Regulatory framework and technical infrastructure for managing radioactive waste

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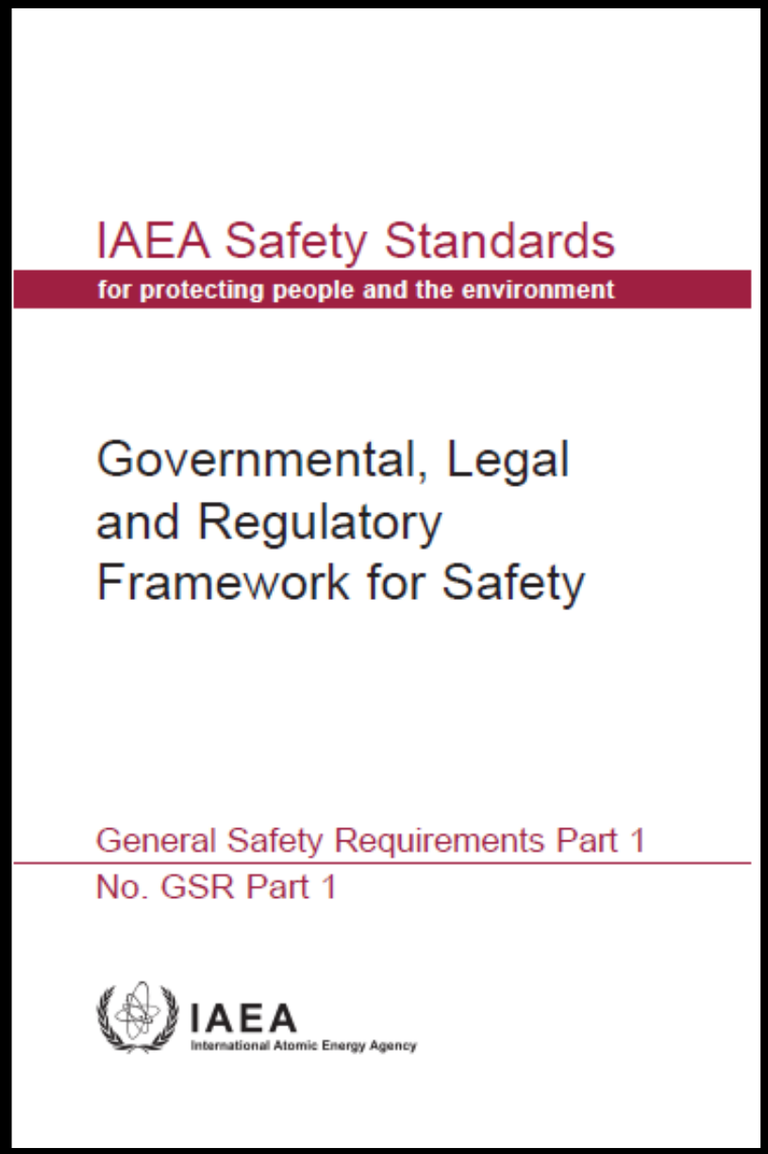
Contents

- Requirements for and of the regulatory framework (GSR Part 1)
- Other technical infrastructure considerations
- Licensing process
- Summary and conclusions

Relevant IAEA Standards

- GSR Part 1 issued 2010, replacing GS-R-1
- Harmonizes GS-R-1 with the Fundamental Safety Principles (IAEA Safety Standards Series No. SF-1)



Scope of GSR Part 1

- The essential aspects of the governmental and legal framework for:
  - Establishing a regulatory body
  - Taking actions necessary to ensure the effective regulatory control of all facilities and activities
    - Covers both existing and new, including all phases of facilities and activities
  - Other responsibilities and functions:
    - Liaison within global safety regime
    - Liaison for providing the necessary services for the purposes of safety
    - Emergency preparedness and response
    - Nuclear security
    - System of accounting for and control of nuclear material

Requirements Established

- 36 requirements are described in four chapters
  - Introduction: background, objective, scope, structure
  - Responsibilities and functions of the Government
  - The global safety regime
  - Responsibilities and functions of the Regulatory body

Governmental Responsibilities

- Requirement 1: Establish a national policy and strategy for safety
  - The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals.
- Requirement 2: Establish a framework for safety
  - The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.

Governmental Responsibilities

- Requirement 3: Establishment of a regulatory body
  - The government, through the legal system, shall establish and maintain a regulatory body, and shall confer on it the legal authority and provide it with the competence and the resources necessary to fulfil its statutory obligation for the regulatory control of facilities and activities.
- Requirement 4: Independence of the regulatory body
  - The government shall ensure that the regulatory body is effectively independent in its safety related decision making and that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.

Governmental Responsibilities

- Requirement 5: Prime responsibility for safety
  - The government shall expressly assign the prime responsibility for safety to the person or organization responsible for a facility or an activity, and shall confer on the regulatory body the authority to require such persons or organizations to comply with stipulated regulatory requirements, as well as to demonstrate such compliance.
- Requirement 6: Compliance with regulations and responsibility for safety
  - The government shall stipulate that compliance with regulations and requirements established or adopted by the regulatory body does not relieve the person or organization responsible for a facility or an activity of its prime responsibility for safety

Governmental Responsibilities

- Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety
  - Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.
- Requirement 8: Emergency preparedness and response
  - The government shall make provision for emergency preparedness to enable a timely and effective response in a nuclear or radiological emergency.

Governmental Responsibilities

- Requirement 9: System for protective actions to reduce existing or unregulated radiation risks
  - The government shall establish an effective system for protective actions to reduce undue radiation risks associated with unregulated sources (of natural and artificial origin) and contamination from past activities or events, consistent with the principles of justification and optimization.

- Requirement 10: Provision for the decommissioning of facilities and the management of radioactive waste and of spent fuel
  - The government shall make provision for the safe decommissioning of facilities, the safe management and disposal of radioactive waste arising from facilities and activities, and the safe management of spent fuel.

Governmental Responsibilities

- Requirement 11: Competence for safety
  - The government shall make provision for building and maintaining the competence of all parties having responsibilities in relation to the safety of facilities and activities.

- Requirement 12: Interfaces of safety with nuclear security and with the State system of accounting for and control of nuclear material
  - The government shall ensure that within the governmental and legal framework adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for and control of nuclear material.

Governmental Responsibilities

- Requirement 13: Provision of technical services
  - The government shall make provision where necessary for technical services in relation to safety, such as services for personal dosimetry, environmental monitoring and the calibration of equipment.

Global Safety Regime

- Requirement 14: International obligations and arrangements for international cooperation
  - The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation to enhance safety globally.

- Requirement 15: Sharing of operating experience and regulatory experience
  - The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and their use by authorized parties, the regulatory body and other relevant authorities

Regulatory Body

- Requirement 16: Organizational structure of the regulatory body and allocation of resources
  - The regulatory body shall structure its organization and manage its resources so as to discharge its responsibilities and to perform its functions effectively; this shall be accomplished in a manner commensurate with the radiation risks associated with facilities and activities.

- Requirement 17: Effective independence in the performance of regulatory functions
  - The regulatory body shall perform its functions in a manner that does not compromise its effective independence.

Regulatory Body

- Requirement 18: Staffing and competence of the regulatory body
  - The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.

- Requirement 19: The management system of the regulatory body
  - The regulatory body shall establish, implement, and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.

Regulatory Body

- Requirement 20: Liaison with advisory bodies and support organizations
  - The regulatory body shall obtain technical or other expert professional advice or services as necessary in support of its regulatory functions, but this shall not relieve the regulatory body of its assigned responsibilities.

- Requirement 21: Liaison between the regulatory body and authorized parties
  - The regulatory body shall establish formal and informal mechanisms of communication with authorized parties on all safety related issues, conducting a professional and constructive liaison.

- Requirement 22: Stability and consistency of regulatory control
  - The regulatory body shall ensure that regulatory control is stable and consistent.

Regulatory Body

- Requirement 23: Authorization of facilities and activities by the regulatory body
  - Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.
- Requirement 24: Demonstration of safety for the authorization of facilities and activities
  - The applicant shall be required to submit an adequate demonstration of safety in support of an application for the authorization of a facility or an activity.

Regulatory Body

- Requirement 25: Review and assessment of information relevant to safety
  - The regulatory body shall review and assess relevant information — whether submitted by the authorized party or the vendor, compiled by the regulatory body, or obtained from elsewhere — to determine whether facilities and activities comply with regulatory requirements and the conditions specified in the authorization. This review and assessment of information shall be performed prior to authorization and again over the lifetime of the facility or the duration of the activity, as specified in regulations promulgated by the regulatory body or in the authorization.
- Requirement 26: Graded approach to review and assessment of a facility or an activity
  - Review and assessment of a facility or an activity shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach

Regulatory Body

- Requirement 27: Inspection of facilities and activities
  - The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization.

- Requirement 28: Types of inspection of facilities and activities
  - Inspections of facilities and activities shall include programmed inspections and reactive inspections; both announced and unannounced.

- Requirement 29: Graded approach to inspections of facilities and activities
  - Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

Regulatory Body

- Requirement 30: Establishment of enforcement policy
  - The regulatory body shall establish and implement an enforcement policy within the legal framework for responding to non-compliance by authorized parties with regulatory requirements or with any conditions specified in the authorization.

- Requirement 31: Requiring of corrective action by authorized parties
  - In the event that risks are identified, including risks unforeseen in the authorization process, the regulatory body shall require corrective actions to be taken by authorized parties.

Regulatory Body

- Requirement 32: Regulations and guides
  - The regulatory body shall establish or adopt regulations and guides to specify the principles, requirements and associated criteria for safety upon which its regulatory judgements, decisions and actions are based.
- Requirement 33: Review of regulations and guides
  - Regulations and guides shall be reviewed and revised as necessary to keep them up to date.
- Requirement 34: Promotion of regulations and guides to interested parties
  - The regulatory body shall notify interested parties and the public of the principles and associated criteria for safety established in its regulations and guides, and shall make its regulations and guides available.

Regulatory Body

- Requirement 35: Safety related records
  - The regulatory body shall make provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities.

- Requirement 36: Communication and consultation with interested parties
  - The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body.

Summary of Required Regulatory Infrastructure

- Adequate regulatory framework and criteria necessary
- Definition of national priorities
- Assignment of responsibilities and funding mechanisms
- Holistic approach to ensure overall optimization of concepts
- Good communication with other government agencies and stakeholders
- Adequate staff and funding of regulatory authority
- Well-planned and structured approval process
- Provisions for inspections and enforcement

Summary of Other Technical Infrastructure

- **Infrastructure for Emergency Preparedness**
- **Infrastructure for Radioactive Waste Management**
- **Infrastructure for Intervention**
- **Infrastructure for Services**

Summary of Other Technical Infrastructure

- Special emergency equipment
- Appropriate medical resources
- Decommissioning
- Closure and the post-closure period
- Site rehabilitation
- Safe management of spent fuel and radioactive waste
- Provision of international cooperation

Summary of Other Technical Infrastructure

- **Infrastructure for Radioactive Waste Management:**
  - **Long term plans and policy for storage and disposal including waste from small users**
  - **Research and development**
  - **Inventory of existing and anticipated waste**
  - **Secured funding for long term waste management**

Summary of Other Technical Infrastructure

- Infrastructure for Intervention
  - The regulatory body shall provide any necessary input to the intervention process.
- Infrastructure for Services
  - Government shall provide for, among other things, the following services:
    - Training and education
    - Dosimetry services
    - Special emergency equipment
    - Appropriate medical resources and
    - International cooperation

Regulatory framework for the licensing process

- **The overall goal of the regulatory review is to verify the facility (or activity) will not cause an unacceptable adverse impact on human health or safety, or on the environment, both now and in the future.**
- **Primary objectives include reviewing the SA & SC and assumptions used.**
- **Secondary objectives (to ensure SC evaluations) include sufficiently complete, data clearly presented by competent personnel, uncertainties listed, and facility operations understood.**

Safety Guides for RWM

- GSR Part 5, Predisposal Management of Radioactive Waste (2009)

- WS-G-1.2, Management of Radioactive Waste from the Mining and Milling of Ores (2002)
- WS-G-2.3, Regulatory Control of Radioactive Discharges to the Environment (2000)
- WS-G-2.5, Predisposal Management of Low and Intermediate Level Radioactive Waste (2003)
- WS-G-2.6, Predisposal Management of High Level Radioactive Waste (2003)
- WS-G-2.7, Management of Waste from the Use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education (2005)
- WS-G-6.1, Storage of Radioactive Waste (2006)
- GSG-1, Classification of Radioactive Waste (2009)
- GSG-3, The Safety Case and Safety Assessment for the Predisposal of Radioactive Waste (2013)
- SSG-15, Storage of Spent Nuclear Fuel (2012)

Safety Guides for RWM

- GSR Part 4, Safety Assessment for Facilities and Activities (2009)
- WS-G-5.2, Safety Assessment for the Decommissioning of Facilities Using Radioactive Material (2009)
- GSG-3, The Safety Case and Safety Assessment for the Predisposal of Radioactive Waste (2013)
- SSG-23, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste (2012)
- SSG-15, Storage of Spent Nuclear Fuel (2012)

Legal & Regulatory Questions of Interest

- **What is the national legal and organizational framework within which radioactive waste management activities are planned and carried out?**

- **How it is ensured nationally that the responsibility for safety lies with the operator of radioactive waste management facilities and/or activities?**

- **What provisions exist to ensure that the continuity of responsibility for safety is maintained in cases of transfer of radioactive waste from one operator to another?**

- **How does the national framework define the country's approach for the long term management of different types of radioactive waste?**

Regulatory Framework for RW Sites

- **Commonly attract both regulator and public attention**
- **Examples of elements of typical regulations governing RW site licensing:**
  - **Public and worker dose limits and constraints**
  - **Worker training and qualifications**
  - **Receipt & shipping of waste packages**
  - **Contamination limits**
  - **Waste acceptance criteria (in particular long lived radionuclides)**
  - **Financial assurance**
  - **Emergency planning**
  - **Decommissioning planning**
  - **Post-closure period**

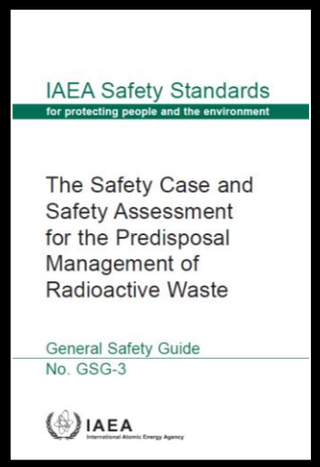
Regulatory Framework for RW sites

- **All regulatory requirements are addressed in the safety case**
- **SA/SC development starts at the earliest stage**
- **Environmental monitoring also begins early (especially when the waste might have a significant impact on the environment):**
  - **To identify background levels for the site**
  - **To ensure the site is suitable for the lifetime of the facility**
- **Iteration and optimization**

Regulatory Framework for RW sites

- **What will be the scope of licensed activities?**
  - **Long term storage - how do you handle:**
    - **package degradation**
    - **markings fading**
    - **inventory control issues.**
  - **Conditioning or thermal destruction**
  - **Is there a criticality concern with the waste?**
- **Need to envision facility layout from start to finish (facilities and activities)**

GSG-3 Additional Guidance



- This Safety Guide aims to assist operators, regulatory bodies and supporting technical specialists in the application of a graded approach to the development and review of the safety case and supporting safety assessment

- Section 2 – Describes the overall process of demonstrating the safety
- Section 3 – Summarizes the main safety principles and safety requirements to be met in the preparation of the safety case.
- Section 4 - Elaborates on the concept of the safety case. The components of the safety case are described and possibilities for building confidence in the safety case are discussed.
- Section 5 – Addresses methodology for the safety assessment, including the management of uncertainties within the safety assessment, as well as on the use of the outcomes of assessments for comparison with assessment criteria.
- Section 6 – Discusses issues that arise in the preparation of a safety case
- Section 7 – Addresses the documentation of the safety case
- Section 8 – Provides guidance and recommendations on the regulatory review of the safety case.
- Annex I provides examples of hazards and initiating events
- Annex II provides a list of topical issues for the regulatory review of the safety case
- Annex III provides a template for the regulatory review report and
- Annex IV provides a framework for the overall safety assessment work.

Before submitting a license

- **Meet with potential licensee**
  - **Safety concerns brought forward by SA/SC**
  - **Timeframes (e.g., when and how long?)**
  - **Only radiological hazards?**
  - **How is data/information transmitted?**
  - **Will parts of the SC be used in the licensing process?**
  - **Have parties agreed to the criteria to be used in evaluating SA/SC?**
  - **Is there any guidance available?**
  - **For the reviewer: are competent personnel available?**
  - **Proper documentation stressed**
  - **The need for preoperational environmental monitoring**

Completing an application

- **Is there a standard application and guidance from the regulator?**
  - **Ensure all parts of the app are completed; ask as needed.**
  - **For new facilities, training and management are important.**

- **Transfer of information from SA/SC, as appropriate.**

- **Periodic meetings with potential licensee**

- **How do you handle issues between the meetings? Phone/email ok? Letter? Agency policy?**

- **If facility will have complex processes, need to establish cold start-up schedule before authorization is fully granted.**

Submitting an application

- **If possible, send draft versions beforehand.**
- **Do national laws/regulations allow applications to be submitted in phases?**
- **Schedule meeting with review team to:**
  - **Introduce who is working on which sections**
  - **Walk through the entire application**
  - **Explain any last minute additions/deletions**
  - **Reconfirm timelines**
  - **Establish communication protocols (e.g., how do the two teams talk with each other?)**

Application Review

- **Should be treated by regulatory body as a separate project performed by a team. With procedures, the application can be very large.**
- **Project needs independent competent reviewers, review plan(s), schedule and budget.**
- **Requests for Additional Information (RAI's)**
- **Documentation of review: traceable, criteria clearly identified, conflict resolution and results.**
- **The graded approach… based upon trust and experience.**

After a license is issued

- **Frequent onsite visits. Possibility of a resident inspector?**
- **What priority is assigned by a regulator for a particular site/facility for inspections?**
- **Enforcement of regulatory requirements**
- **Identification of deviations from approved license and process for interventions**

Amendments & Renewals

- **Does the SA/SC need to be updated?**
- **Periodic review should be mandatory at periods determined by the regulatory body**
- **Periodic safety reviews may also be required to justify:**
  - ✓ **Life extension of the facility beyond its original design life,**
  - ✓ **Changes in the ownership or management of a facility**
  - ✓ **Changes in regulations.**
- **Do these actions have requirements for formal public involvement?**

License Termination

- **Planned or forced (e.g., bankruptcy)?**
- **Has a graded approach been used to slowly terminate authorization for processes at the site?**
- **Has a decommissioning plan been instituted?**
- **Disposal site(s) available?**

Summary

- During a facility lifecycle, the authorization will change as the site evolves. The regulator and proponent need to establish a professional relationship starting from concept development and siting through shutdown and decommissioning.

- Predisposal waste management includes a wide range of facilities and/or activities, and characteristics of waste processed. The graded approach allows the regulator and operator to develop a level of comfort for different degrees of hazard/risk.

- Radioactive material authorization is complex without the waste component. The uncertainties and assumptions should be clearly identified.

Summary

- Passive safety functions are better than procedural compliance.
- Worker training and management oversight play key roles in the day-to-day safe operation of a radioactive waste facility, especially at a new facility.
- The geographical location and expected lifetime of the facility needs to be sufficient for the activities being undertaken. Contingency may be needed and should be accounted for.
- Waste Acceptance Criteria must be consistent with Safety Case and license.

Thank you for your time.

Any questions?