

IAEA Safety Standards

for protecting people and the environment

Radiation Safety of Gamma, Electron and X Ray Irradiation Facilities

Specific Safety Guide No. SSG-8



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Under the terms of Article III of its Statute, the IAEA is authorized to establish or adopt standards of safety for protection of health and minimization of danger to life and property, and to provide for the application of these standards.

The publications by means of which the IAEA establishes standards are issued in the **IAEA Safety Standards Series**. This series covers nuclear safety, radiation safety, transport safety and waste safety. The publication categories in the series are **Safety Fundamentals**, **Safety Requirements** and **Safety Guides**.

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The site provides the texts in English of published and draft safety standards. The texts of safety standards issued in Arabic, Chinese, French, Russian and Spanish, the IAEA Safety Glossary and a status report for safety standards under development are also available. For further information, please contact the IAEA at PO Box 100, 1400 Vienna, Austria.

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RADIATION SAFETY OF GAMMA,
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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

IAEA SAFETY STANDARDS SERIES No. SSG-8

RADIATION SAFETY OF GAMMA, ELECTRON AND X RAY IRRADIATION FACILITIES

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2010



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Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
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email: sales.publications@iaea.org
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Printed by the IAEA in Austria
July 2010
STI/PUB/1454

IAEA Library Cataloguing in Publication Data

Radiation safety of gamma, electron and x ray irradiation facilities : specific safety guide. — Vienna : International Atomic Energy Agency, 2010.
p. ; 24 cm. — (IAEA safety standards series, ISSN 1020-525X ; no. SSG-8)
STI/PUB/1454
ISBN 978-92-0-103710-7
Includes bibliographical references.

1. Irradiation plants. 2. Irradiation devices. 3. Gamma ray sources.
4. Work environment — Safety measures. I. International Atomic Energy Agency. II. Series.

IAEAL

10-00641

FOREWORD

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. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and all Member States are urged to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the contracting parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment 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 IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

THE IAEA SAFETY STANDARDS

BACKGROUND

Radioactivity is a natural phenomenon and natural sources of radiation are features of the environment. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry and agriculture. The radiation risks to workers and the public and to the environment that may arise from these applications have to be assessed and, if necessary, controlled.

Activities such as the medical uses of radiation, the operation of nuclear installations, the production, transport and use of radioactive material, and the management of radioactive waste must therefore be subject to standards of safety.

Regulating safety is a national responsibility. However, radiation risks may transcend national borders, and international cooperation serves to promote and enhance safety globally by exchanging experience and by improving capabilities to control hazards, to prevent accidents, to respond to emergencies and to mitigate any harmful consequences.

States have an obligation of diligence and duty of care, and are expected to fulfil their national and international undertakings and obligations.

International safety standards provide support for States in meeting their obligations under general principles of international law, such as those relating to environmental protection. International safety standards also promote and assure confidence in safety and facilitate international commerce and trade.

A global nuclear safety regime is in place and is being continuously improved. IAEA safety standards, which support the implementation of binding international instruments and national safety infrastructures, are a cornerstone of this global regime. The IAEA safety standards constitute a useful tool for contracting parties to assess their performance under these international conventions.

THE IAEA SAFETY STANDARDS

The status of the IAEA safety standards derives from the IAEA's Statute, which authorizes the IAEA to establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection

of health and minimization of danger to life and property, and to provide for their application.

With a view to ensuring the protection of people and the environment from harmful effects of ionizing radiation, the IAEA safety standards establish fundamental safety principles, requirements and measures to control the radiation exposure of people and the release of radioactive material to the environment, to restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation, and to mitigate the consequences of such events if they were to occur. The standards apply to facilities and activities that give rise to radiation risks, including nuclear installations, the use of radiation and radioactive sources, the transport of radioactive material and the management of radioactive waste.

Safety measures and security measures¹ have in common the aim of protecting human life and health and the environment. Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security.

The IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are issued in the IAEA Safety Standards Series, which has three categories (see Fig. 1).

Safety Fundamentals

Safety Fundamentals present the fundamental safety objective and principles of protection and safety, and provide the basis for the safety requirements.

Safety Requirements

An integrated and consistent set of Safety Requirements establishes the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. If the requirements are not met, measures must be taken to reach or restore the required level of safety. The format and style of the requirements facilitate their use for the establishment, in a harmonized manner, of a national regulatory framework. The safety requirements use ‘shall’ statements together with statements of

¹ See also publications issued in the IAEA Nuclear Security Series.

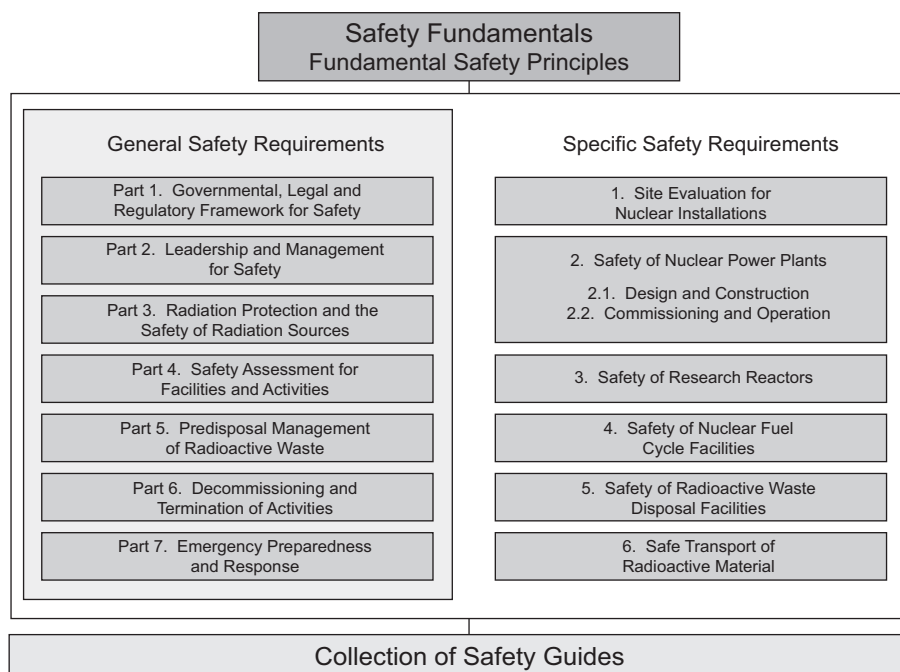


FIG. 1. The long term structure of the IAEA Safety Standards Series.

associated conditions to be met. Many requirements are not addressed to a specific party, the implication being that the appropriate parties are responsible for fulfilling them.

Safety Guides

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus that it is necessary to take the measures recommended (or equivalent alternative measures). The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. The recommendations provided in Safety Guides are expressed as ‘should’ statements.

APPLICATION OF THE IAEA SAFETY STANDARDS

The principal users of safety standards in IAEA Member States are regulatory bodies and other relevant national authorities. The IAEA safety

standards are also used by co-sponsoring organizations and by many organizations that design, construct and operate nuclear facilities, as well as organizations involved in the use of radiation and radioactive sources.

The IAEA safety standards are applicable, as relevant, throughout the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes and to protective actions to reduce existing radiation risks. They can be used by States as a reference for their national regulations in respect of facilities and activities.

The IAEA's Statute makes the safety standards binding on the IAEA in relation to its own operations and also on States in relation to IAEA assisted operations.

The IAEA safety standards also form the basis for the IAEA's safety review services, and they are used by the IAEA in support of competence building, including the development of educational curricula and training courses.

International conventions contain requirements similar to those in the IAEA safety standards and make them binding on contracting parties. The IAEA safety standards, supplemented by international conventions, industry standards and detailed national requirements, establish a consistent basis for protecting people and the environment. There will also be some special aspects of safety that need to be assessed at the national level. For example, many of the IAEA safety standards, in particular those addressing aspects of safety in planning or design, are intended to apply primarily to new facilities and activities. The requirements established in the IAEA safety standards might not be fully met at some existing facilities that were built to earlier standards. The way in which IAEA safety standards are to be applied to such facilities is a decision for individual States.

The scientific considerations underlying the IAEA safety standards provide an objective basis for decisions concerning safety; however, decision makers must also make informed judgements and must determine how best to balance the benefits of an action or an activity against the associated radiation risks and any other detrimental impacts to which it gives rise.

DEVELOPMENT PROCESS FOR THE IAEA SAFETY STANDARDS

The preparation and review of the safety standards involves the IAEA Secretariat and four safety standards committees, for nuclear safety (NUSSC), radiation safety (RASSC), the safety of radioactive waste (WASSC) and the safe transport of radioactive material (TRANSSC), and a Commission on Safety Standards (CSS) which oversees the IAEA safety standards programme (see Fig. 2).

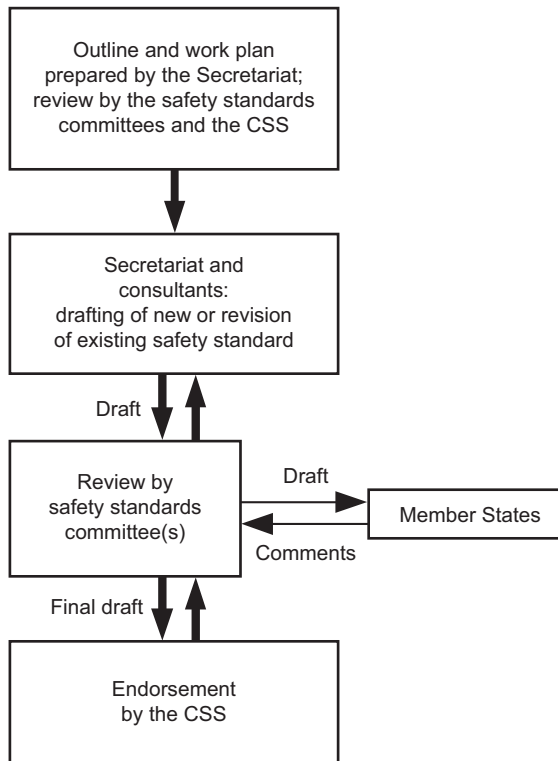


FIG. 2. The process for developing a new safety standard or revising an existing standard.

All IAEA Member States may nominate experts for the safety standards committees and may provide comments on draft standards. The membership of the Commission on Safety Standards is appointed by the Director General and includes senior governmental officials having responsibility for establishing national standards.

A management system has been established for the processes of planning, developing, reviewing, revising and establishing the IAEA safety standards. It articulates the mandate of the IAEA, the vision for the future application of the safety standards, policies and strategies, and corresponding functions and responsibilities.

INTERACTION WITH OTHER INTERNATIONAL ORGANIZATIONS

The findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of international

expert bodies, notably the International Commission on Radiological Protection (ICRP), are taken into account in developing the IAEA safety standards. Some safety standards are developed in cooperation with other bodies in the United Nations system or other specialized agencies, including the Food and Agriculture Organization of the United Nations, the United Nations Environment Programme, the International Labour Organization, the OECD Nuclear Energy Agency, the Pan American Health Organization and the World Health Organization.

INTERPRETATION OF THE TEXT

Safety related terms are to be understood as defined in the IAEA Safety Glossary (see <http://www-ns.iaea.org/standards/safety-glossary.htm>). Otherwise, words are used with the spellings and meanings assigned to them in the latest edition of The Concise Oxford Dictionary. For Safety Guides, the English version of the text is the authoritative version.

The background and context of each standard in the IAEA Safety Standards Series and its objective, scope and structure are explained in Section 1, Introduction, of each publication.

Material for which there is no appropriate place in the body text (e.g. material that is subsidiary to or separate from the body text, is included in support of statements in the body text, or describes methods of calculation, procedures or limits and conditions) may be presented in appendices or annexes.

An appendix, if included, is considered to form an integral part of the safety standard. Material in an appendix has the same status as the body text, and the IAEA assumes authorship of it. Annexes and footnotes to the main text, if included, are used to provide practical examples or additional information or explanation. Annexes and footnotes are not integral parts of the main text. Annex material published by the IAEA is not necessarily issued under its authorship; material under other authorship may be presented in annexes to the safety standards. Extraneous material presented in annexes is excerpted and adapted as necessary to be generally useful.

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1. INTRODUCTION

BACKGROUND

1.1. The applications of ionizing radiation bring many benefits to humankind, ranging from power generation to uses in medicine, industry and agriculture. Irradiators that utilize ionizing radiation are used in a variety of beneficial applications such as food irradiation and sterilization of medical products. However, ionizing radiation can also be harmful unless it is properly controlled. Industrial irradiators produce very high dose rates during irradiation, such that a person accidentally present in the radiation room¹ could receive a lethal dose within minutes or even seconds.

1.2. Several fatalities have occurred in gamma irradiators in various States. In addition, serious overexposures have occurred at electron beam irradiators in several States. The IAEA has investigated these and other accidents, and has published a report [1] on lessons learned so that similar accidents may be prevented in the future.

1.3. The accidents described in Ref. [1] involved workers who entered radiation rooms unaware of the high dose rates. There are also other potential radiation hazards at gamma irradiators, including contamination from damaged radioactive sources, sources becoming dislodged from source racks, accidents in handling sources, fires and breaches in security.

1.4. The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) [2] establish the basic requirements for protection of people against exposure to ionizing radiation and for the safety of radiation sources². The implementation of these requirements at irradiation facilities is intended to prevent accidents of the type described here and, generally, to provide for the best possible protection and safety measures under the prevailing circumstances. The magnitudes and likelihood of exposures and the numbers of individuals exposed are required to be kept as low as reasonably achievable, economic and social factors being taken into account.

¹ The radiation room is that region of the irradiator that is enclosed by radiation shielding and is made inaccessible when the radiation source is in use.

² The term 'radiation source' includes radioactive sources and radiation generators. 'Radiation' as used in the IAEA safety standards means ionizing radiation.

1.5. Unless otherwise stated, terms are used with the meanings ascribed to them in the IAEA Safety Glossary (2007 Edition) [3].

OBJECTIVE

1.6. The objective of this Safety Guide is to provide recommendations on how to meet the requirements of the BSS with regard to irradiation facilities. This Safety Guide provides specific, practical recommendations on the safe design and operation of gamma, electron and X ray irradiators for use by operating organizations and the designers of these facilities, and by regulatory bodies.

SCOPE

1.7. The facilities considered in this publication include five types of irradiator, whether operated on a commercial basis or for research and development purposes. This publication is concerned with radiation safety issues and not with the uses of irradiators, nor does it cover the irradiation of product³ or its quality management. The five types of irradiator are:

- Panoramic dry source storage irradiators (see Fig. 1);
- Underwater irradiators, in which both the source and the product being irradiated are under water (see Fig. 2);
- Panoramic wet source storage irradiators (see Fig. 3);
- Electron beam irradiation facilities, in which irradiation is performed in an area that is potentially accessible to personnel, but that is kept inaccessible during the irradiation process (see Fig. 4);
- X ray irradiation facilities, in which irradiation is performed in an area that is potentially accessible to personnel, but that is kept inaccessible during the irradiation process (see Fig. 5).

Consideration of non-radiation-related risks and of the benefits resulting from the operation of irradiators is outside the scope of this Safety Guide. The practices of radiotherapy and radiography are also outside the scope of this Safety Guide. Category I gamma irradiators (i.e. ‘self-shielded’ irradiators) are outside the scope of this Safety Guide.

³ Product in this context means the objects or materials that are intentionally irradiated.

STRUCTURE

1.8. Designs of irradiation facilities are categorized according to radiation type and methods of accessibility and shielding, as described in Section 3 of this Safety Guide. The notification and authorization of irradiation practices, the responsibilities of the operating organization and general radiation safety issues are discussed in Section 4. The individual monitoring of workers and workplace monitoring are described in Sections 5 and 6, respectively.

1.9. Section 7 provides a description of security measures for controlling radioactive sources. Section 8 deals with design and operational safety aspects of irradiation facilities. Section 9 discusses the testing and maintenance of equipment.

1.10. Section 10 focuses on the transport and loading and unloading of radioactive sources. Section 11 addresses emergency preparedness and emergency response.

2. JUSTIFICATION OF PRACTICES

2.1. The Fundamental Safety Principles [4] state the fundamental safety objective as being to protect people and the environment from harmful effects of ionizing radiation. Principle 4, Justification of facilities and activities, states that “Facilities and activities that give rise to radiation risks must yield an overall benefit.” This may be taken as being equivalent to the well established principle of justification of practices, the operation of irradiation facilities being one example [2].

2.2. The basic requirements for radiation protection for practices established in the BSS [2] are: justification of practices, individual dose limits, and optimization of protection and safety. The basic requirement for the justification of practices is expressed as follows:

“No practice or source within a practice should be authorized unless the practice produces sufficient benefit to the exposed individual to offset the radiation harm that it might cause; that is: unless the practice is justified, taking into account social, economic and other relevant factors” (Ref. [2], para. 2.20).

2.3. When the principle was first formally expressed, many practices such as the operation of irradiators were already in widespread use, and in general their justification was implicit. Under normal conditions, the design, construction, operation and maintenance of irradiators result in negligible doses to workers and the public. However, as indicated above, the operation of irradiators occasionally results in doses to workers in excess of authorized limits as a result of accidents. Also, the operation of irradiators carries with it other radiation risks, including those associated with the security of radioactive sources, the transport of radioactive sources and, ultimately, the disposal of radioactive sources.

2.4. The decision as to whether the operation of irradiators is justified is specific to the circumstances and benefits of their use, taking into account national priorities; thus definitive recommendations regarding justification cannot be provided. Ultimately, the decision as to whether the operation of an irradiator is justified should be made on a case by case basis by the appropriate governmental authority, which should weigh the various benefits and risks associated with its use in determining whether the specific practice is justified. The governmental authority's decision as to whether the operation of irradiators in the State is justified may also be made on a general basis for all irradiators of a specific type.

3. TYPES OF IRRADIATOR

GAMMA IRRADIATION FACILITIES

3.1. For the purposes of this Safety Guide, there are four general categories of gamma irradiator, defined on the basis of the design of the facility and, in particular, the accessibility and shielding of the radioactive source^{4,5}. Category I gamma irradiators (i.e. self-shielded irradiators) are not dealt with in this Safety Guide, since they are distinct for the purposes of radiation safety. For the purposes of this Safety Guide, the relevant categories of gamma irradiator are

⁴ The four categories of gamma irradiator have historically been designated with Roman numerals I–IV. The categories of gamma irradiator should not be confused with the categories used in the IAEA's Categorization of Radioactive Sources [5], which uses Arabic numerals 1–5.

⁵ In this context the term 'radioactive source' may apply to one individual sealed source or collectively to a number of radioactive sources in a source array.

Category II (panoramic dry source storage irradiators), Category III (underwater irradiators) and Category IV (panoramic wet source storage irradiators).

Category II (panoramic dry source storage irradiators)

3.2. A panoramic dry source storage irradiator is a controlled human access irradiator in which the radioactive source is: enclosed in a dry container constructed of solid materials, fully shielded⁶ when not in use and exposed within an area that is kept inaccessible during operation by means of an entry control system (Fig. 1).

3.3. Dry source storage facilities generally consist of either a built-in or a transportable radioactive source storage container constructed of solid materials. Inserts, brackets and other hardware are used to anchor or hold in place such items as the source holder⁷, guide rods or cables, and various pipes for other services.

3.4. Components of irradiators that are subjected to high dose rates should be resistant to radiation damage. Surfaces in close proximity to radioactive sources should be able to be easily decontaminated and should be constructed of materials that are corrosion resistant and metallurgically compatible with each other and with other components, including the source capsules⁸. The irradiator should be designed to maintain the integrity of its radiation shielding under conditions of normal use, anticipated operational occurrences and plausible accident conditions such as fire conditions.

Category III (underwater irradiators)

3.5. A self-contained wet source storage irradiator is an irradiator in which the radioactive source is stored in a pool of water, the source is shielded at all times, and human access to the source and to the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use (Fig. 2).

⁶ 'Fully shielded' means the condition in which the source is stored is such that dose rates in the radiation room are optimized, allowing the room to be occupied by workers.

⁷ The source holder is that component of the irradiator within which the radioactive source is positioned, including any retaining screws, pins, clips, etc.

⁸ The source capsule is the protective envelope of a sealed source which prevents leakage of radioactive material.

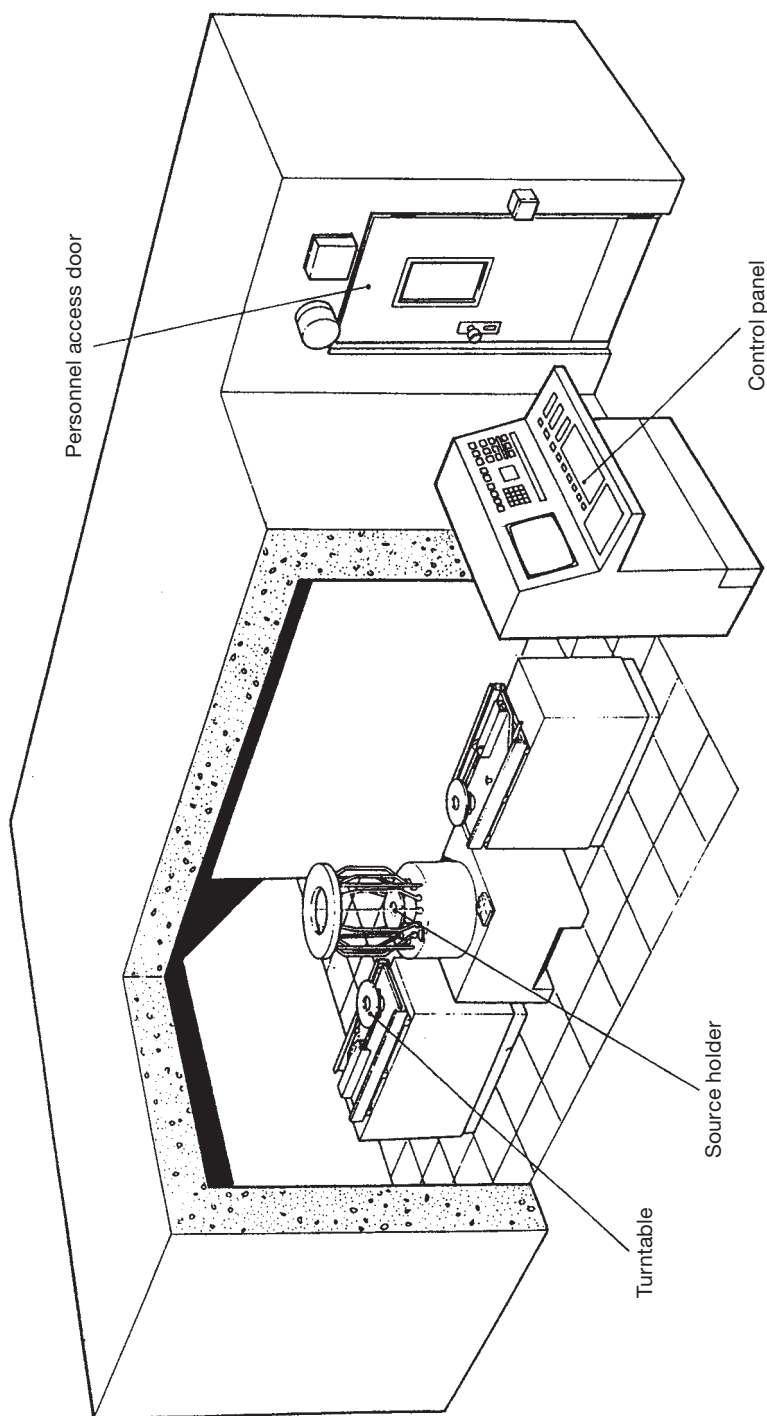


FIG. 1. Category II gamma irradiation facility: Panoramic dry source storage irradiator.

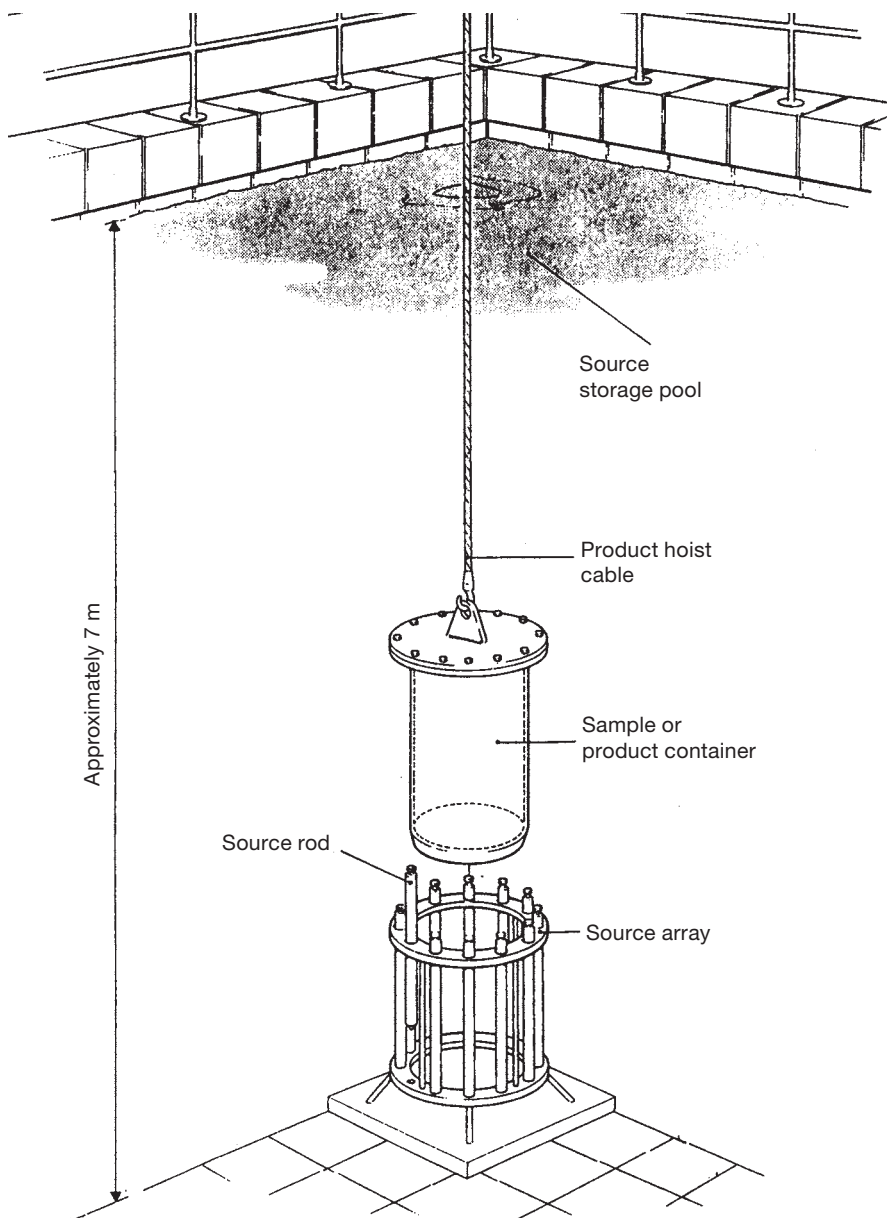


FIG. 2. Category III gamma irradiation facility: Underwater irradiator.

Category IV (panoramic wet source storage irradiators)

3.6. A panoramic wet source storage irradiator is a controlled human access irradiator in which the radioactive source is stored and fully shielded in a pool of water when not in use. The source is exposed within a radiation room that is kept inaccessible during operation by means of an entry control system (Fig. 3).

IRRADIATION FACILITIES WITH RADIATION GENERATORS

3.7. A similar categorization may be applied to irradiators utilizing radiation generators, with Category I irradiators being integrally shielded units with safety interlocks⁹. Category I electron beam irradiation facilities and X ray irradiation facilities are not within the scope of this Safety Guide. Category II units are housed in shielded rooms which are kept inaccessible during operation by means of an entry control system (Figs 4 and 5).

3.8. Irradiators with radiation generators include equipment that accelerates electrons within a vacuum system. The electron beam is used to irradiate product directly or, in X ray irradiators, is directed at a target to generate X rays that irradiate product.

3.9. Category II electron beam irradiators and X ray irradiators may give rise to radiation protection issues that are not relevant for gamma irradiators, with regard to neutron radiation fields and the activation of materials. The thresholds above which these issues may be relevant are dependent upon a number of factors, such as product material and target material, but are typically only significant at energies above 10 MeV for electron beams and 5 MeV for X ray irradiators.

⁹ A safety interlock is an engineered device for precluding exposure of an individual, either by preventing entry to the controlled area or by automatically removing the cause of the hazard.

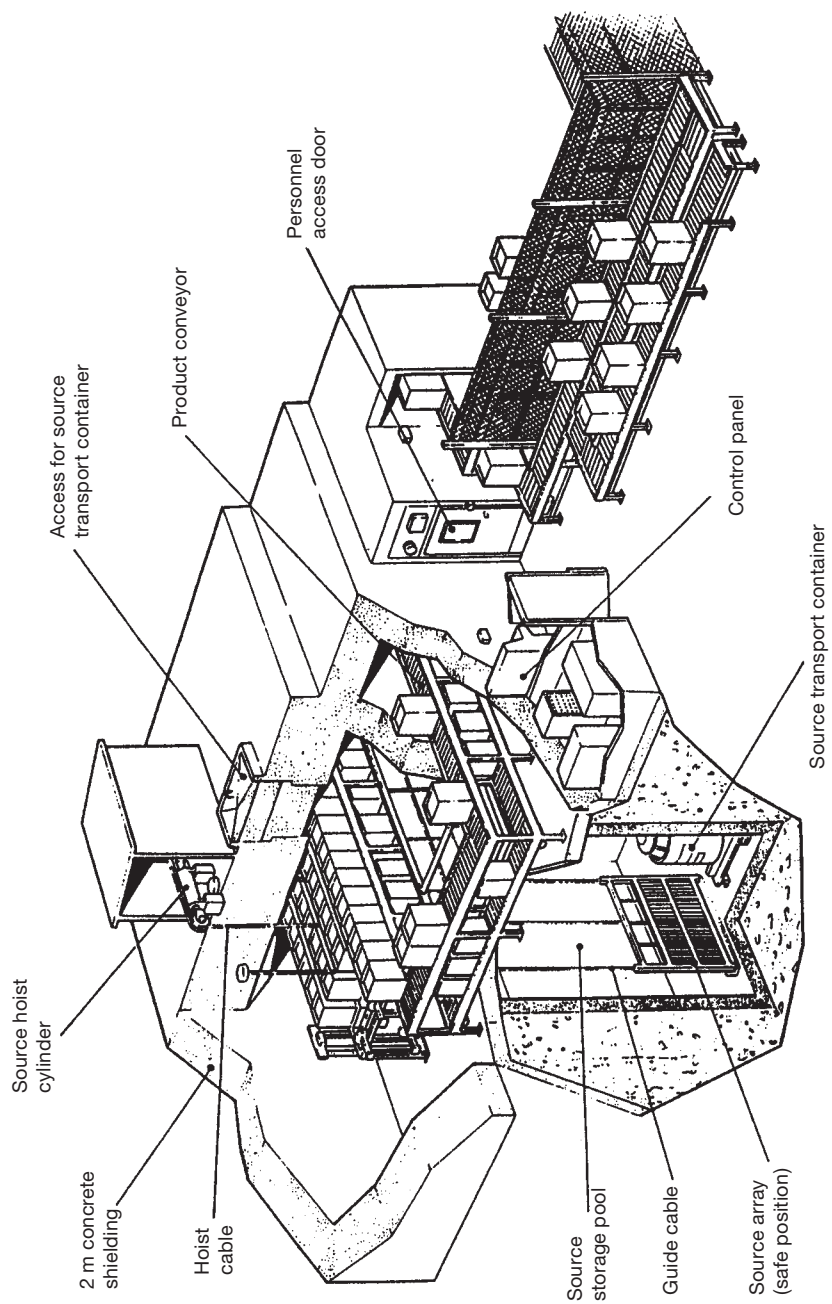


FIG. 3. Category IV gamma irradiation facility: Panoramic wet source storage irradiator.

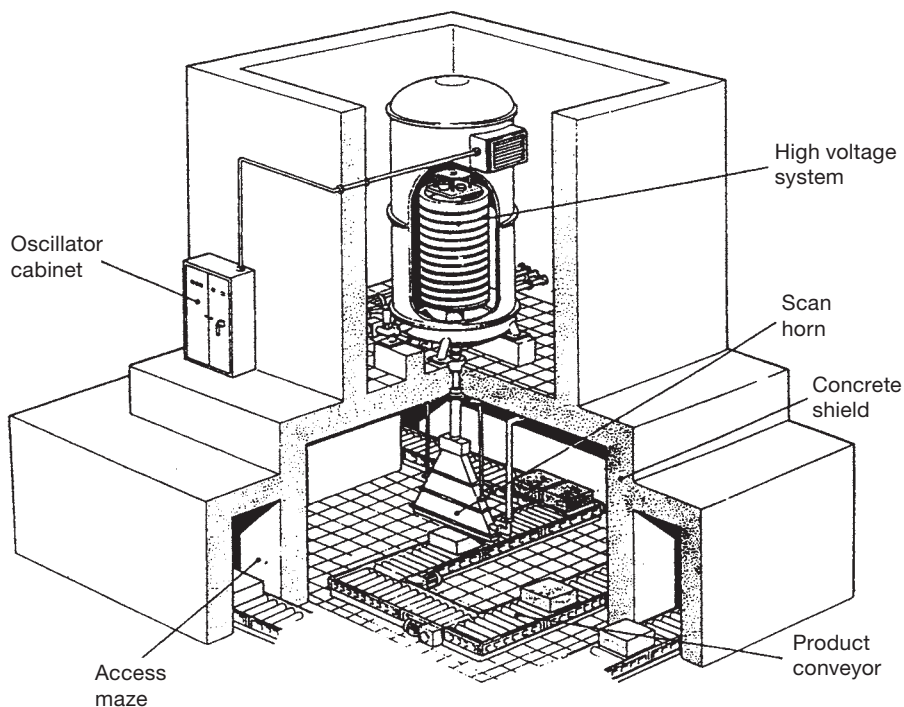


FIG. 4. Category II electron beam irradiation facility: Unit housed in shielded rooms kept inaccessible during the irradiation process.

4. PRINCIPAL ELEMENTS OF PRACTICES

NOTIFICATION AND AUTHORIZATION OF THE PRACTICE

4.1. The BSS [2] require, in paras 2.10 and 2.11, that a person or organization intending to build or operate an irradiation facility notify the regulatory body of this intention and submit an application for authorization. This application should contain information that demonstrates the safety of the practice. The type and amount of information that should be provided in the application is discussed in Ref. [6]. Specific guidance relating to the preparation of an application for the authorization of an irradiator, and its subsequent review by the regulatory body, is included in a supplement to that Safety Guide [7]. As required by the BSS [2], in paras 2.11 and 2.12, given the risks involved in the operation of an irradiator, the authorization granted by the regulatory body should take the form of a licence rather than registration.

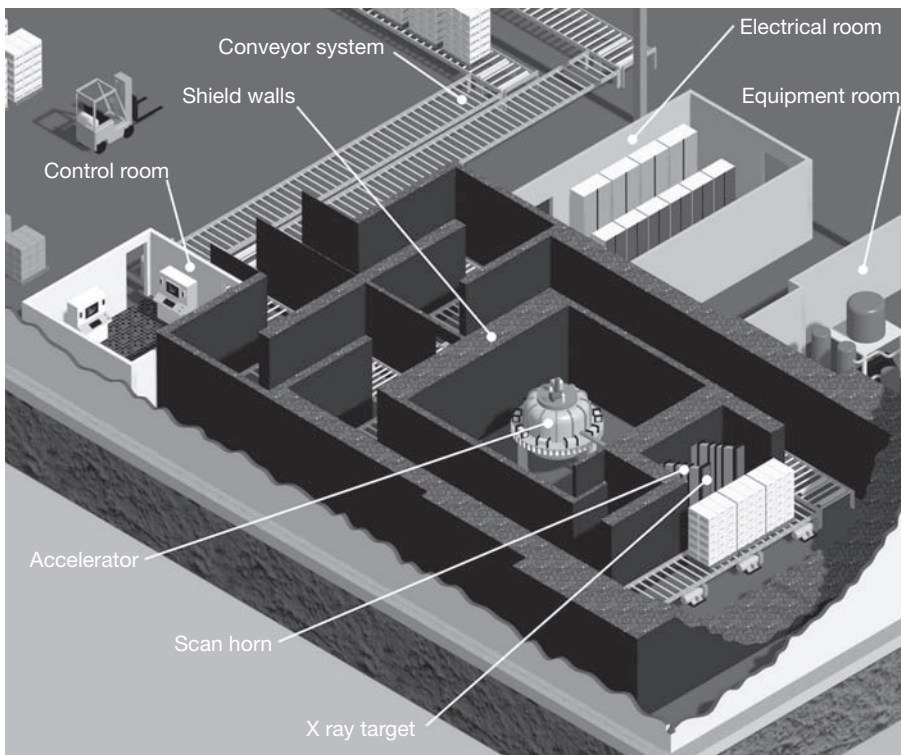


FIG. 5. Category II X ray irradiation facility: Unit housed in shielded rooms kept inaccessible during the irradiation process (courtesy of Sterigenics International).

4.2. The operating organization should obtain the approval of the regulatory body before implementing any modifications of the irradiator that may have significant implications for radiation protection. The manufacturer(s) of the irradiator and of its sources and key components should also be contacted, where appropriate, regarding proposed modifications of the irradiator (see para. 9.15).

RESPONSIBILITIES OF THE OPERATING ORGANIZATION

4.3. The operating organization's management is responsible for the operation of the irradiator and for its safety. For new facilities, the operating organization will obtain a licence from the regulatory body for the siting, design, construction, acquisition, storage and operation of the irradiator. The operating organization is responsible for the operation of the irradiator in accordance with regulatory requirements.

4.4. The operating organization of an irradiator should ensure that the facility is designed to meet the radiation safety objectives given in paras 4.13–4.16, as well as any more specific safety requirements of the regulatory body pertaining to site selection and evaluation, construction, installation, operation, maintenance and decommissioning. This should be achieved by:

- Using a qualified expert in radiation safety who is accredited according to criteria specified by the regulatory body and who is knowledgeable about the safe design of irradiation facilities.
- Ensuring that the following items are provided:
 - A detailed description of the design and operation of the safety systems, including control circuit diagrams.
 - Detailed operating procedures and maintenance procedures, including the type and frequency of checks of safety and control systems, routine monitoring and radiation surveys.
 - Safety assessments using formal methods of analysis appropriate to the level of risk associated with the facility. The operating organization should also carry out a safety assessment on the basis of information provided by the supplier and the operating organization's own administrative rules.
 - Instructions and procedures to be followed in an emergency, as outlined in Section 11.

4.5. The operating organization of an irradiation facility should ensure that all documents provided by the manufacturer, supplier and installer (operating manuals, operating rules and procedures, and emergency procedures) are available in the local language and are understandable to the users.

4.6. The BSS [2], in para. IV.23, require operating organizations to ensure that information on both normal and abnormal operations significant to protection and safety is disseminated or made available, as appropriate, to the regulatory body and to manufacturers and/or suppliers, as specified by the regulatory body. This information would cover, for example, maintenance data, descriptions of events, information regarding defects in materials and equipment, weaknesses in operating procedures and corrective actions. The operating organization should ensure that any new information of this type that is known to manufacturers and suppliers is obtained from them as rapidly as possible. It may be necessary for the operating organization to periodically seek this information from the manufacturer and/or supplier, rather than relying upon them to provide it.

4.7. The operating organization of a facility should ensure that construction and installation work does not compromise the safety of the facility. On completion of the installation, or at appropriate stages during construction, the operating organization should ensure that a qualified expert¹⁰ thoroughly and critically reviews the facility and any component part before it is commissioned. This should ensure that:

- Safety features and warning signals and alarms have been properly installed and operate correctly;
- Radiation protection for workers and members of the public and protection of the environment are adequate.

4.8. The operating organization of a facility should ensure that the constructor or installer provides it with adequate information about the proper operation, maintenance and decommissioning of the facility. The operating organization should also ensure that designers, manufacturers, constructors and installers cooperate to provide employees with the necessary theoretical and practical training to enable them to work in a safe manner.

4.9. The operating organization should permit inspection of its facilities and records by the regulatory body.

4.10. The operating organization should notify the regulatory body of any proposed modifications of the irradiator or changes to key personnel, in particular senior managers, the principal radiation protection officer, qualified experts and irradiator operators.

4.11. The operating organization should notify the regulatory body of, and should submit a plan for, the transfer or disposal of radioactive sources when they are no longer in use.

4.12. At the end of the operating lifetime of the irradiation facility, the operating organization should ensure that: buildings and equipment are free from radioactive material and contamination before disposal or resale; all radioactive

¹⁰ The term ‘qualified expert’ is used in various places in this Safety Guide without modification. It should be noted that the individual should be a qualified expert in a field (e.g. radiation protection or design and operation of irradiation facilities) that is relevant to the issues being described.

sources are properly accounted for¹¹ before they are returned to the supplier or disposed of in accordance with national regulations; and any radioactive waste resulting from decontamination is disposed of in accordance with regulatory requirements.

MANAGEMENT AND ORGANIZATIONAL RESPONSIBILITIES

General

4.13. Operating organizations should provide the human and material resources necessary to ensure safe working conditions and compliance with regulatory requirements.

4.14. Operating organizations should ensure that all aspects of protection and safety are provided for in a systematic manner. To meet this objective, operating organizations should establish and maintain a radiation protection programme that includes a commitment by management to developing and promoting a safety culture that encourages a questioning and learning attitude to protection and safety, and that discourages complacency. The commitment should also include the allocation of adequate time, personnel and equipment.

Radiation protection programme

4.15. The general objective of a radiation protection programme is to discharge the management's responsibility for radiation protection and safety through the adoption of management structures, policies, procedures and organizational arrangements that are commensurate with the nature and extent of the radiation risks. The radiation protection programme represents the totality of actions undertaken to achieve the stated aims of the operating organization for radiation protection and safety. Doses received by workers and members of the public should thus be kept well below the relevant dose limits specified in the BSS [2].

4.16. Application of the optimization principle should be the principal driving force behind the establishment and implementation of radiation protection programmes, including in many cases measures to prevent or reduce potential

¹¹ 'Accounting' in this context means physically checking that all radioactive sources are present in their intended locations. This may be undertaken by means of an appropriate radiation survey.

exposures and to mitigate the consequences of accidents. The existence of a radiation protection programme is not sufficient in itself; managers and workers should demonstrate their ongoing commitment to the programme and its objectives. Detailed guidance on establishing and maintaining a radiation protection programme that focuses on the protection of workers is provided in IAEA Safety Standards Series No. RS-G-1.1 [8].

Structure of the radiation protection programme

4.17. The radiation protection programme may include a top level policy document supported by detailed and specific procedures or ‘local rules’ and a comprehensive system of records. These components should consist of the following:

- A policy document specifying:
 - Objectives;
 - Responsibilities;
 - Training;
 - Safety assessment;
 - Quality management.
- Procedures and local rules covering:
 - Operation (e.g. access control, startup and shutdown procedures);
 - Maintenance and loading and unloading of radioactive sources¹²;
 - Transport of radioactive sources (see footnote 12);
 - Individual monitoring;
 - Training;
 - Leakage testing of radioactive sources (see footnote 12);
 - Testing of radiation monitors;
 - Routine checks by a radiation protection officer;
 - Audits and safety assessments by a qualified expert;
 - Response to visible and audible alarms;
 - Incident reporting and investigation;
 - Emergency response.
- A system of records covering:
 - Documentation of authorization and any correspondence between the operating organization and the regulatory body;
 - Name of the authorized person responsible for the radiation protection programme;

¹² This applies for gamma irradiation facilities only.

- Safety assessment reports;
- Operation logbook;
- Routine checks of safety systems by a radiation protection officer;
- Individual doses (current and prior work history);
- Results of workplace monitoring;
- Radiation monitor test reports;
- Results of leakage tests of radioactive sources (see footnote 12);
- Inventory of radioactive sources (see footnote 12)¹³;
- Records of movements of radioactive sources (see footnote 12);
- Reports on investigations of incidents and accidents;
- Audits and reviews of the radiation safety programme (by a qualified expert);
- Installation, maintenance and repair work;
- Facility modifications;
- Training provided (initial and refresher);
- Transport of radioactive sources (see footnote 12):
 - Transport documentation;
 - Contamination surveys and radiation level surveys;
- Disposal or return of radioactive sources (see footnote 12);
- Records of training, which should include the following information:
 - Name of the person who received the instruction or training;
 - Name of the institution or person who provided the instruction or training;
 - Date and duration of the instruction or training;
 - A summary or list of the topics addressed;
 - Results of examinations taken;
 - Copies of training certificates.

Safety assessment

4.18. In order to comply with the requirement in para. IV.3 of the BSS [2], a formal method of safety assessment such as probabilistic safety assessment (PSA) should be used. Examples of the application of techniques of probabilistic safety assessment to industrial irradiators are given in ICRP Publication No. 76 [9]. Guidance on methods of probabilistic safety assessment is provided in IAEA Safety Standards Series No. RS-G-1.10 [10].

¹³ ‘Inventorying’ means conducting a campaign to physically check all radioactive sources under the responsibility of a person or organization, by specifically and uniquely identifying each individual source using appropriate means such as serial numbers.

4.19. In 2003, an IAEA coordinated research project studied the benefits and limitations of the application of techniques of probabilistic safety assessment to radiation sources. In this research project, techniques of probabilistic safety assessment were applied to a Category IV gamma irradiator. The results of this project were presented in IAEA-TECDOC-1494 [11].

4.20. The operating organization should demonstrate to the regulatory body how the design of the irradiation facility and the related operational procedures will contribute to the prevention of accidents or to the mitigation of the effects of accidents. This information should be provided in the form of a documented safety assessment describing and evaluating the predicted response of the plant to incidents (including postulated malfunctions or failures of equipment, common cause failures and human errors) and external events that could lead to accident conditions. These analyses should include consideration of combinations of such malfunctions, failures, errors and events.

4.21. Examples of issues to be examined in the safety assessment include:

- Loss of access control;
- Malfunctions and failures of structures, systems and components;
- Loss of control over the system for the movement of radioactive sources, including a source rack becoming stuck in the unshielded position (see footnote 12);
- Loss of integrity of systems or components, including shielding integrity, encapsulation of sealed sources and pool integrity (see footnote 12);
- Electrical distribution faults, from localized faults to complete loss of external energy sources;
- Failures of safety systems caused by fires within the facility;
- Failures of safety systems resulting from external causes such as storms, floods, earthquakes or explosions;
- Failures of personnel to observe proper, safe procedures (for whatever reasons);
- Breakdown of procedures for preventing access to the facility by unauthorized persons;
- Breakdown of administrative procedures, leading to unsafe practices;
- Detection of contamination;
- High radiation levels in locations where high levels would not be expected.

Verification of safety

4.22. Paragraphs 2.38–2.40 of the BSS [2] require that monitoring and measurements be conducted of the parameters necessary for the verification of compliance with the safety standards. The BSS also require that equipment used for this purpose be properly maintained, and be tested and calibrated at appropriate intervals against standards that are traceable to national or international reference standards.

4.23. Operating organizations should conduct periodic audits to verify compliance with the requirements of the regulatory body. However, the regulatory body has the overall responsibility for ensuring that practices within its jurisdiction remain in compliance with regulatory requirements. Audits that are conducted by the regulatory body when the irradiator is being commissioned, as well as at regular intervals during its operation, should be part of the verification process. General information about the inspection of radiation sources and regulatory enforcement, including examples of checklists for the inspection of industrial irradiators, are included in IAEA-TECDOC-1526 [12].

Radiation protection officer

4.24. A radiation protection officer should be a person technically competent in radiation protection matters of relevance for a given type of irradiator who is designated by the operating organization to oversee compliance with the requirements of the safety standards. Radiation protection officers play a supervisory role in assisting the operating organization in discharging its responsibilities with regard to radiation safety. A principal radiation protection officer should report directly to senior management and should have sufficient authority to discharge his/her duties.

4.25. In cases where there is a potential conflict between operational responsibilities, such as responsibilities for meeting production targets and responsibilities for radiation safety, radiation safety requirements should always take priority. At least one radiation protection officer should be available, though not necessarily physically present, at all times. In addition to a principal radiation protection officer, irradiation facilities will often have several radiation protection officers who are present at the facility during different work shifts throughout the day. The operating organization should notify the regulatory body of the appointment of radiation protection officers in accordance with regulatory requirements.