

IAEA Safety Standards

for protecting people and the environment

Radiation Safety of Accelerator Based Radioisotope Production Facilities

Specific Safety Guide

No. SSG-59



IAEA

International Atomic Energy Agency



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IAEA SAFETY STANDARDS

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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**RADIATION SAFETY OF
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RADIOISOTOPE PRODUCTION
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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-59

RADIATION SAFETY OF ACCELERATOR BASED RADIOISOTOPE PRODUCTION FACILITIES

SPECIFIC SAFETY GUIDE

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2020

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FOREWORD

The IAEA's Statute authorizes the Agency to “establish or adopt... standards of safety for protection of health and minimization of danger to life and property” — standards that the IAEA must use in its own operations, and which States can apply by means of their regulatory provisions for nuclear and radiation safety. The IAEA does this in consultation with the competent organs of the United Nations and with the specialized agencies concerned. A comprehensive set of high quality standards under regular review is a key element of a stable and sustainable global safety regime, as is the IAEA's assistance in their application.

The IAEA commenced its safety standards programme in 1958. The emphasis placed on quality, fitness for purpose and continuous improvement has led to the widespread use of the IAEA standards throughout the world. The Safety Standards Series now includes unified Fundamental Safety Principles, which represent an international consensus on what must constitute a high level of protection and safety. With the strong support of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its standards.

Standards are only effective if they are properly applied in practice. The IAEA's safety services encompass design, siting and engineering safety, operational safety, radiation safety, safe transport of radioactive material and safe management of radioactive waste, as well as governmental organization, regulatory matters and safety culture in organizations. These safety services assist Member States in the application of the standards and enable valuable experience and insights to be shared.

Regulating safety is a national responsibility, and many States have decided to adopt the IAEA's standards for use in their national regulations. For 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 regulatory bodies and operators around the world to enhance safety in nuclear power generation and in nuclear applications in medicine, industry, agriculture and research.

Safety is not an end in itself but a prerequisite for the purpose of the protection of people in all States and of the environment — now and in the future. The risks associated with ionizing radiation must be assessed and controlled without unduly limiting the contribution of nuclear energy to equitable and sustainable development. Governments, regulatory bodies and operators everywhere must ensure that nuclear material and radiation sources are used beneficially, safely and ethically. The IAEA safety standards are designed to facilitate this, and I encourage all Member States to make use of them.

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. Requirements, including numbered ‘overarching’ requirements, are expressed as ‘shall’ statements. 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

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

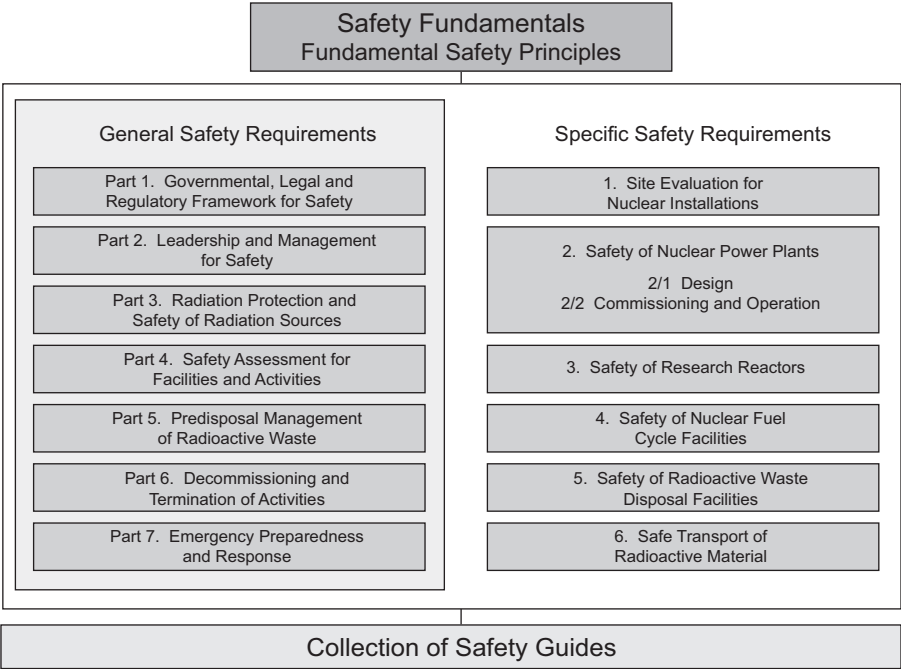


FIG. 1. The long term structure of the IAEA Safety Standards Series.

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 five safety standards committees, for emergency preparedness and response (EPReSC) (as of 2016), 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).

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.

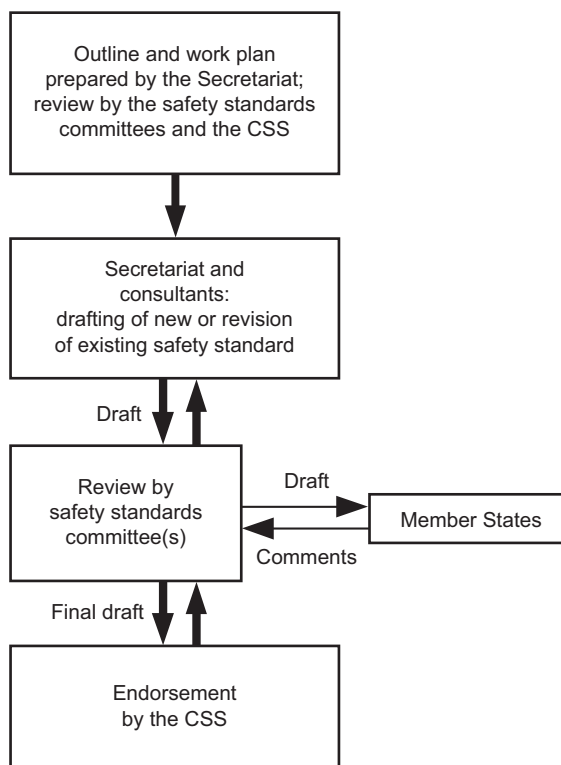


FIG. 2. The process for developing a new safety standard or revising an existing standard.

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. Radionuclides are used worldwide in a range of medical, industrial, research and academic applications that bring many benefits to humankind. Most of these radionuclides are produced in reactors and particle accelerators. Facilities that produce radionuclides and facilities in which radionuclides are processed are referred to collectively as ‘radioisotope production facilities’¹. The operation of reactors and particle accelerators and the subsequent processing of radioactive material can present significant radiation hazards to workers, the public and the environment unless these facilities are properly controlled.

1.2. In 2017, there were 238 research reactors in operation, of which approximately 83 were deemed useful for regular radioisotope production [1]. In 2015, it was estimated that there were approximately 1200 cyclotrons worldwide used to some extent for radioisotope production [2]. The number of institutions that operate cyclotrons and manufacture and distribute radiopharmaceuticals that are used in positron emission tomography and single photon emission computed tomography is significant and growing.

1.3. IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3] establishes the basic requirements for protection of people and the environment against exposure to ionizing radiation and for the safety of radiation sources². The application of these requirements at radioisotope production facilities is intended to prevent accidents and, generally, to provide for the best possible protection and safety measures under the prevailing circumstances. The magnitudes and likelihood of exposures and the number of individuals exposed are required to be kept as low as reasonably achievable, economic and societal factors being taken into account.

¹ The term ‘radioisotope’ is commonly used in the context of the facilities considered in this Safety Guide and is therefore retained here. Strictly, the word ‘radionuclide’ ought to be used or the word ‘radioisotope’ would need to be qualified by the name of the element to which it relates (e.g. a radioisotope of cobalt).

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

1.4. Unless otherwise stated, terms are used with the meanings ascribed to them in the IAEA Safety Glossary [4] and the definitions provided in GSR Part 3 [3].

OBJECTIVE

1.5. The objective of this Safety Guide is to provide recommendations on how to meet the requirements of GSR Part 3 [3] with regard to radioisotope production facilities. This Safety Guide provides specific, practical recommendations on the safe design and operation of radioisotope production facilities for use by operating organizations, the designers of these facilities, and regulatory bodies.

SCOPE

1.6. This Safety Guide addresses the radiation safety and protection aspects of the process in which radioisotopes are produced in accelerators (principally cyclotrons), and of the process in which radioisotopes that have been produced in accelerators, or have been purified from other sources, are processed into radioactive products for subsequent use in, for example, nuclear medicine. It also addresses elements of the design and operation of accelerators (principally cyclotrons) that pertain directly to the production of radioisotopes.

1.7. The following types of facility that produce radioisotopes are within the scope of this Safety Guide:

- (a) Facilities that process targets that have been irradiated by the charged particle beam of an accelerator to produce radioisotopes.
- (b) Accelerator facilities with energies of less than 70 MeV/nucleon that are operated principally to produce radioisotopes. This Safety Guide addresses the following four types of accelerator:
 - (i) Low energy (<20 MeV/nucleon) cyclotrons used for medical radioisotope production;
 - (ii) 20–40 MeV/nucleon cyclotrons used for radioisotope production;
 - (iii) >40 MeV/nucleon cyclotrons used for both research and radioisotope production;
 - (iv) Linear accelerators used for radioisotope production.

1.8. The use of radioactive material after its manufacture, and the standards and quality assurance procedures that pertain to its production, are outside the scope

of this Safety Guide. The production of fissile material is outside the scope of this Safety Guide.

1.9. The design and operation of reactors is outside the scope of this Safety Guide; safety requirements for research reactors are established in IAEA Safety Standards Series No. SSR-3, Safety of Research Reactors [5].

1.10. Centralized radiopharmacies that manufacture radiopharmaceuticals from bulk quantities of radioisotopes are outside the scope of this Safety Guide.

1.11. Radiation generators (e.g. linear accelerators used in radiotherapy applications) that produce radioisotopes as a by-product of their operation are outside the scope of this Safety Guide.

1.12. Consideration of non-radiological risks and of the benefits of radioisotopes that are produced in radioisotope production facilities is outside the scope of this Safety Guide.

1.13. The Safety Guide provides information on the need for appropriate nuclear security measures and on their interface with safety measures, but does not provide specific guidance on such nuclear security aspects. Additional guidance on nuclear security is provided in the IAEA Nuclear Security Series [6–9].

STRUCTURE

1.14. The justification of radioisotope production facilities is addressed in Section 2 of this Safety Guide. Designs of irradiation facilities are grouped according to the design of the facility and the resultant radiation protection provisions necessary, as described in Section 3. The authorization of irradiation practices, the responsibilities of the operating organization and general radiation safety issues are described in Section 4. Safety assessment and the radiation protection programme are described in Sections 5 and 6, respectively. Section 7 provides recommendations on education and training of personnel of radioisotope production facilities. Section 8 deals with individual monitoring of workers of radioisotope production facilities. Section 9 provides recommendations on workplace monitoring. Section 10 focuses on environmental monitoring and discharge of radioactive effluents. Section 11 addresses personal protective equipment used by personnel. Section 12 sets out nuclear security considerations. Sections 13 to 16 provide recommendations on testing and maintenance of

equipment, radioactive waste management, transport of radioactive material, and emergency preparedness and response, respectively.

1.15. Annex I sets out examples of key radiation safety issues to be considered in planning the production of radioisotopes, while examples of emergency response actions are provided in Annex II.

2. JUSTIFICATION OF PRACTICES

2.1. IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [10] states that the fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation. Principle 4 on justification of facilities and activities states that **“Facilities and activities that give rise to radiation risks must yield an overall benefit.”**

2.2. The basic requirements for radiation protection for facilities and activities established in GSR Part 3 [3] cover justification of practices, optimization of protection and safety, and individual dose limits.

2.3. When the principle of justification was first formally expressed, many practices, such as the operation of radioisotope production facilities, were already in widespread use, and in general their justification was implicit. Under normal conditions, the design, construction, operation and maintenance of radioisotope production facilities result in doses to workers and the public that are a small fraction of the respective dose limits in GSR Part 3 [3]. However, the operation of radioisotope production facilities can on occasion result in doses to workers and releases of radioactive material to the environment that might be in excess of authorized limits. Furthermore, the operation of inadequately designed facilities could result in elevated dose rates in both uncontrolled areas and unsupervised areas, which could result in dose limits being exceeded. In addition, there are other inherent radiation risks, including those associated with the security of radioactive material, the transport of radioactive material and also, ultimately, the disposal of radioactive waste.

2.4. IAEA Safety Standards Series No. RS-G-1.9, Categorization of Radioactive Sources [11] establishes a categorization system for radioactive sources based on the concept of dangerous quantities of radioactive material (D values). The D value is that quantity of radioactive material, which, if uncontrolled, could

result in the death of an exposed individual or a permanent injury that decreases that person's quality of life [12].

2.5. Within this categorization system [11], sources in Category 1 are considered to be the most dangerous because they can pose a very high risk to human health if not managed safely and securely. An exposure of only a few minutes to an unshielded Category 1 source could be fatal. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, these sources could give rise to doses in excess of the dose limits if not properly controlled, and therefore they need to be kept under appropriate regulatory control. The finished products of radioisotope production generally fall into Categories 3–5. The category of such products should be determined on a case by case basis for each product.

2.6. The decision as to whether the operation of a radioisotope production facility is justified is specific to the circumstances and benefits of its use, including national priorities, so definitive recommendations regarding justification cannot be provided. Ultimately, the decision as to whether the operation of such a facility is justified should be made on a case by case basis by the appropriate governmental authority or authorities, which should consider the various benefits and risks associated with its operation. The decision as to whether the operation of radioisotope production facilities in the State is justified may also be made on a general basis for all radioisotope production facilities of a specific type.

3. TYPES OF RADIOISOTOPE PRODUCTION FACILITY

3.1. For the purposes of this Safety Guide, the following general types of radioisotope production facility (see para. 1.7) are defined on the basis of the design of the facility and the resultant radiation protection provisions necessary:

- (a) Facilities that process targets that have been irradiated by the charged particle beam of an accelerator to produce radioisotopes.
- (b) Accelerator facilities with energies of less than 70 MeV/nucleon that are operated principally to produce radioisotopes. This Safety Guide addresses the following four types of accelerator:
 - (i) Low energy (<20 MeV/nucleon) cyclotrons used for medical radioisotope production;

- (ii) 20–40 MeV/nucleon cyclotrons used for radioisotope production;
- (iii) >40 MeV/nucleon cyclotrons used for both research and radioisotope production;
- (iv) Linear accelerators used for radioisotope production.

When recommendations in this Safety Guide only apply to specific types of radioisotope production facility, those types are specified.

3.2. When an accelerated particle such as a proton collides with the nucleus of a target atom a reaction occurs forming a radioisotope product. Many of the radionuclides produced in accelerators cannot be produced by the neutron reactions that occur in reactors. In some cases, the radioisotopes produced by accelerators have higher specific activities than those radionuclides produced in reactors. Accelerators are used for activation of isotopes for use in research and in the production of radiopharmaceuticals. Examples of different types of accelerator can be found in section 6 of Ref. [13].

3.3. Some accelerators are designed specifically for the production of positron emission tomography radiopharmaceuticals (e.g. ^{18}F). Such accelerators are designed for use in radioisotope production facilities or hospitals. To produce ^{18}F , the target is irradiated and the liquid mixture (^{18}O water containing ^{18}F) is transferred in capillary pipes to a processing hot cell.

3.4. Accelerators for the production of radioisotopes are generally located in the same building in which the radioisotopes are processed into radioactive products for subsequent use.

4. DUTIES AND RESPONSIBILITIES

GENERAL

4.1. IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [14] establishes requirements for the governmental, legal and regulatory infrastructure for safety of facilities and activities, including those associated with radioisotope production facilities, and attributes duties and responsibilities to all relevant parties. GSR Part 3 [3] provides the general framework for these duties and responsibilities, and this section provides further guidance in the context of radioisotope production facilities.

4.2. The operating organization responsible for the radioisotope production facility has the prime responsibility for safety. Other parties also have specified responsibilities with regard to protection and safety. In accordance with para. 3.6 of SF-1 [10], the operating organization is responsible for:

- “— Establishing and maintaining the necessary competences;
- Providing adequate training and information;
- Establishing procedures and arrangements to maintain safety under all conditions;
- Verifying appropriate design and the adequate quality of facilities and activities and of their associated equipment;
- Ensuring the safe control of all radioactive material that is used, produced, stored or transported;
- Ensuring the safe control of all radioactive waste that is generated.”

4.3. For a radioisotope production facility located within a hospital, the operating organization for the hospital has the prime responsibility for safety.

4.4. The operating organization is also responsible for establishing plans and procedures to respond to any nuclear or radiological emergency that might arise at the facility and for coordinating exercises to test such plans and procedures [3, 15].

4.5. Specific responsibilities for the design, operation and eventual decommissioning of the facility will, however, be assigned to individuals and groups at a range of hierarchical levels within the designer, constructor and operating organization, including senior management, the radiation protection officer, workers who operate the facility and handle radioactive material, and qualified experts or radiation protection advisers.

MANAGEMENT OF RADIATION SAFETY AND SAFETY CULTURE

4.6. The operating organization is responsible for the establishment and implementation of the technical and organizational measures necessary to ensure protection and safety and for compliance with the relevant legal and regulatory requirements. If this expertise is not available in-house, an external qualified expert or radiation protection adviser should be appointed to provide advice regarding radiation safety and compliance with regulatory requirements.

4.7. Responsibility for overseeing radiation safety and verifying that all activities involving radioactive material are performed in accordance with regulatory

requirements may be delegated to a senior manager. Other responsibilities in relation to radiation safety assigned within the operating organization should be agreed to by all relevant individuals and recorded in writing. The operating organization is required to set up and implement the technical and organizational measures necessary for the protection of workers, the public and the environment, and to ensure that doses are kept as low as reasonably achievable (optimization of protection and safety). All policies and procedures are required to be documented [3], and should be made available to all staff and the regulatory body as appropriate.

4.8. Managers are required to foster and sustain a strong safety culture within their organization, to encourage a questioning and learning attitude to protection and safety at all levels in the organization, and to discourage complacency with regard to safety [16]. A strong and effective safety culture is promoted by management arrangements and workers' attitudes, which interact to foster a safe approach to the performance of work. Safety culture is not confined to radiation protection; it should also extend to conventional safety.

4.9. In cases where there is a potential conflict between operational responsibilities, such as responsibilities for meeting a production schedule, and responsibilities for radiation safety, as an overriding priority the protection and safety issues should receive the attention warranted by their significance. If necessary, to ensure that radiation safety decisions are given priority, the radiation protection officer should be independent of the production department.

4.10. In order to foster and sustain a strong safety culture, management of the operating organization should consider all the circumstances in which incidents could occur; all individuals within the operating organization should strive to learn from their mistakes, maintain a questioning attitude and seek continuous improvement in the safety of work processes. If an incident occurs, the question of acceptability of behaviour should be addressed and, in some cases, disciplinary measures may be appropriate.

4.11. As stated in IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [16], the operating organization is required to establish, apply, sustain and continuously improve a management system to ensure safety. This integrated management system should specify the responsibilities of all relevant persons and set out the key radiation protection and safety requirements for personnel, equipment and the facility. The management system should be based on national or international standards [16, 17, 18]. It should incorporate mechanisms for routine internal inspections and audits, as well as third party

audits, as appropriate. The radiation protection programme should be a part of the integrated management system.

Facilities and resources

4.12. The operating organization is required to ensure that appropriate equipment and safety systems are provided to enable work to be performed safely and in accordance with regulatory requirements [3].

Notification and authorization

4.13. An application for authorization should contain information that demonstrates the safety of the practice. Recommendations on the preparation of an application for the authorization of a radioisotope production facility, and its subsequent review by the regulatory body, are provided in IAEA Safety Standards Series No. GSG-13, Functions and Processes of the Regulatory Body for Safety [19].

4.14. When applying for an authorization, the operating organization is required to provide the regulatory body with the appropriate documentary evidence to demonstrate that an adequate level of radiation safety will be afforded and maintained [3].

4.15. The documentary evidence necessary to support an authorization request should include, at a minimum, specific information concerning the following:

- (a) Identification of the operating organization and the individual(s) representing the operating organization;
- (b) The radioisotopes and the chemical forms of the material to be processed and stored;
- (c) The characteristics of the particle accelerator, i.e. its type (cyclotron or linear accelerator), energy, current, beam characteristics and layout, including its size and geometry;
- (d) The facility in which the particle accelerator will be located and/or the radioactive material will be processed and stored, including specific information on the associated safety systems and equipment, e.g. radiation shielding, interlock systems, fume hoods, remote handling tools, building ventilation system (including details of air pressures, the air flow pattern and the type of filters), effluent exhaust systems, monitoring systems and warning systems, emergency stop switches/trip wires, and their appropriate locations in the facility;

- (e) The locations where the particle accelerator will be operated and radioactive material will be processed and stored;
- (f) Means of verification that the recipient has an authorization to receive any radioactive material being transferred out of the facility;
- (g) The inventory system to be used to account for radioactive material, including targets;
- (h) Identification and details of qualifications of the radiation protection officer and, where appropriate, qualified experts or radiation protection advisers;
- (i) The operating organization's requirements for the training and qualification of all relevant staff;
- (j) Information supporting the justification for the facility;
- (k) The safety assessment covering the operation of the facility;
- (l) The radiation protection programme;
- (m) Arrangements for the management of radioactive waste;
- (n) Arrangements for responding to a nuclear or radiological emergency within the facility premises (see Section 16);
- (o) The initial decommissioning plan and financial assurance;
- (p) A radiological environmental impact analysis of the gaseous effluents discharged during normal operations and any gaseous radioactive releases due to accidents.

4.16. The operating organization should obtain the approval of the regulatory body before commencing construction of a new facility or implementing modifications to the facility. The operating organization should notify the regulatory body of any changes to key personnel, in particular senior managers and the principal radiation protection officer.

RADIATION PROTECTION OFFICER

4.17. The operating organization is required to appoint at least one employee as a radiation protection officer in accordance with criteria established by the regulatory body to oversee the day to day implementation of the radiation protection programme and to perform the duties required by the programme [3]. Although the radiation protection officer oversees the application of safety standards, the prime responsibility for safety remains with the operating organization. The radiation protection officer should be technically competent in radiation protection matters of relevance for the given type of radioisotope production facility. The radiation protection officer should report directly to senior management and should have sufficient authority to discharge his or her duties. The radiation protection officer should have the authority to intervene to stop an unsafe or non-compliant activity.

4.18. During times when the radiation protection officer is not available to provide oversight on radiation safety matters, such as during periods of absence from the facility, arrangements should be made for the prompt provision of authoritative advice concerning radiation safety matters. Such arrangements could include timely access to qualified experts or radiation protection advisers or the designation of deputy radiation protection officers who are present at the facility during times of operation.

4.19. The responsibilities of the radiation protection officer should include the following, some of which may require consultation with, or assistance from, a qualified expert:

- (a) Oversight of facility operations to assist the operating organization in complying with regulatory requirements;
- (b) Oversight of the review of the shielding design and of records regarding occupancy and workload;
- (c) Optimizing exposure controls and maintaining safety systems and other equipment that contributes to controlling exposure of workers and members of the public;
- (d) Oversight of the inspection and maintenance of safety systems, personal protective equipment, radiation monitoring equipment and warning systems;
- (e) Establishment of controlled areas and supervised areas and oversight of access control for controlled areas;
- (f) Periodic review of arrangements for individual monitoring of workers;
- (g) Investigation of high, unexpected or reportable exposures and overexposures;
- (h) Ensuring that workers are suitably trained in the use of equipment and in radiation protection, and that they receive regular refresher training;
- (i) Ensuring that emergency plans and procedures are established and maintained and that exercises are conducted as appropriate (see Section 16);
- (j) Oversight of arrangements for environmental monitoring, including review of the results of such monitoring;
- (k) Establishment, issue and periodic review of local rules (including work permits where appropriate);
- (l) Investigation and reporting of incidents, including accidents;
- (m) Liaising with contractors, designers and suppliers with regard to radiation protection matters and significant changes to physical or operational aspects of the facility;
- (n) Ensuring the adequacy of safety assessments and emergency plans for any reasonably foreseeable incidents with consequences for radiation protection;

- (o) Oversight of issues relating to the safe transport of sources, including the receipt of packages containing radioactive material and the preparation of packages for shipment;
- (p) Maintaining records relevant to the radiation protection programme, including records concerning the radioactive material inventory, records of occupational exposure from workplace monitoring and individual monitoring, records of environmental monitoring and records relating to radioactive waste management.

QUALIFIED EXPERTS AND RADIATION PROTECTION ADVISERS

4.20. A qualified expert or radiation protection adviser is an individual who, by virtue of certification by appropriate boards or societies, professional licences or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization. The qualifications of a qualified expert are described in paras 3.65 to 3.71 of IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [20].

4.21. The operating organization may identify one or more qualified experts or radiation protection advisers to provide advice on various matters concerning radiation safety in the design and operation of the facility. A qualified expert or radiation protection adviser need not be a full time employee of the operating organization but could be employed on a part time or an ad hoc basis. Regardless, arrangements should be made for the advice of a qualified expert or radiation protection adviser to be available when necessary. As with the radiation protection officer, the operating organization cannot delegate its responsibility for safety to a qualified expert.

4.22. The qualified expert or radiation protection adviser should be experienced in radiation protection matters and should:

- (a) Have had theoretical training that includes training in radiation protection and the properties of the radiation present in the radioisotope production facility;
- (b) Have a thorough knowledge of the hazards associated with the radiation and other potential hazards present and the ways in which the hazards can be controlled and minimized;
- (c) Have knowledge of the emergency preparedness category of the facility in the context of the emergency plans in accordance with the relevant requirements [15];

- (d) Have an understanding and detailed knowledge of the working practices in the facility, as well as general knowledge of the working practices in other similar facilities;
- (e) Have a detailed working knowledge of all regulatory provisions, relevant codes of practice and protection standards, guidance material and other information necessary for giving advice in connection with the work with radiation undertaken in the radioisotope production facility;
- (f) Have an awareness of regulatory requirements that could affect the work with radiation on which the qualified expert or radiation protection adviser gives advice;
- (g) Have the ability to give advice so that the operating organization can comply with regulatory requirements and follow good practices in relation to radiation protection;
- (h) Have the personal qualities to be able to communicate effectively with workers and their representatives;
- (i) Have the ability to keep up to date with developments in the use of radiation in the field in which the qualified expert or radiation protection adviser gives advice and with developments in radiation protection in general.

4.23. The operating organization should provide the qualified expert or radiation protection adviser with adequate information and resources as may be necessary for the qualified expert or radiation protection adviser to work effectively. The information should include a clear statement of the scope of the advice that the qualified expert or radiation protection adviser is expected to give.

4.24. The operating organization may consult the qualified expert or radiation protection adviser on a wide range of issues relating to radiation safety, including the following:

- (a) Optimization of protection and safety;
- (b) Maintenance of engineering features and other equipment;
- (c) Workplace monitoring, individual monitoring and environmental monitoring;
- (d) Investigation of high exposures and overexposures;
- (e) Staff training;

- (f) Safety assessment and emergency arrangements³;
- (g) Examination of any plans for a new facility or for modifications of an existing facility;
- (h) Independent audits relating to radiation safety matters;
- (i) Quality management;
- (j) Emergency preparedness and response (see Section 16);
- (k) Radioactive waste management.

WORKERS

4.25. While the prime responsibility for safety lies with the operating organization, workers (including assistants and trainees) have a responsibility to work safely and to take all reasonable actions to restrict their own exposure and those of other workers and members of the public. Workers include individuals whose work involves exposure to radiation or work activities that could result in exposures of other individuals, such as process operators, operators working with product shipments, operators working with waste, research scientists, pharmacists, laboratory technicians, personnel with housekeeping duties and personnel who perform routine maintenance activities. The competence of workers to perform their duties in a safe manner should be verified by the radiation protection officer. In order to meet Requirement 22 of GSR Part 3 [3], workers:

- (a) Should follow the local rules (see para. 4.29) and any relevant procedures.
- (b) Should wear their individual dosimeters in the correct place at all times during work where radiation exposure could occur and record their daily doses. If the dose exceeds the level set by the local rules they should report it to the responsible (senior) manager or the radiation protection officer (see Section 6).
- (c) Should use radiation monitors properly and in a systematic manner (see Section 8).
- (d) Should cooperate with the radiation protection officer and qualified experts on all radiation safety issues.
- (e) Should participate in any training concerning radiation safety, including emergency drills and exercises.

³ Emergency arrangements are “the integrated set of infrastructural elements, put in place at the preparedness stage, that are necessary to provide the capability for performing a specified function or task required in response to a nuclear or radiological emergency” [15]. These elements may include authorities and responsibilities, organization, coordination, personnel, plans, procedures, facilities, equipment or training.