuing effort. They constitute an integral part of the activities of the regulatory body prior to the authorization process and in the preparation of a periodic safety review. The scope and content of a system of regulations and guides that is sufficient to fulfill the needs of the regulatory body and the operators will emerge gradually and will change over time.

In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards [].

The extent and detail of the system of regulations and guides established or adopted by the regulatory body will depend on several factors, including: the regulatory philosophy and the level of detail with which regulatory controls will be applied; the nature of the nuclear/radiation programme, including the types of facilities and the number of operators, and the extent of regulatory experience with the technologies utilized; and the risks posed by the facilities.

Although the development effort may be lengthy, basic regulations should be established at an early stage. A range of engineering factors and also judgement or probabilistic safety assessments may contribute to setting priorities for topics to be covered by additional and more detailed regulations and guides. These should be sufficiently comprehensive and should be kept up to date to ensure that all essential safety requirements can be considered in a systematic and orderly manner in the authorization process.

Information to be included in the regulations needed for a nuclear/radiation programme, which may comprise different types of facility, may be divided into three categories:

Category 1: safety objectives, principles and criteria; Category 2: requirements for structuring and conducting the authorization process; Category 3: technical and managerial requirements relating to the stages of the authorization process.

Initiating a State's nuclear programme, priority should be given to the establishment of regulations dealing with safety objectives, principles and criteria, in particular those relating to radiation protection (including dose limits).

The requirements covering applications for authorization and the related documents should be clearly defined from the outset. Initially these requirements may be limited to a single design of facility and may be expressed in a letter to an operator, possibly with reference to international requirements or regulations of other States. As a nuclear programme matures, however, a more standard and uniform procedure will be beneficial and should be used

As regards technical and managerial requirements, at an early stage the safety considerations relating to site evaluation have priority, and for the purposes of design these considerations should include interactions between the facility and the site.

Regulations establishing general design criteria such as defence in depth, use of multiple barriers, redundancy and diversity should be developed first. Later, more detailed regulations or guides should be developed which cover the details of design requirements for systems, components and equipment, their functional and testing requirements, and the requirements for the analysis of normal operation and fault conditions.

Requirements relating to quality assurance should also be covered by regulations and guides and should be applied early enough to ensure that adequate quality assurance systems are put in place by the operator for all phases of a facility's lifetime.

Requirements for operation, decommissioning or closure will have an impact on the design and construction of a facility. For this reason, safety objectives, principles and criteria covering these stages should also be established at an early stage. At a later stage, detailed regulations and guides should be developed to cover aspects such as the conduct of operations, training of staff, reporting requirements and emergency preparedness.

Scope of regulations The scope should be as unambiguous as practicable; anything that is not included in the scope is excluded or is considered outside the boundary of the regulations. The first

step towards the development of Nuclear / radiation safety regulations should be to identify clearly the practices, to which regulatory requirements are to be applied; that is, the scope of the regulations. For reasons of clarity, some things that are excluded from the scope should be specified.

Topics to be covered :The regulatory body should ensure that the following administrative and procedural topics and requirements are covered in the regulations:

- (a) The exact name and location of the regulatory body;
- (b) The purpose of the regulations, their scope and their date of entry into force;
- (c) The powers of the regulatory body, such as powers of authorization, inspection and enforcement;
- (d) The relationship of a given set of regulations to other governmental regulations in force;
- (e) The criteria to be met in an application for exemption from certain procedural aspects of the regulatory requirements;
- (f) The requirements for performing safety
- (g) The financial assurance for dealing with accidents and waste management (including decommissioning and waste disposal).

5. Prescriptive versus performance based regulations

The principal purpose in establishing a system of regulations is to codify safety requirements of general applicability. The development of any particular regulation will involve a balance between the need for flexibility (to permit easy adaptation of the regulation to developing circumstances and technology) and the need to include detailed requirements (to facilitate determination of whether the requirements have been met).

Performance based regulations specify primarily the overall safety objectives. Performance based regulations can be comparatively easy to develop and are focused on what is to be achieved in terms of protection and safety. By setting objectives rather than prescribing specific requirements, performance based regulations have the advantage that they will not need to be changed so frequently to reflect changing technology or new knowledge. In addition, the use of objectives will tend to promote continual safety related improvements and the search for better approaches by the operator. Performance based regulations need greater involvement by the operator in determining how objectives are to be met. The regulatory body should assess whether the intent of the regulations has been fulfilled by judging how the operator has interpreted these regulations in each specific situation. The preparation of regulatory guides that set out acceptable ways of meeting performance based regulations should be considered.

A prescriptive regulation is more specific than a performance based one and states how to achieve safety. Prescriptive regulations have the advantage of providing both the regulatory body and the operator with clearly defined provisions for a particular activity or situation. They prescribe the means and

methods to be used in order to comply with regulatory requirements for achieving an adequate level of protection and safety. Prescriptive regulations reduce the time and skills necessary to perform a licensing review or conduct an inspection. They enable the authorization and inspection process to focus on verification of compliance. However, they are more difficult to prepare, needing more detailed and expert knowledge of the specific practice in question on the part of the regulatory body. They are narrowly applicable to a specific activity or situation and need to be regularly reviewed and amended, as necessary, to keep pace with technological changes. One difficulty with prescriptive regulations is that they tend to limit the flexibility of the operator in achieving safety; in addition, they may not be of help in the development of a safety culture.

A regulatory system should include both types of regulations, striking an appropriate balance between performance based and prescriptive regulations (or guides) to match the anticipated workload and the skills of the regulatory body's staff. A prescriptive regulation is more specific and states how to achieve Nuclear/radiation safety. Most regulations should contain both performance requirements and prescriptive requirements. However, the general national approach to regulations and the result achieved by the regulatory body will often dictate whether the regulations are either predominantly performance oriented or predominantly prescriptive in nature. The development of any particular safety regulation will involve a balance between two concerns: the need for flexibility to permit easy adaptation of the regulations to evolving circumstances and technology (performance regulations) versus the need to include detailed requirements for safety which also make it easier to determine whether the requirements are being met (prescriptive regulations).

6. Steps for developing regulations and guides

The regulatory body should follow a consistent procedure for establishing, revising and revoking regulations and guides. A general procedure should be prepared that details the general format and style of language to be used in the regulations and guides. This procedure should be distributed to members of working groups engaged in drafting and should be adhered to by all parties involved. These procedures should be efficient and flexible enough to permit revisions to be made to take account of changing conditions, or as justified by advances in technology. Because of differences in the legal systems and practices of States, it is impossible to provide detailed procedural guidance for establishing regulations and guides that can be used by all States. However, certain basic steps for establishing regulations and guides can be specified.

The procedure used by the regulatory body to establish regulations and guides should include the following steps:

1. Determination of the need for the regulations and guides.
2. Setting the priority for the development of regulations and guides.
3. Determination of the scope of the regulations and guides.
4. Determination of the resources necessary.

These four steps should form the basis for a decision on whether or not to prepare the proposed regulations and guides, including the adoption or adaptation of regulations issued by others.

These additional steps should follow a positive decision:

Collection of information. The information necessary to prepare the proposed regulations and guides should be collected. This would include collecting regulations, guides or recommendations from other States or from international organizations such as the IAEA, the International Commission on Radiological Protection (ICRP), the International Commission on Radiological Units and Measurements (ICRU), the International Electrotechnical Commission (IEC), the ILO, the International Organization for Standardization (ISO), the OECD/NEA, the PAHO and the WHO.

Drafting of the regulations and guides:

The staff of the regulatory body, consultants, professional societies or advisory committees may draft the initial versions of the regulations and guides. Regulations and guides should be written in a style that is clear and easy to understand. They should be relevant, precise and unambiguous so as to be readily applicable and enforceable.

Review of the regulations and guides:

Although practices vary widely, legal staff and special advisory committees, as appropriate, would usually review the initial versions of the proposed regulations and guides. "In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. In some States, operators, professional societies or other organizations participate in these reviews. A draft version may also be published provisionally with an invitation for comment from the public. Comments received as a result of the review should be analysed, evaluated and resolved as appropriate. Whichever review process is adopted, a formal procedure should be established to ensure that advice on the proposed regulations is obtained from all concerned parties. The regulatory body should then make a final decision with regard to the advice before the regulations are finalized. At this stage consideration should also be given to the implications of the regulations for existing facilities.

Establishing and issuing the regulations and guides:

The regulations should be established and promulgated in a manner that makes them legally binding according to the national legal system, thereby ensuring that their provisions can be enforced by the regulatory body. Guides may be formally issued with a lower level of approval, however, since they are only advisory in nature.

7. Guides versus Regulations

Guides, of a non-mandatory nature, on how to comply with the regulations shall be prepared, as necessary[. Irrespective of the degree to which the regulatory body has developed prescriptive regulations, the regulatory body is required to give consideration to supplementing its regulations with guidance documents. Guides directed at those practices that have the greatest potential to cause exposure are a useful supplement to the performance regulations.

There may be a need to provide for some flexibility in their application. Guides are intended for use by the regulatory body, operators, technical service providers and equipment manufacturers, or combinations of these. Their purpose is to provide guidance on how to implement regulatory requirements, thus enhancing radiation safety and improving effectiveness and efficiency.

The regulatory body should also support the production of guidance documents by professional bodies wishing to help their members in the discharge of their regulatory responsibilities regarding safety.

The regulatory body should also prepare detailed guidance for specific concerning facilities and equipment, operating procedures and protocols (e.g. for nuclear medicine, radiotherapy, diagnostic and interventional radiology, dental radiology, industrial radiography, industrial irradiation, well logging), and the qualification and training of personnel, that pertain to a specific radiation practice and that can be adopted by operators as a means of meeting performance regulations; Practical Radiation/ nuclear safety manuals covering various practices and procedures that serve as aids for the training of workers and for management in setting up local radiation safety rules ;Procedural guides such as those pertaining to instrument calibration, individual monitoring, environmental surveys and radioactive waste management, for use by operators and/or technical service providers; Guidance relating to the protection of persons undergoing medical exposure; Safety assessment plans that identify areas that need to be evaluated or reviewed for the authorization and inspection ;Guidance on the safe transport of radioactive material ;Procedures for the conduct of investigations; Plans and procedures for emergency preparedness and response.

The regulatory body should also prepare detailed guidance for operators on how to notify and to apply for authorization. This may include printed (or electronic) forms to be completed by operators in a question and answer format, so that all relevant information is gathered.

8. Process for review and revision of regulations and guides

The regulatory body should ensure that regulations and guides are kept up to date and should establish procedures for their periodic review. This according to procedures prescribed in quality management system. Experience in implementing the regulations should be examined and any problems or difficulties that may arise should be duly considered. The status of applicable requirements should also be examined in the light of new, safety related developments. The possible effects of frequent changes in regulations and guides on the stability of the regulatory system should be taken into account. However, events may occasionally occur that necessitate more frequent revisions. The reasons for revising regulations may include: changes in legislation; feedback of information and experience from events, incidents and accidents; technological advances; and the need to improve or eliminate any impractical, misleading, unenforceable or otherwise inadequate regulations.

The procedures applicable in the development of regulations can also be followed when making any necessary revisions. Advice should be obtained from all parties concerned. Operators and others potentially affected by the revised regulations should be

given adequate time to complete any preparations that may be necessary to enable them to comply with newly established requirements.

Examples of regulation to be issued by National RB:

- LICENSING OF RELEVANT INSTALLATIONS
- SPECIFIC AUTHORIZATIONS FOR THE PERSONNEL OF RELEVANT INSTALLATIONS
- OCCUPATIONAL EXPOSURE
- LIMITATION OF RADIOACTIVE EFFLUENTS
- ACCIDENT-RELATED RADIOLOGICAL CRITERIA
- GENERAL SAFETY CRITERIA FOR DESIGN
- FAILURE ANALYSIS FOR RISK ASSESSMENT
- SAFETY IN FIRE PREVENTION
- REACTOR CORE
- HEAT REMOVAL SYSTEMS
- PRIMARY PRESSURE CIRCUIT
- FUEL PERFORMANCE IN THE REACTOR
- SAFETY-RELATED PROTECTION AND INSTRUMENTATION SYSTEM
- SHUTDOWN SYSTEMS
- CONFINEMENT SYSTEMS
- ESSENTIAL POWER SUPPLY
- QUALITY ASSURANCE
- PRE-NUCLEAR COMMISSIONING
- NUCLEAR COMMISSIONING
- GENERAL CRITERIA FOR OPERATIONAL SAFETY
- COMMUNICATION OF RELEVANT EVENTS
- EARTHQUAKE PROTECTION
- LIMITATION OF RADIOACTIVE EFFLUENTS FROM RESEARCH AND IRRADIATION REACTOR

9. REFERENCES

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, (2000) Legal and Governmental Infrastructure for Nuclear, Radiation, *Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1, IAEA, Vienna.*
- [2] INTERNATIONAL ATOMIC ENERGY AGENCY, (2002) Organization and Staffing of the Regulatory Body for Nuclear Facilities, *Safety Standards Series No. GS-G-1.1, IAEA, Vienna.*
- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, (2002) Review and Assessment of Nuclear Facilities by the Regulatory Body, *Safety Standards Series No. GS-G-1.2, IAEA, Vienna.*
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, (2002) Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, *Safety Standards Series No. GS-G-1.3, IAEA, Vienna.*

- [5] INTERNATIONAL ATOMIC ENERGY AGENCY, (2001) Safety Assessment and Verification for Nuclear Power Plants, *Safety Standards Series No. NS-G-1.2*, IAEA, Vienna (2001).
- [6] INTERNATIONAL ATOMIC ENERGY AGENCY (2002) Application of the Management System for Nuclear Facilities *DRAFT SAFETY GUIDE DS349 Date: 22 Jan. 2007*
- [7] Nuclear Energy Act Ministry of Trade and Industry, Finland Ministry of Trade and Industry, Finland 990/1987; amendments up to 769/2004 included
- [8] INTERNATIONAL ATOMIC ENERGY AGENCY, (2002) DOCUMENTATION FOR USE IN REGULATING NUCLEAR FACILITIES *SAFETY STANDARDS SERIES No. GS-G-1.4*, SAFETY GUIDE, VIENNA, .
- [9] INTERNATIONAL ATOMIC ENERGY AGENCY, (2003) *Categorization of Radioactive Sources*, IAEA-TECDOC-1344, Vienna.
- [10] INTERNATIONAL ATOMIC ENERGY AGENCY, (2002) Preparedness and Response for a Nuclear or Radiological Emergency, *Safety Standards Series No. GS-R-2*, IAEA, Vienna.
- [11] INTERNATIONAL ATOMIC ENERGY AGENCY, (1997) Method for the Development of Emergency Response Preparedness for Nuclear or Radiological Accidents, IAEA-TECDOC-953, Vienna (1997).
- [12] INTERNATIONAL ATOMIC ENERGY AGENCY, (2000) Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), *Safety Series No. TS-R-1 (ST-1, Revised)*, IAEA, Vienna
- [13] INTERNATIONAL ATOMIC ENERGY AGENCY, (2001) Building Competence in Radiation Protection and the Safe Use of Radiation Sources, *Safety Standards Series No. RS-G-1.4*, IAEA, Vienna.
- [14] INTERNATIONAL ATOMIC ENERGY AGENCY, (2001) Assessment by Peer Review of the Effectiveness of a Regulatory Programme for Radiation Safety, IAEA-TECDOC-1217, Vienna.
- [15] INTERNATIONAL ATOMIC ENERGY AGENCY, (1994) Convention on Nuclear Safety, *Legal Series No. 16*, IAEA, Vienna.