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Radiation Safety of Accelerator Based Radioisotope Production Facilities

DRAFT SAFETY GUIDE No. SSG-

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CONTENTS

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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 2017, there were approximately 11700 clinical accelerators in operation worldwide, including both linear accelerators and cyclotrons, which were being 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 sources[2]. 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 a 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 following 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 or generators 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 are 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, 7, 8, 9].

STRUCTURE

1.14. The justification of radioisotope production facilities is addressed in Section 2. Designs of irradiation facilities are grouped according to radiation type and methods of accessibility and shielding, as described in Section 3 of this Safety Guide. 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 focusses 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 an example of key radiation safety issues to be considered in planning the production of radioisotopes, while an example of emergency response procedures is provided in Annexes 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 [11] establishes the categorization system of 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 source 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, general types of radioisotope production facility (~~refer~~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 a 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. ~~The principal~~ In some cases, ~~advantage of accelerator~~the ~~accelerator based~~ radioisotopes produced by accelerators have ~~production is the~~ higher specific activities~~y~~ than ~~is the case for~~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 accelerators 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, 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:

(a) "Establishing and maintaining the necessary competences;

(b) Providing adequate training and information;

(c) Establishing procedures and arrangements to maintain safety under all conditions;

(d) Verifying appropriate design and the adequate quality of facilities and activities and of their associated equipment;

(e) Ensuring the safe control of all radioactive material that is used, produced, stored or transported;

(f) 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 may 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 carried out 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~~,~~, ~~in order~~ to ~~enforce~~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 behavior should be addressed and, in some cases, disciplinary measures may be appropriate.

4.11. As stated in GSR Part 2 [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 carried out 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, as 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, ~~effluent exhaust systems, a description of~~building ventilation system (~~of the building with~~including details of air pressures, ~~the type of filters,~~ the air flow pattern and ~~the type of filters)~~~~air pressure~~, 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~~.~~;

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~~(o)~~(p) A radiological~~n~~ environmental impact analysis~~study~~ of the gaseous effluents discharged ~~exhausted into the environment~~ during normal operations and any gaseous radioactive releases due to ~~and~~ accident~~sal situations~~.

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 to oversee the day to day implementation of the radiation protection programme and to carry out 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 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 ~~preparedness and response~~ 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 expert to work effectively. The information should include a clear statement of the scope of the advice that the expert 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:

(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 arrangements[3];

[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

(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. 4.27) and any relevant procedures;
(b) Should wear their individual dosimeters in the correct place at all times during radiation work 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;

nuclear or radiological emergency" [14]. These elements may include authorities and responsibilities, organization, coordination, personnel, plans, procedures, facilities, equipment or training.

(f) Should abstain from any willful action that could put themselves or others in contravention of regulatory requirements or of the operating organization's local rules;

(g) Should contribute to building a safety culture.

4.26. Workers should promptly inform the radiation protection officer of any event or circumstances that could adversely affect protection and safety and/or result in radiation doses that exceed the organization's dose investigation level. Such events could include failures or observed deficiencies in safety systems and warning systems, errors in following procedures, or inappropriate behaviour. A written report should be made to the radiation protection officer as soon as practicable after the event or observation.

4.27. Radiation safety should be incorporated into the daily routine of work by all personnel.

4.28. Temporary workers should comply with the work practices and local rules of the facility.

LOCAL RULES AND PROCEDURES

4.29. The operating organization should ensure that local rules and procedures for protection and safety are fully understood by the workers. Local rules and procedures should, as a minimum, include the following (see also GSG-7 [20]):

(a) A description of the nature of the hazards posed by the facility and the safety features used to minimize the risks.

(b) Written emergency plans, procedures and instructions in line with their respective duties (see Section 16).

(c) A description of the functions, duties and responsibilities of key individuals within the operating organization with regard to radiation safety, including the qualified expert or radiation protection adviser and the radiation protection officer.

(d) The means of ensuring that persons entering controlled areas are wearing appropriate radiation monitoring devices and that the results of the monitoring are recorded.

(e) Access and egress monitoring procedures for workers and visitors.

(f) Written instructions covering actions to be taken in the event of malfunctions. These instructions should identify individuals to be notified in the event of a malfunction and should provide a general outline of the corrective actions to be taken.

(g) Written instructions to ensure that the facility is maintained as prescribed in the design documentation.

(h) Written instructions to require that workers call for assistance from the radiation protection officer when a hot cell or particle accelerator shielding is to be opened.

(i) Written instructions describing the wearing of suitable personal protective clothing in supervised and controlled areas;

(j) Written instructions to require that workers check with the radiation protection officer that the facility is safe before entering.

5. SAFETY ASSESSMENT

GENERAL

5.1. This section provides recommendations on meeting the requirements of GSR Part 4 (Rev. 1) [21] and Requirement 13 of GSR Part 3 [3] in respect of radioisotope production facilities.

PURPOSE AND DEVELOPMENT PROCEDURE

5.2. Requirement 4 of GSR Part 4 (Rev. 1) [21] states that the primary purposes of the safety assessment are "to determine whether an adequate level of safety has been achieved for a facility or activity and whether the basic safety objectives and safety criteria established by the designer, the operating organization and the regulatory body, in compliance with the requirements for protection and safety as established in GSR Part 3 [3], have been fulfilled".

RESPONSIBILITY FOR DEVELOPMENT OF THE SAFETY ASSESSMENT

5.3. In accordance with Requirement 13 of GSR Part 3 [3] and with Requirement 3 of GSR Part 4 (Rev. 1) [21] the operating organization is required to conduct a safety assessment that, depending on the type of practice or source, is either generic or specific to the practice or source for which they are responsible.

5.4. The preparation for the safety assessment, in terms of assembling the expertise, tools and information required to carry out the work, is addressed in Requirement 5 of GSR Part 4 (Rev. 1) with detailed requirements established in paras 4.18 (a)–(d) of GSR Part 4 (Rev. 1) [21].

5.5. A diagram of a safety assessment for a radioisotope production facility is shown in Fig. 1. This figure outlines the key aspects of the radioisotope production facility that should be addressed in a safety assessment. The individual risk assessments (e.g. assessments regarding shielding, emissions, engineering controls and decommissioning) should be collated into a safety assessment report for the facility. The same approach should be adopted whether the safety assessment is for a new standalone facility or a modification to an existing and approved facility. Some specific examples of safety arrangements (e.g. for shielding, interlocks, transfer lines, remote handling, fume hood and ventilation) are provided in paras 5.13–5.45.

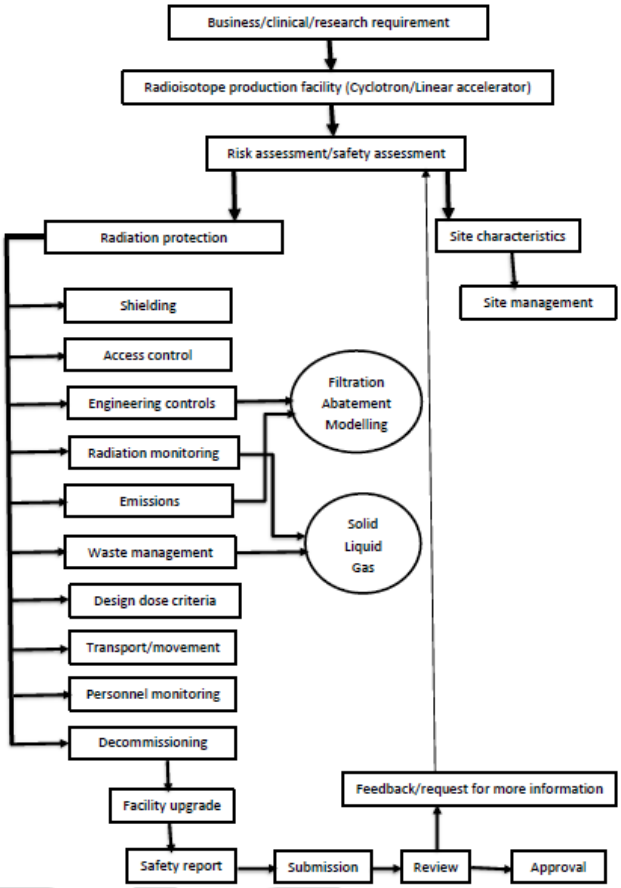

FIG. 1. Diagram of a safety assessment for a radioisotope production facility

5.6. Requirement 6 of GSR Part 4 (Rev. 1) [21] requires that the possible radiation risks associated with the facility or activity be identified and assessed. The key areas of radiation risk associated with a radioisotope production facility are shown in Fig. 2.

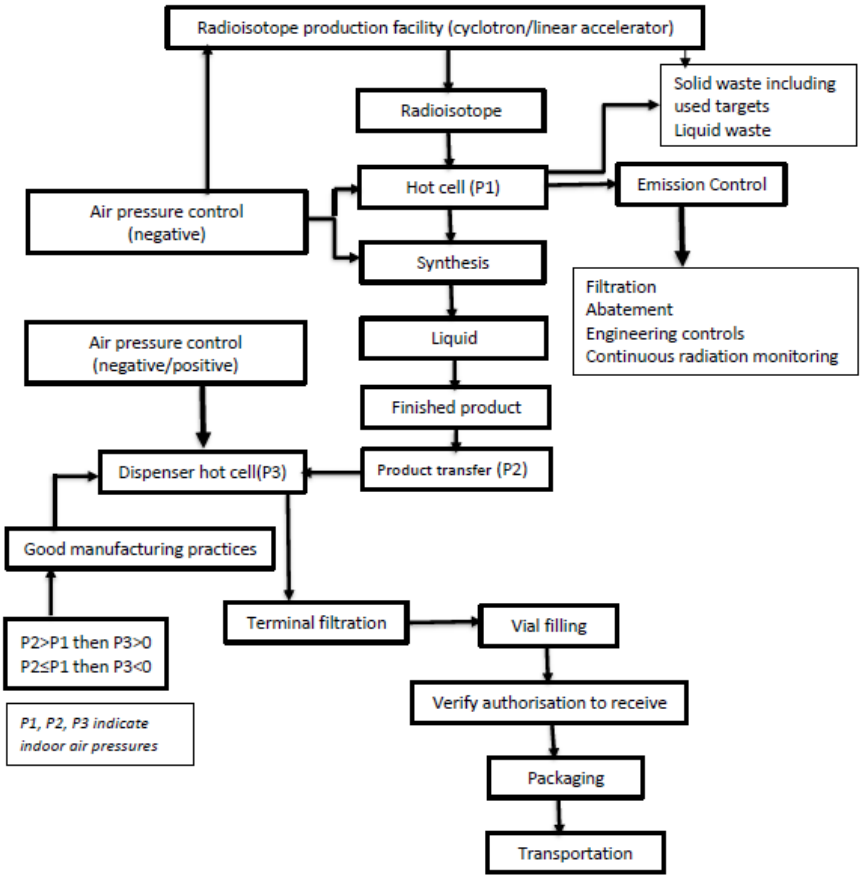

FIG. 2. Key areas of radiation risk associated with a radioisotope production facility.

5.7. During and post irradiation, there is a risk of volatile radioactive products being released to the environment; this may occur while the product is being transferred to the hot cell.

5.8. During synthesis in the hot cell, there is a risk of radioactive contamination of the environment outside and inside the building, which could potentially result in exposure of workers and a limited number of the members of the public in the local vicinity. This risk is directly related to the potential presence of volatile products within the hot cell during radiosynthesis. The risk of such contamination should be minimized by an appropriate negative pressure regime in the hot cell. The risk of a radiological release to the atmosphere should be controlled by appropriate engineering controls (e.g. filtration, use of a motorized damper and an abatement system).

5.9. During filling of the finished product in the dispenser hot cell, the appropriate engineering controls should be in place (i.e. good medical practices or other standards for aseptic manufacturing) to ensure that workers are protected and products are safe. Specifically, any volatile radioactive material in the synthesis hot cell should be prevented from entering the dispensing hot cell. This can be achieved by using the appropriate pressure regime or other options (e.g. ensuring flow remains laminar and filtration). In dispensing the finished product for use in humans, local rules covering good medical practices should be complied with; this may include dispensing in positive pressure regimes.

5.10. The operating organization should verify that the recipient has a permit or authorization to receive radioactive material being transferred out of the facility. Transport of the finished products in shielded containers should comply with the IAEA Transport Regulations [22] or equivalent national regulations.

5.11. There are also risks during the maintenance of accelerators and consideration should be given to protection and safety when maintenance work is undertaken. For example, the physico-chemical nature of contaminants, and the presence of activated products coming from the targets, radionuclides with longer half-lives and melted pieces of equipment may differ during maintenance compared to normal operation.

SAFETY ARRANGEMENTS

Shielding

5.12. Direct radiation exposure of workers and members of the public due to the operation of the radioisotope production facility should be attenuated to optimized levels by the use of appropriate shielding. Concrete is often used to construct the accelerator room shielding, but other materials such as earth fill, steel and lead are also used in its construction. The shielding properties of particular materials are well established [23–30], and experience deriving from existing radioisotope production facilities should be taken into account in designing the appropriate shielding. Adequate consideration should be given to shielding neutrons that could be generated in accelerator facilities, for example by using borated concrete for the shielding material. The shielding should provide adequate reductions in radiation levels to keep doses within the dose constraints established or agreed to by the regulatory body.

5.13. Penetrations of the shielding are necessary for entry and exit ports for personnel and products and for the ventilation system and other ducting. These penetrations can potentially

create particular challenges for the design of the shielding, and it should be ensured that there is no direct radiation leakage path, and that the use of maze entrances and shield plugs is sufficient to reduce external radiation fields to optimized levels. Care should be taken to ensure that all significant radiation paths are fully shielded. Consideration should also be given to the possible skyshine effect. Where practical, all tubes, pipes and conduits should take a curved or stepped path through the shielding material to reduce external radiation levels or should be embedded in the concrete slab using pits and trenches.

5.14. Secondary neutrons generated during radioisotope production give rise to neutron activation of the cyclotron or linear accelerator components and vault room wall. Additional forms of shielding may be required to attenuate and shield the neutrons. Activation of the shielding material may pose additional risks for decommissioning of the facility. Therefore, a strippable layer of concrete (a 'sacrificial layer') of appropriate thickness may be incorporated that may be helpful during the decommissioning.

5.15. Once the shielding has been designed, no subsequent changes should be made, unless they have been carefully considered and agreed with the regulatory body.

5.16. Radioactive material in the hot cells should be handled using remote handling tools, such as tongs or robotic manipulators, if the chemical processing system is not fully automated.

Inner surfaces of hot cells

5.17. The inside of a hot cell should have an air tight liner to prevent the release of radioactive material from the hot cells. The liner should also be suitable for the process that takes place inside the hot cell (e.g. the liner should have an acid fume resistant coating in solid target dissolution stations where hot acid can be present). The edges of the liner should be rounded with an appropriate radius to prevent the accumulation of contaminated dust. The surface should not have unnecessary protruding parts for easy decontamination of the surface. The liner itself should have enough mechanical strength to support any heavy system intended to be installed. For the production of radiopharmaceuticals, the inner liner should be designed to comply with the air quality and air flow requirements (e.g. flow to remain laminar when filling machines or dispensing systems are used for handling open radiopharmaceuticals). Air l~~L~~eakage tests should be performed on the shielded hot cell ~~should be performed~~ at a defined frequency and in the event of any significant change of design of the hot cell.

Fume hoods

5.18. Fume hoods are appropriate for the handling of hazardous and radioactive materials when the potential for airborne contamination is high and when external dose rates are low. Partial-enclosure fume hoods allow good accessibility by chemists and manipulation of special equipment, while affording protection from chemical fumes and radioactive aerosols. The sash height should be adjusted to maintain the face velocity of air entering the hood opening, which should be greater than the capture velocity of contaminants likely to be released into the fume hood work area to prevent releases into the general laboratory area.[4]

5.19. Fume hoods may require external shielding depending on the dose rate associated with the intended operation.

5.20. Inspection and maintenance of the fume hood should be performed on a scheduled frequency. The face velocity should be checked prior to use.[5]

5.21. The exhaust air should be monitored for effluents. The volume of exhaust air can be determined if the face velocity and sash area are known. The exhaust air should be routed through an appropriate filtration system to limit releases of radioactive material to the external environment.

Gloveboxes

5.22. Gloveboxes are air containment systems that isolate hazardous or radioactive materials from the laboratory environment. Gloveboxes can be used for non-gamma emitting radioisotopes where shielding of the hot cell is not necessary .

5.23. Gloveboxes are constructed from mild steel, stainless steel or aluminium, with the interior surfaces coated with chemical-resistant epoxy paint, laminated safety glass panels for viewing work activities inside the box, and heavy neoprene gloves (in the glove port) that allow the operator to handle materials safely inside the glovebox. Gloveboxes should be equipped with adequate lighting as well as pressure control tools. Gloveboxes should be maintained periodically and their integrity checked (for leaks and damage).

[4] A typical face velocity is around 0.4 to 0.6 m s^{-1}.

[5] Fume hoods need a large volume of air and this may have design implications for the volume of air needed in the radioisotope production facility.

Clean environment considerations

5.24. In order to maintain a clean environment in the radioisotope production facility, the production line should be in a clean room or isolator to ensure the required air quality is achieved. If cleaning agents are used to achieve a sterile or aseptic environment in the hot cell (e.g. H_2O_2), a risk assessment should be carried out to ensure that the use of such agents not adversely affect the filtration system.

Interlocks

5.25. A robust 'failsafe' interlock that cannot easily be defeated ~~(such as failsafe model)~~ should be installed at the access door to controlled areas, such as cyclotron or linear accelerator rooms and target rooms, to protect workers. Interlocks should also be installed on the transfer system ~~in order~~ to prevent any transfer of radionuclides if the hot cell connected to the targets ~~focused~~ is open and if the pressure regime inside the hot cell is out of specification~~s~~. Interlocks should also be installed~~, and~~ on hot cell doors ~~in order~~ to prevent ~~any~~these ~~opening~~ doors from being opened when the radiation fi~~l~~eld is elevated. Specialist advice on the suitability of interlocks should be sought.

5.26. Access by personnel to the elevated radiation field following irradiation, securing of the radiation room prior to initiating irradiation, and irradiation start procedures should incorporate a series of sequential safety interlocks and controls. Such safety interlocks and controls should be designed such that any attempt to pre-empt the controls or to apply them out of sequence will automatically prevent the intended operation.

Transfer systems

5.27. Transfer systems for radioactive material differ depending on what types of material are being transferred.

5.28. Transferring radioisotopes from the cyclotron or linear accelerator to the hot cell is achieved by using shielded transfer lines and inert gases to move the product from the target to the hot cell.

5.29. Transferring radioactive material between hot cells can be done through a simple shield door and/or a pass box installed between hot cells. A conveyor can also be employed to transfer the radioactive material. Liquids can be delivered through the tubing either by vacuum or

pressure. Delivery of gases can also be done by using a method similar to that for liquid. In particular, gas transfer should be done in a closed system to ensure that there is no risk of a radioactive release to the environment.

5.30. Transferring target materials from the target room to the processing hot cells is similar to the transfer of radioactive gases and liquids. However, the transfer of solid targets necessitates physical transfer systems that are more robust, and which utilize pneumatic systems as opposed to inert gases.

5.31. Transport of bulk amounts of radioactive material, dispensed vials and sealed sources to outside of the building should follow the protocols for the transport of radioactive material described in Section 15.

Ventilation and other systems

5.32. For a radioisotope production facility within a larger organization (for example, a radioisotope production facility sited within a hospital environment), systems and procedures should be put in place to ensure that no personnel can access the ventilation system or power distribution unit of the facility without prior information and consent of the facility management and the radiation protection officer. The operating organization should enforce appropriate standard operating procedures for the maintenance of all shared and interfacing infrastructure.

5.33. Air pressure within the radioisotope production facility should generally be kept lower than the external air pressure at all times so that air flows from outside the facility to the inside. Any air that leaves the building should pass through ducting equipped with filtration and monitoring equipment. Appropriate filters should be used depending upon the chemical compounds or radioisotopes produced.

5.34. Redundancy of essential ventilation systems should be provided:

(i) To ensure the safety of the site during maintenance of the ventilation system;
(ii) To ensure back-up power for essential ventilation systems.

5.35. Redundancy of power to essential parts of the ventilation should be provided. The use of diesel or gas generators and an uninterruptible power supply should be considered.

5.36. The ducting (piping) for the intake and exhaust air should be constructed of stainless steel or mild steel epoxy lined or galvanized and should be designed in accordance with industry standards.

5.37. The supply air to all 'clean rooms' should have terminal HEPA filters, which should be tested in accordance with industry standards. The air handling units should have appropriate intake filters and set up to condition the supply air. These air handlers should supply 100% fresh air with no recirculation. The exhaust air should be monitored for radioactive contamination (in the exhaust stack) prior to discharge from the facility. The exhaust air duct ~~of~~from the synthesis process and the exhaust air duct ~~of~~from the cyclotron bunker should be separated from other general building exhausts as far as ~~until to~~ the final discharge point. Further recommendations air emission controls are provided in Section 10.

Site selection

5.38. During the process of site selection, particular consideration should be given to potential hazards that cannot be addressed by means of engineering measures[6]., ~~such as hazards relating to geological phenomena in areas of potential or actual subsidence, uplift, collapse, faulting or volcanic activity~~ [31]. The hazard analysis should also consider nearby chemical or other industrial installations that could constitute potential external hazards.

Waste management

5.39. A safety assessment should be conducted of waste management at the radioisotope production facility. The safety assessment should be documented and periodically updated as required. Measures to control the generation of radioactive waste, in terms of type, volume and activity, should be put in place throughout the lifetime of the radioisotope production facility, beginning with the design stage, through the selection of materials for the construction of the facility, and by the control of materials and the selection of the processes, equipment and procedures used throughout operation and decommissioning of the facility. The following measures should be put in place:

[6] Such hazards may include geological phenomena in areas of potential or actual subsidence, uplift, collapse, faulting or volcanic activity, however, a limited scope consideration may be used that is focused on the specific circumstances that exist.

(i) A handling system for liquid waste with a decay tank for liquid radioactive waste and chemical waste from quality control activities or target processing (e.g. dissolution of solid targets);

(ii) A containment and storage room for solid waste;

(iii) Measures for control of the generation of gaseous waste;

(iv) A long term storage facility for solid waste (the availability of such a long term storage facility will depend on the national policy and strategy for radioactive waste management [32]).

Safety assessment report

5.40. The operating organization should demonstrate to the regulatory body how the design of the radioisotope production facility and the related operating procedures will contribute to radiation safety during normal operation, to the prevention of accidents, and to the mitigation of the radiological consequences of accidents if they occur. This information should be provided in the form of a documented safety assessment report describing and evaluating the predicted response of the facility to incidents (including postulated malfunctions or failures of equipment, common cause failures and human errors) and external events of natural origin and human induced origin that could lead to ~~accident~~ emergency conditions. These analyses should include the consideration of combinations of such malfunctions, failures, errors and external events.

5.41. The results of all the risk assessments referred to in this section should be included in the safety assessment report.

Design specification of the facility and equipment

5.42. An integral part of the safety assessment is the design specification of the facility and the equipment to be utilized therein. The design of each radioisotope production facility will be unique and dependent on the purpose of the facility, the proposed site and the national regulatory requirements. The ~~S~~safety assessment should also consider the resistance to radiation ~~resistance~~ of ~~other~~ tools and equipment such as camera, cables and~~,~~ sensors ~~etc~~ used in the accelerator room.

5.43. Before ~~operating~~implementing any changes in design of the facility or process, an assessment of all modifications and their consequences should be performed. ~~Safety assessment~~

~~should also consider radiation resistance of other tools and equipment such as camera, cables, sensors etc used in the accelerator room.~~

~~5.42.~~5.44. Annex I lists some of the key radiation safety issues to be considered in setting up a new radioisotope production facility or modifying an existing radioisotope production facility.

6. RADIATION PROTECTION PROGRAMME

GENERAL

6.1. The general objective of a radiation protection programme is to discharge the operating organization'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 is a key factor in relation to the development and maintenance of the safety culture within an organization [20], and it should meet the regulatory requirements. Detailed recommendations on establishing and maintaining a radiation protection programme for the protection of workers are provided in GSG-7 [20].

6.2. The operating organization should develop, document and implement a radiation protection programme [20]. The radiation protection programme should include information on the radiation protection arrangements, the safety assessment, the measures for implementing the arrangements, and the mechanism for the review and updating of the arrangements.

6.3. Application of the optimization principle should be the principal driving force behind the establishment and implementation of the radiation protection programme, including in many cases measures to prevent or reduce potential exposures and to mitigate the consequences of accidents if they occur. The existence of a radiation protection programme is not sufficient in itself; managers and workers should demonstrate their on-going commitment to the programme and its objectives.

6.4. The radiation protection programme should be based on the operating organization's safety assessment, and it should address planned exposure situations as well as reasonably foreseeable accidents.

6.5. The operating organization is required to ensure that information on both normal and abnormal operations that are relevant to radiation protection and safety is disseminated or made available, as appropriate, to the regulatory body and to manufacturers or suppliers, as specified by the regulatory body [3]. Such information should include 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 of equipment is obtained from them once it is available. It may be necessary for the operating organization to seek this

information from the manufacturer or supplier periodically rather than relying upon them to provide it.

STRUCTURE OF THE RADIATION PROTECTION PROGRAMME

6.6. Recommendations on the radiation protection programme are provided in section 3 of GSG-7 [20]. The radiation protection programme should include a top level policy document supported by detailed and specific procedures or 'local rules' and a comprehensive system of records (a quality management system).

MANAGEMENT STRUCTURE AND POLICIES

6.7. The radiation protection programme should include a description of the management structure as it relates to protection and safety. This structure, which could be presented in the form of an organizational chart, should show the names of the senior managers responsible for radiation safety and of the various responsible employees (e.g. the radiation protection officer). The chart should clearly show the lines of reporting, from the workers to the senior managers with overall responsibility. If the operating organization has more than one location of operations, the management structure should clearly specify the responsible persons at each location.

6.8. The radiation protection programme should include a commitment by the management to keeping radiation doses as low as reasonably achievable and to fostering a strong safety culture.

Assignment of responsibilities for radiation safety

6.9. The posts for which responsibilities are allocated should include the senior managers of the operating organization (which has the prime responsibility for safety), the radiation protection officer, the qualified expert or radiation protection adviser and other workers who have responsibility for radiation safety, as described in Section 4. Personnel should be informed of their responsibility for radiation safety. Specific responsibilities regarding certain procedures and records should be allocated to specific workers.

Local rules and supervision

6.10. Local rules that describe the procedures for carrying out radiation work should be developed and written in a language that is understood by the people who will follow the rules. These local rules should cover all procedures associated with work where there is the potential

for radiation exposure, such as routine operations, cell maintenance and transport (see Sections 10 and 11). Emphasis should be given to the development of procedures for target change-outs, maintenance and repairs. Careful consideration should be given to carrying out a pre-survey, and to the development of radiation work permits, which should include details of required additional surveys, dosimetry, personal protective equipment and maximum occupancy time while working with targets, based on expected or measured radiation levels. The radiation work permit should be signed by the responsible officer of the operating organization, the radiation protection officer and the worker or group of workers concerned. The local rules are an important tool in the restriction of radiation doses. They should include sufficient information and guidance to allow workers to carry out their duties safely and in compliance with regulatory requirements.

6.11. A copy of the local rules should be provided to all workers and other relevant persons, and additional copies should be displayed in the work area. In smaller organizations with a limited amount of work, it may be appropriate to have one set of local rules covering all procedures. Management should ensure that all relevant persons have read and understood the local rules.

6.12. In larger organizations, it might be appropriate to have several sets of site specific local rules, depending upon the nature, likelihood and magnitude of exposures. Facility specific local rules should also be established. Workers should be informed about all such procedures.

6.13. Visitors should be provided with radiation safety information that is tailored to the purpose of their visit. If visitors are to be escorted at all times, a short briefing on arrival may be sufficient.

6.14. Itinerant workers should be made aware of and trained in relevant sections of the local rules. Detailed recommendations for itinerant workers are provided in GSG-7 [20].

6.15. The radiation protection officer should oversee the day to day implementation of the radiation protection programme and carry out duties as required by the programme. Details of the duties of the radiation protection officer are provided in Section 4.

6.16. The operating organization is required to ensure that female workers who are liable to enter controlled or supervised areas are provided with information regarding the risk to an embryo or foetus from exposure to radiation and the importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant. After a worker

has notified her employer of her pregnancy, the employer is required to adapt the working conditions to ensure that the embryo or fetus is afforded the same broad level of protection as is required for members of the public. Considerations relating to potential internal contamination should be given for breast feeding female workers if they are working with unsealed radioactive material (see also section 6 of GSG-7 [20]).

Designation of controlled areas or supervised areas

6.17. Paragraphs 3.88 to 3.91 of GSR Part 3 [3] establish requirements on controlled areas and supervised areas. The radiation protection programme should describe how controlled areas[7] and supervised areas[8] are to be designated at the radioisotope production facility. Controlled areas should be used to restrict exposures of workers in radioisotope production facilities. The designation of controlled areas and supervised areas should be based on the safety assessment.

6.18. Normally the area at the side of the cells where transfer containers are coupled should be designated as a controlled area. The front of the cell should be designated as a supervised area because there is a lower probability of contamination and radiation. The internal compartment of all hot cells should be designated as controlled areas.

6.19. The active maintenance area at the side of the cells where transfer containers are coupled should be designated as a controlled area because of the higher probability of contamination and radiation in that area.

6.20. The area where the products are received into the hot cell and dispensed normally has a higher probability for contamination and radiation and should therefore be designated as a controlled area.

6.21. ~~Normally in the accelerator room the probability of contamination and radiation will be low, however, c~~C~~onsidering~~Due to the risks associated with the failure of a target, the accelerator room should ~~b~~be designated as a controlled area. If the cyclotron is not self-shielded, the cyclotron bunker should be designated as controlled area. In storage rooms ~~of~~for gaseous

[7] A controlled area is a defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions and preventing or limiting the extent of potential exposures [3].

[8] A supervised area is a defined area not designated a controlled area but for which occupational exposure conditions are kept under review, even though no specific protective measures or safety provisions are normally needed [3].

exhausted effluents~~,~~ the risk of contamination and radiation is high and these areas should be ~~treated~~designated as controlled areas.

~~6.21.~~6.22. The designation of controlled areas and supervised areas should be reviewed regularly, and may be changed or extended during initial installation, maintenance, and in order to meet the operational requirements of the facility.

Periodic reviews and audits of the performance of the radiation protection programme

~~6.22.~~6.23. As an integral part of the operating organization's management system, the radiation protection programme and its implementation should be assessed on a regular basis. This periodic review should be carried out to identify problems to be addressed and any modifications that could improve the effectiveness of the radiation protection programme.

~~6.23.~~6.24. A key part of this periodic review process is a series of workplace audits. The operating organization should specify the designation and qualifications of the persons who will conduct them, the frequency of audits, the expectations of the audit team, and the procedures for reporting of results and their follow-up.

Management system and process improvement

~~6.24.~~6.25. Radioisotope production work and its associated activities should be carried out in accordance with the established management system. This management system should be designed to ensure that all equipment and safety systems are regularly checked and tested, and that any faults or deficiencies are promptly brought to the attention of the management and quickly remedied.

~~6.25.~~6.26. Management should also ensure that the correct operating procedures are being followed, and that the management system specifies the relevant checks and audits to be made and the records to be kept. The relevant regulatory requirements should be taken into account and reflected in the content and details of the management system.

~~6.26.~~6.27. The management system should include a mechanism for the collection and feedback of lessons from day to day operations, emergencies and incidents (including those reported within the organization and by other organizations), and how these lessons can be used to enhance safety.

HEALTH SURVEILLANCE PROGRAMME

~~6.27.~~6.28. The radiation protection programme should include details of a programme for periodic health surveillance of radioisotope production personnel and other workers as appropriate. The objective of a health surveillance programme is ~~–~~to assess the initial and continuing fitness of workers for their intended tasks. A qualified expert or radiation protection adviser and/or an appropriately qualified medical doctor should be consulted regarding the establishment of the programme for health surveillance, which should be consistent with regulatory requirements.

RADIATION SAFETY COMMITTEE

~~6.28.~~6.29. A radiation safety committee should be established for the purpose of regularly reviewing the performance of the radiation protection programme. For radioisotope production facilities located within a hospital, the radiation safety committee may be dedicated to radiation safety or it may have in addition other (conventional) safety related responsibilities. The radiation safety committee should include the senior manager(s) responsible for radiation safety, the radiation protection officer(s), qualified experts or radiation protection advisers and representatives of the workforce. The responsibilities of the radiation safety committee should include, but not be limited to:

(a) Conducting regular reviews of all aspects of the radiation protection programme;

(b) Conducting reviews of occupational radiation doses and any accident reports prepared by the radiation protection officer;

(c) Making recommendations for improvements in the radiation protection programme;

(d) Provision of guidance and direction on the performance of the radiation protection officer's duties;

(e) Preparation and dissemination of regular reports to all staff about relevant radiation safety issues;

(f) Review of the emergency plan for the facility~~;~~.

(g) Making arrangements ~~to~~for ensuring compliance~~y~~ with regulatory requirements and reviewing reports that should be submitted to regulatory body.

7. TRAINING AND EDUCATION

GENERAL

7.1. The operating organization of the radioisotope production facility is responsible for ensuring that work is carried out safely and in compliance with all relevant regulations and safety standards [3]. The operating organization should, therefore, ensure that work in the facility is carried out only by workers who are trained, and who are competent and trained in radiation protection and safety. Apprentices and trainees should work under direct supervision of a suitably trained person.

7.2. The workers in a radioisotope production facility should have undergone training and received qualifications that are specifically related to their area of responsibility. Some of this training might have included only a limited amount of training in radiation protection and safety. In such cases, this training should be supplemented with additional training specifically in radiation protection and safety. Such additional training may be provided by specialized training organizations rather than by the operating organization.

7.3. Designated emergency workers are required to be trained in arrangements for preparedness for and response to an emergency that can arise in the course of the production, use or transfer of radionuclides (see Section 16).

TRAINING PROGRAMME

7.4. The radiation protection programme should describe the full scope of the training programme in radiation protection and safety for all workers directly involved in routine radioisotope production activities and emergency response. It should include basic awareness training in radiation protection, where appropriate, for other personnel, including managers, research scientists, laboratory technicians, trainees, workers such as cleaners and maintenance personnel who might be inadvertently exposed, and contractors. The radiation protection programme should also specify the minimum educational and professional qualifications for all relevant staff including those involved in an emergency response, especially the radiation protection officer, hot cell or cyclotron or linear accelerator operators, and pharmacists, in accordance with regulatory requirements.

7.5. Training records keeping should be consistent with regulatory requirements [3], and they should be specified in the radiation protection programme.

7.6. The training programme should be reviewed periodically or when there are significant changes in design of the facility or processes.

Design of a training programme

7.7. The operating organization should define necessary competences and knowledge for operating the facility and accelerator. This training programme in radiation protection and safety may be provided by the operating organization or by a specialized training organization. The operating organization should take into consideration the levels of competence based on the workers' training and experience. In the case where the operating organization does not have the capability or resources to establish a training programme, workers should attend a training programme on radiation protection and safety provided by competent training providers, including post-secondary education institutions, radiation protection institutions and training consultants.

7.8. Programmes should be established for the different levels of training corresponding to the responsibilities of the worker. The workers could be divided into the following groups:

—Hot cell and cyclotron or linear accelerator operators;

—Pharmacists;

—Radiation protection officers;

—Laboratory technicians;

—Research scientists;

—Maintenance personnel, packaging personnel and decontamination workers;

—Operators handling radioactive waste.

7.9. The training programme should establish the criteria for passing theoretical and practical examinations, as well as the procedures to be followed if an applicant fails an examination. The details of the training programme should be incorporated into the radiation protection programme.

STRUCTURE AND CONTENT OF TRAINING COURSES

7.10. Each training course should be structured around specific aims and objectives and should be customized to the needs of the target audience. The training may include the following topics

— Basic concepts of ionizing radiation;

— Radiation quantities and units;

— Instruments for detection of ionizing radiation;

— Biological effects of radiation;

— The system of radiation protection (the radiation protection principles of justification, optimization and dose limitation);

— Regulatory requirements;

— The designation of controlled areas and supervised areas; local rules and procedures;

— Dose limits, dose constraints and investigation levels;

— The effects of time, distance and shielding;

— Individual monitoring (external and internal monitoring) and how to interpret measurements;

— Working practices to limit doses and maintain them as low as reasonably achievable;

— The radiation protection programme;

— Emergency preparedness and response.

7.11. Topics in the area of practical radiation protection should include:

— Handling of radioactive material, including radioactive material in unsealed forms;

— Implementation of emergency arrangements;

— Specific task related issues.

7.12. For hot cell operators, the training should additionally cover:

— Operation of hot cells (e.g. opening hot cells for operation or maintenance);

— Handling of manipulators (e.g. tongs).

7.13. For research scientists, the training should additionally cover:

— Specific training on radiation protection and working procedures tailored to the nature of their work.

7.14. For maintenance workers, the training should additionally cover:

— Maintenance of the target system, radioisotope transfer system, hot cells and manipulators and operations significant to radiation safety.

7.15. For individuals carrying out decontamination services, the training should additionally cover:

— Decontamination after incidents involving contamination.

7.16. For operators of waste management facilities, the training should additionally cover:

— Handling instructions for radioactive waste;

— Waste management procedures;

— Task related practical information;

— Storage and shipment of radioactive material;

— Local rules and procedures.

7.17. For shipping clerks, the training should additionally cover:

International and national requirements on transport of radioactive material

— Storage of radioactive material;

— Access control procedures;

— Security procedures;

— Local rules;

— Practical radiation protection including handling and transport of radioisotopes;

— Measurement of radiation fields and the units of measurement;

— Accidents and other incidents involving the production, use and transport of radioisotopes, their consequences and lessons learned.

7.18. The training should include practical exercises, including drills involving dealing with abnormal events (e.g. a vial containing a medical isotope that breaks during dispensing). However, actual radioactive sources, unless they are exempt, should never be used in such training. Cells that are not in use can be used for training in the use of manipulators and coupling and uncoupling of transfer containers.

7.19. The radiation protection officer and a qualified expert or radiation protection adviser should provide advice on staff training needs and on how those needs can best be satisfied. In many cases, the radiation protection officer will be able to provide much of the necessary training.

7.20. Where appropriate, workers should receive adequate training and refresher training in the proper use of personal protective equipment.

REFRESHER TRAINING

7.21. Management should ensure that workers' knowledge and skills are kept up to date through a programme of refresher training. Such training should include a review of the fundamentals of protection and safety, and information on changes to equipment, policies and procedures, and any changes in regulatory requirements.

7.22. The frequency of refresher training should be consistent with regulatory requirements. Refresher training is typically given at intervals of less than two years but not exceeding five years. However, changes in regulations or occurrences of safety issues should be disseminated as written instructions as soon as practicable, and then followed up by inclusion in the next scheduled refresher training.

8. INDIVIDUAL MONITORING OF WORKERS

INDIVIDUAL DOSE ASSESSMENT AND RECORD KEEPING

8.1. The production of radioisotopes increases the potential for exposure to ionizing radiation, radioactive substances and aerosols by workers. External ionizing radiation fields are created during the process of target irradiation.

8.2. All workers who usually work in a controlled area at a radioisotope production facility, or who occasionally work in a controlled area and may receive a significant dose from occupational exposure, are required to be monitored, where appropriate, to assess their individual dose due to external and internal exposure [3].

~~8.3.~~ Target assemblies are encapsulated to limit the release of radioactive material or aerosols to the work environment. However, work activities during radioisotope production, target processing, radiochemical separation and purification activities, and radioisotope handling and packaging activities increase the potential for release and inadvertent intakes of radionuclides by workers. For work activities having increased potential for internal exposure, workers should be monitored by direct measurements and indirect bioassay to assess internal intake of radioisotopes [20].

~~8.4.~~8.3. ~~The designation of controlled areas and supervised areas should be reviewed regularly, and may be changed or extended during initial installation, maintenance, and in order to meet the operational requirements of the facility.~~

~~8.5.~~8.4. All visitors in the controlled areas should be supplied with individual dosimeters depending up on the radiation levels in the areas to be visited. A record of the dose received by such visitors should be retained.

~~8.6.~~8.5. Records of dosimetry –provide the means for tracking individual occupational exposure (external and internal exposure) from sources of ionizing radiation for both routine work and inadvertent or accidental exposures. Records of doses should be used to demonstrate regulatory compliance and support planning of activities. These records should include the results of individual monitoring of workers for both external exposure and intakes of radioactive material. Records should include all applicable measurement data, measurement dates and times, names of personnel monitored individually, and methods used to measure external dose

or calculate internal dose. Records of occupational exposure and dosimetry records should be maintained in retrievable forms, as specified in para. 3.104 of GSR Part 3 [3].

~~8.7.~~8.6. The State should establish a national dose registry in order to collect and maintain records of all doses received by workers at different facilities. Detailed guidance on keeping records of occupational exposure is provided in GSG-7 [20].

EXTERNAL EXPOSURE

~~8.8.~~8.7. Individual monitoring tracks individual cumulative exposure, provides input into the optimization process and the assessment of exposures in a radioisotope production facility and provides essential information for record keeping. Recommendations on establishing external radiation monitoring for individual workers are provided in GSG-7 [20].

~~8.9.~~8.8. Workers who enter controlled areas in the radioisotope production facility should be monitored continuously for exposure to ionizing radiation using appropriate methods and technology.

~~8.10.~~8.9. A programme for individual monitoring of external exposure should be established to demonstrate that workers' exposures are being monitored, to provide information for the optimization of protection and safety and to verify the adequacy of work procedures. Recommendations on determining the type of radiation field (e.g. photon, beta, neutron or other high energy particles) present in working areas, on establishing monitoring programmes for external exposure, on selection of appropriate dosimeters, on interpretation of measurements, on record keeping and on quality management are provided in GSG-7 [~~19~~20].

Types of monitoring for external exposure

~~8.11.~~8.10. Each worker should wear an above-the-waist, whole body dosimeter (e.g. a film badge, thermoluminescent dosimeter, or optically stimulated luminescent dosimeter) capable of accurately recording and integrating cumulative exposure to gamma radiation.

~~8.12.~~8.11. Hot cell operators, radiation protection officers, pharmacists, decontamination workers, laboratory technicians, researchers and maintenance staff who routinely enter controlled areas should be subject to individual monitoring. In addition to whole body dosimeters (see para. 8.11), these individuals should wear an electronic personal dosimeter to ensure effective dose management.

8.13.8.12. Workers who handle or process beta-emitters in close proximity to the eyes and skin surfaces should wear multi-purpose (gamma, beta) dosimeters with capability for thin-window beta-ray detection.

8.14.8.13. Appropriate extremity personal dosimeters should be worn for situations requiring the monitoring of exposure of the hands. This may be relevant for workers involved in the maintenance of cyclotrons (or cyclotron targets) ~~maintenance~~, or in radioisotope production, quality control~~.~~ or dispatch, or in waste handling. ~~and expedition area where the processed radioisotopes are handled for sending to different destinations.~~

8.15.8.14. Appropriate eye dosimeters should be worn or an established method for measuring the equivalent dose to the lens of the eye should be used for situations ~~requiring~~ in which the monitoring of doses to the lens of the eye is necessary [33]. This may be relevant for workers performing maintenance of cyclotrons ~~and~~or cyclotron targets.

8.16.8.15. Workers should position dosimeters under any protective clothing worn (under the lab coat, apron or overalls) in order to reflect the dose to the body. This will also prevent the contamination of the dosimeter. However, in the case of exposures to beta radiation, dosimeters should be positioned appropriately to avoid shielding by protective clothing.

8.17.8.16. Dosimeters should be read at least every three months or more frequently, depending on the nature of the work and the technical specifications of the dosimeter.

8.18.8.17. Electronic dosimeters should be used in a radioisotope production facility whenever multiple or variable work activities are performed, such as equipment maintenance or hot cell modifications, involving potentially hazardous radiation levels.

8.19.8.18. The tools and procedures for individual monitoring for exposure of workers, including the type of dosimeter necessary and the necessary frequency of replacement, should be chosen in consultation with the radiation protection officer or with a qualified expert or radiation protection adviser, in accordance with regulatory requirements. Dosimeters should be provided to and processed by a laboratory or company that has been authorized by the regulatory body and is traceable to a standards dosimetry laboratory approved by the regulatory body.

8.20.8.19. The operating organization should make arrangements to ensure that dose records are maintained for each worker in accordance with regulatory requirements (see GSR Part 3

[3], para 3.104). The operating organization should ensure that records of individual dose are provided to workers upon termination of their employment and are available to individual workers at other times.

~~8.21.~~8.20. The operating organization should prepare procedures describing the way in which individual dosimeters are to be administered; these procedures should address the following:

(i) Ordering and receiving dosimeters from the dosimetry laboratory;

(ii) Distribution of dosimeters to workers;

(iii) Collection and dispatch of dosimeters to the dosimetry laboratory for processing;

(iv) Review and maintenance of dose records.

~~8.22.~~8.21. The operating organization should provide suitable storage facilities for personal dosimeters not in use that protect the dosimeters from inadvertent exposure to radiation and from adverse environmental conditions such as extremes of heat or cold and/or humidity. Personal dosimeters should not be stored close to any area where dose rates are above normal background levels of radiation. Normally dosimeters should not be put through scanners that utilize X rays (e.g. mail inspection systems and airport security scanners). In exceptional circumstances, adequate control or background reference dosimeters may be used to evaluate the actual exposure of dosimeters.

~~8.23.~~8.22. In accordance with para. 3.83(b) of GSR Part 3 [3], monitored workers should take good care of their dosimeters, and take precautions to protect them from loss, theft, tampering or damage and from inadvertent exposure to radiation. Workers should return dosimeters promptly at the end of the specified period of wearing. Workers should inform a radiation protection officer without delay if a dosimeter is missing or damaged or if it has been exposed to radiation when they were not wearing it.

~~8.24.~~8.23. If a dosimeter is lost, all reasonable steps should be taken to recover it. If the dosimeter cannot be located, the operating organization should carry out an investigation and should prepare a report that includes an estimate of the dose received by the worker for the relevant period of time. In some States, the approval of the regulatory body may be required prior to the entry of such estimates into a person's dose record.

INTERNAL EXPOSURE

8.25.8.24. The likelihood of intakes of radionuclides by ingestion or inhalation should be established in the safety assessment for the radioisotope production facility. A monitoring programme should be established in cases where there is a likelihood of such intakes. The frequency of the monitoring and the type of monitoring should be determined on the basis of the likelihood of such intakes. Guidance on internal dosimetry is established in GSG-7 [20].

Types of assessment of internal exposure

8.26.8.25. Methods for the assessment of radioisotope intakes include direct in vivo counting, bioassay measurements of urine, faeces, sputum, nasal swipes, or blood, and biokinetic modelling using measurement data and information about the chemical and physical characteristics of the material to which workers might be exposed.

8.27.8.26. Methods used to assess radioactivity intakes and uptakes should be appropriate for the radioisotopes under consideration; for example, for beta emitters a 24-hour urine sample should be taken and sent for analysis for the isotope in the urine. The results of such measurements should then be used to calculate the internal dose.

8.28.8.27. Biokinetic models have been developed for a broad array of forms of radioactive material, modes of intake and metabolic pathways to facilitate calculation of internal dose to the whole body, critical organs and tissues [20]. Calculations of internal dose are typically facilitated using computer software or dose conversion factors per unit intake.

Criteria for internal monitoring

8.29.8.28. Under normal conditions the contamination level in the air, in general, should not exceed 1/10 of the derived air concentration of the relevant isotope ~~^{131}I~~. Guidance on derived air concentration values and criteria for internal monitoring is provided in GSG-7 [20].

8.30.8.29. In cases where there is a likelihood that contamination in the air could exceed 1/10 of the derived air concentration of the applicable isotope, a routine internal monitoring programme appropriate for this isotope should be established for the workers.

INVESTIGATION OF OVEREXPOSURES

8.31.8.30. The operating organization should instruct workers to notify the radiation protection officer immediately if they know or suspect that they have been exposed to high levels of radiation (e.g. if the radiation field experienced by the worker increases unexpectedly)

or to elevated airborne contamination. If the individual concerned was wearing a personal dosimeter, it should be sent immediately to a dosimetry laboratory and the laboratory should be informed of the urgency of the case. In the case of exposure to airborne contamination, the individual should be monitored for the appropriate isotope for estimating internal doses.

~~8.32.~~8.31. The operating organization is required to conduct a formal investigation, as specified by the regulatory body, if the recorded dose exceeds the investigation level. The investigation is required to be initiated as soon as possible after the event, and a written report is required to be prepared concerning the cause of the event. This report is required to include a determination or verification of any doses received, details of corrective or mitigating actions carried out, and instructions or recommendations on how to avoid a recurrence of the event [3].

~~8.33.~~8.32. The report is required to be provided to all concerned parties within the appropriate time frame, as prescribed by the regulatory body [3].

9. WORKPLACE MONITORING

9.1. Paragraph 3.96 of GSR Part 3 [3] states:
"Registrants and licensees, in cooperation with employers where appropriate, shall establish, maintain and keep under review a programme for workplace monitoring under the supervision of a radiation protection officer or qualified expert."

9.2. Paragraph 3.97 of GSR Part 3 [3] states:
"The type and frequency of workplace monitoring:

(a) Shall be sufficient to enable:

(i) Evaluation of the radiological conditions in all workplaces;

(ii) Assessment of exposures in controlled areas and supervised areas;

(iii) Review of the classification of controlled areas and supervised areas;

(b) Shall be based on dose rate, activity concentration in air and surface contamination, and their expected fluctuations, and on the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions."

9.3. Detailed recommendations regarding workplace monitoring, including the use of installed and portable radiation dose rate meters, contamination control and air sampling are provided in GSG-7 [20].

9.4. Dosimetry should be performed by calibrated and suitable instrumentation. Detailed recommendations on the selection of the proper radiation survey instrument for a given application are provided in GSG-7 [20]. The following subsection summarizes information with regard to the radiation meters and monitors that are normally employed in radioisotope production facilities.

RADIATION MONITORS

Installed and portable radiation dose rate meters

9.5. For both installed and portable dose rate monitors, the detector probes and detector windows should be carefully selected to suit the type of radiation being emitted (e.g. photon, beta or neutron). Under production conditions in the hot cell it is possible to measure beta

emitting products at the outlet of the hot cell after the end of the technology process. It is not often practicable to measure beta radiation inside the hot cell because of the presence of mixed gamma and beta radiation. Depending on the activities in the radioisotope production facility, a range of radiation detectors may be necessary.

9.6. Fixed or installed dose rate meters are normally referred to as area monitors. Area monitors serve as an important safety feature to ensure the safety of workers in the workplace. Alarms should be used to alert workers to an elevated radiation dose rate. Both audible and visual alarm signals should be provided to warn personnel of an abnormal situation in the monitored area. The number and location of area monitors should be determined based upon the safety assessment. Locations for area monitors can include:

(a) Door openings from hot cells, cyclotron or linear accelerator bunkers and caves, with a probe inside the enclosure interlocked to the door control;

(b) Locations where maintenance activities may inadvertently cause elevated dose rates, for example ~~at the front of~~around hot cells, the shielding ~~covering~~ around filters~~filtration~~, the ventilation system room, the quality control room and the ~~the waste expedition~~radioisotope dispatch room.

9.7. An important consideration in determining the location and alarm pre-sets for area monitors is the avoidance of nuisance alarms. In a radioisotope production facility, packages and raw materials are in movement throughout the site, so it is important to have area monitors set not to alarm due to such routine processes. Routine operational verifications should be preceded by a verbal alert that testing is happening.

9.8. Persons carrying out work in radioisotope production facilities should be equipped with adequate radiation detection equipment. The operating organization should ensure the availability of the required number of portable detectors in good condition. Such portable detectors might include different dose rate meters, for example:

— Large volume open air ionization (ion) chambers with thin end windows for evaluation of beta and low energy gamma (<~50 keV) dose rates: These ion chambers may have desiccants inside, which is an important consideration as humidity fluctuations might render the chamber inoperable. These detectors are useful for obtaining a reliable dose rate at 1 metre for transport measurements; however, because of their size, they are difficult to use to evaluate contact readings or small diameter beams. High dose rate

(smaller volume) open air ion chambers with thick side walls are useful for localizing high energy beta activity or contamination in hot cells.

— Large volume pressurized ion chambers: Although these are not capable of detecting beta or low energy gamma radiation, they are useful for providing stable dose rate measurements and do not suffer from humidity fluctuations as they are sealed in order to maintain their pressurized gas. These detectors are useful for obtaining a reliable dose rate at relatively close distances to the source.

— Proportional counters: These may be used as dose rate meters, though they are more commonly designed for use as contamination meters. When used as dose rate probes, proportional counters are normally sealed and therefore do not suffer the effects of humidity.

— Geiger-Müller type detectors: These are available in a variety of sizes and configurations. Larger probes have increased dead times and are not suitable for high dose rate measurements, whereas smaller volume probes can be used in evaluating dose rates produced by small diameter beams. Geiger-Müller probes smaller than an ion chamber provide better evaluation for dose rates near contact on surfaces. Thin end window Geiger-Müller probes may be suitable for beta detection, though they typically over respond to low energy gamma rays via the thin window. Thin end window Geiger-Müller probes often have greater directional dependence than other detectors, which is an important consideration in training staff in their use. Geiger-Müller probes are sealed and so do not suffer from humidity fluctuations. They are the most commonly used detector type because of their cost, ruggedness and ease of use, but they are not best suited to all types of radiation.

— Portable dose rate meters that have an extending pole: These are useful in radioisotope production facilities as distance can be maximized to protect workers when high or unknown dose rates are suspected. Extending detectors are essential tools at many radioisotope production facilities and are used to assess cyclotron and target interventions, dose rates around duct work and hot cells, and for routine surveys. The information gathered by an extending detector will inform workers of whether it is safe to proceed with work at a closer distance and will enable estimation of the length of time permissible to perform the planned work.

— Moderator based survey instruments: These are a common type of equipment used for neutron surveys. Examples include portable proportional counters filled with BF_3 or ^3He gases.

Detection of surface contamination

9.9. Contamination surveys are sometimes performed using direct measurement, but when there are varying or elevated background radiation levels in the radioisotope production facility, such surveys are more frequently performed by taking swipe samples.

9.10. Contamination monitoring should be performed when utilizing gloveboxes and fume hoods or when non-routine work is being carried out. Depending on the potential for contamination of individuals, appropriate hand and foot monitors may be installed at the exits of controlled areas.

9.11. Surface contamination surveys fall into two categories: routine surveys and surveys conducted as and when necessary. When background radiation levels are varying or elevated, contamination surveys are often performed by taking swipe samples or other indirect means. Criteria for acceptable surface activity levels (in terms of activity per unit area, Bq/cm^2) should be defined in the radiation protection programme. If necessary these values can be conservatively converted to the units of the detector (cps or cpm) for ease of use by the operator. Factors that should be considered in conducting surface contamination surveys are swipe efficiency, detection efficiency of the contamination meter for the radioisotope concerned, geometry of the detector surface to swipe area and counting time.

9.12. It is normal practice to assume that 10% of loose contamination on a surface is removed with a swipe. This value could be used in calculations for such indirect contamination surveys.

9.13. Routine contamination surveys are an essential part of application of the concept of defence in depth. Routine surveys include checks of equipment and personnel at barrier doors, and routine floor and surface checks. Minimum frequencies for routine floor and surface checks should be specified in the radiation protection programme and can vary from weekly at a small facility, to daily or multiple times a day at a large radioisotope production facility. Routine floor surveys in general areas and hallways provide an indication of whether contamination is being tracked from processing areas. Indirect floor surveys can be performed by taking swipe samples with a dry mop with a replaceable cloth and directly checking the mop for contamination.

9.14. In addition to such routine surveys, contamination surveys should also be performed when:

a) Items enter or exit cells, gloveboxes and fume hoods;
b) The potential to perform intervention work is evaluated in areas that might have non-fixed contamination (e.g. cyclotron bunkers and caves and cells);
c) Packages are being prepared for shipment.

Monitoring for airborne contamination

9.15. Typically, there are two methods to assess airborne contamination in a radioisotope production facility: either by using an installed or portable continuous air monitor with a shielded contaminant probe, or by taking a grab sample on a filter, and then removing the filter media for measurement at an analytical laboratory.

9.16. Grab sample filters can be fixed or mobile. Achieving a flow rate across a filter at the assumed breathing rate of a worker (for example 20 L/min) normally requires equipment that is too heavy for the worker to wear. Personal air samplers, which can be worn on a worker's lapel, normally operate at low flow rates (for example 2 L/min) and are more directly placed in the workers breathing zone, but might get covered by the worker's clothing or have a limited battery life.

9.17. The following should be considered when establishing the programme for monitoring breathing air:

a) Setting levels at which a room is not permitted to be entered, or for which respiratory protection has to be used. Such levels should be based upon filter efficiency, detector efficiency, line losses, pump flow rate and dose conversion factors for inhalation [34].

b) Place alarming continuous air monitors in locations of high risk for intakes of radioactive substances (e.g. radioiodine processing areas, waste, cyclotron or linear accelerator bunker)

c) Ensuring that the number of bends in tubing for continuous air monitors is minimized to avoid line losses. Tubing material for continuous air monitors should be correctly chosen so that contamination is minimally deposited on tubing. Tubing lengths to continuous air monitors should be as short as possible.

9.18. As continuous air monitors are optimally placed as close as possible to the source of air activity, they are frequently placed in radiation fields that vary in intensity over time. Therefore, a significant amount of shielding is necessary to avoid generating incorrect signals due to variations in local background radiation levels caused by movement of products, waste or raw materials. Packages placed near an insufficiently shielded continuous air monitor will appear to cause an increase in air activity or mask air activity. If the continuous air monitor has two detectors, one can be used to correct the variations in the background radiation levels. Filter material should be placed to adequately filter the aerosols. Examples of filter materials are paper and fiberglass for particulates and activated charcoal and silver zeolite for radioiodine.

Maintenance and calibration

9.19. Following calibration of monitoring equipment, a label should be attached to the instrument to provide information, including the organization that performed the test, the test certificate number and the date of the test or the date when the next test is due. Tests should be carried out by an organization that maintains reference radiation fields traceable to national or international primary standards.

9.20. Installed radiation monitoring instruments are not calibrated in the same sense as radiation survey meters. Since their operation is 'pass–fail', installed instruments should be subject to periodic operational testing to ensure that they retain the capability to respond to relevant radiation levels. For example, check sources can be used on a monthly basis to verify that a radiation room monitor responds appropriately. In some applications, such as in using a single channel analyser for monitoring of airborne effluents, the instrument should be calibrated periodically to ensure that the detector voltage and window settings are still applicable.

9.21. Further information on the establishment and operation of calibration facilities for radiation survey instruments and recommended calibration procedures is provided in Ref. [35].

Records of radiation and contamination surveys

9.22. Reports on radiation and contamination levels should include the following information:

- Survey date;
- Information on the survey instrument (manufacturer, model number and serial number);

- Calibration date of the survey instrument;
- Correction factors, subtraction of background radiation, conversions or other calculations for the survey instrument if used;
- Name of the person performing the survey;
- Radiation levels and the corresponding locations, recorded on sketches of the section of the building that was surveyed;
- Contamination levels and the corresponding locations;
- Cause of the contamination, if known;
- Any actions taken on the basis of information yielded by the survey.

10. ENVIRONMENTAL MONITORING AND EFFLUENT DISCHARGE

ENVIRONMENTAL MONITORING

10.1. Radioisotope production and processing inherently pose a risk of dispersal of radioactive material to the environment, which can be as the primary product or a decay product. The environmental monitoring required is normally limited to performing and documenting dose rate surveys external to the controlled area, with the objective of demonstrating that members of the public are receiving effective doses less than 1 mSv in a year. In some cases, the boundary for performing these measurements is within the building. For new facilities, detailed dose rate surveys should be performed, and any deficiencies in design and construction should be corrected to ensure that the facility can safely operate under the conditions at which maximum dose rates could occur. Once the facility is in operation, routine environmental dose rate surveys should be carried out regularly.

10.2. The results of environmental monitoring should be periodically confirmed by measurement of groundwater or soil samples for relevant radionuclides.

EFFLUENT DISCHARGE

10.3. The production technology, the adopted practices and the facility design should all aim to control the quantities of radionuclides routinely discharged and to minimize the risk of unplanned radioactive releases.

10.4. Effluent discharges from the radioisotope production facility should be within authorized discharge limits, which should be developed by the operating organization and made subject to approval by the regulatory body. IAEA Safety Standards Series No. GSG-9, Regulatory Control of Radioactive Discharges to the Environment [36] provides more detailed guidance on methodology and procedures to develop such authorized discharge limits.

10.5. The effluent streams should be considered carefully prior to planning and construction of the facility. Effluents should also be considered when planning and implementing new production lines, when methods or equipment are changed, or when operating conditions of the facility itself change (e.g. ventilation and pressures).

10.6. Effective means should be put in place for confining radioactive releases before they leave the facility. Best practices include in-process means of capturing and securing gaseous, liquid

and particulate solid waste. Filtration and trapping systems should be designed to be as close as possible to the source production in order to minimize unnecessary contamination of ducts and piping. The handling of the effluent streams should include safe means of removing other hazardous components (e.g. air filters might not only be installed to reduce release of activity into the atmosphere, but also to minimize releases of other toxic chemicals).

MONITORING OF AIRBORNE EFFLUENTS

10.7. GSG-9 [36] and IAEA Safety Standards Series No. RS-G-1.8, Environmental and Source Monitoring for Purposes of Radiation Protection [37] provide recommendations on monitoring releases of airborne effluents.

10.8. Quantitative on-line monitoring of gases or aerosols in released air should be performed using:

- A well shielded detector that is directed at a cross-section of the stack and is oriented not to detect other sources of radiation;
- A well shielded continuous air monitor for sampling the stack;
- A gas flow through ion chamber detector or other means for monitoring inert gases.

However, in all cases a representative sample or isokinetic sampling [38] of the effluent should be taken.

10.9. Off-line measurements should be made using filters (cartridge filters or other types of filter) that are replaced daily or weekly (as necessary) and measured.

10.10. If sampling lines are used, the number of bends in the tubing should be minimized to avoid line losses. Tubing material should be correctly chosen so that the deposition of contamination on tubing is minimized.

10.11. Experimental evidence should sometimes be used to validate sampling systems. One such example is to release an approved amount of ^{11}C labelled carbon dioxide ($^{11}CO_2$) to calibrate systems at positron emission tomography facilities.

10.12. The stability of sampling pump flow rates and stack flow rates should be taken into account and variations in such flow rates should be recorded.

10.13. Other aspects that should be considered with respect to monitoring of airborne emissions include:

(a) The emitted activity is dependent on the concentration and the rate of air flow.

(b) The monitor should be capable of measuring relevant radionuclides with sufficient sensitivity.

(c) The monitor(s) should be shielded from variations in background radiation.

(d) If several radionuclides are present, they should, if possible, be identified and quantified.

FILTERING OF AIRBORNE EMISSIONS

10.14. All airstreams in the facility that might contain radionuclides should be considered. This could include air from all controlled areas as well as storage areas, target loading and unloading areas and potentially also from areas containing radioisotope generation equipment.

10.15. Air filters should be suitably placed in the ventilation system prior to the release of air from the building. If the filter (e.g. charcoal) is in an uncontrolled area, it should be adequately shielded to minimize the risk of exposure of personnel.

10.16. Corrosive substances (e.g. acids) should not be ventilated through the ventilation system. In such instances adequate scrubbing using appropriate chemicals or water and filtering should be done before release to the environment.

10.17. Filters should be changed on a regular basis (e.g. annually). The frequency of changing might need to be increased if an elevated trend in emissions is observed.

10.18. If radioactive material is produced that cannot be trapped by the air filtration system, abatement systems (e.g. exhaust bags) should be utilized to store the radioactive material until the radioactivity has decayed to background levels.

10.19. Decisions relating to placement of filters, height of stack, ejection speeds and meteorological considerations [398] should take into account occupied areas and worst case scenarios, including the worst case committed dose to the representative person, and the reference to suitable guidelines for this, and possible general dose constraints (typically 1/10 of the annual dose limit for members of the public). Compliance with this dose constraint is the responsibility of the operating organization, and could be part of the authorization for operation.

10.20. Channels, filters and other components should be manufactured from materials that will not be attacked by components of the air stream, nor should they yield unnecessary particle burdens themselves (e.g. they should be manufactured from stainless steel or epoxy coated). Instructions should be provided to workers on avoiding extensive boiling with strong mineral acids, as well as on good practices to minimize corrosion risks from acid fumes (e.g. by means of gas washers or scrubbers).

10.21. Filters that are likely to contain large amounts of radionuclides at any point in time should be located in controlled areas and, if appropriate, also shielded or separated from areas of any occupancy.

10.22. Pressure drops and the integrity of essential filters should be kept under control by suitable measures. The efficacy of filters should be tested regularly.

10.23. Filters should be removable under radiologically safe conditions (e.g. provisions should be made for safely bagging filters).

10.24. Practices for the removal of non-filterable contaminants include:

(i) The placement of filters as close as possible to the source, at points of lowest airflow.

(ii) The use of activated charcoal filters.

(iii) The use of acid filters or scrubbers.

10.25. Non-filterable, non-condensable airborne contaminants that should be addressed include:

(i) Radioactive noble gases;

(ii) PET cyclotron products, some of which (e.g. $^{13}N_2$) cannot be removed from the air stream (some other PET cyclotron products, such as [^{11}C]-CH_4 or [^{11}C]-CO_2, [^{18}F]-FCH_3 or [^{18}F]-F_2 and [^{13}N]-NH_3, can be removed from the air stream with suitable chemical traps);

(iii) Tritium, and some tritiated and ^{14}C labelled compounds.

10.26. In case such contaminants pose a significant risk to either workers or members of the public, measures should be taken to limit and control the release of such contaminants.

The most efficient way to control the release of contaminants is to contain and trap the contaminants at the source itself using gas bags or traps (liquid nitrogen or cartridges) or to use tank storage for decay (in case of gases from positron emission tomography).

MONITORING OF LIQUID EFFLUENTS

10.27. National, regional and municipal regulations should be applied to limit the discharge to liquid effluent streams, in terms of chemical and biological materials, suspended solids, radioactivity and other hazards.

10.28. Liquid effluents should be monitored on-line or representative samples should be taken from a delay tank. Procedures should be developed to ensure that the delay tank contents are adequately mixed so that the sample taken is representative. If a sub-sample is to be taken from the representative sample (e.g. for liquid scintillation counting), then the sample should also be agitated to ensure adequate mixing.

MINIMIZING EFFLUENT DISCHARGES

10.29. In planning, consideration should be given to the confinement of liquid borne radionuclides in case of flooding, pipe ruptures or fire-fighting with water.

10.30. Process water should be kept and treated separately. Coolants should be diluted only with inactive water prior to ultimate disposal. Further details on the control of radioactive discharges are provided in GSG-9 [36].

10.31. Water used for washing and cleaning in radioisotope production facilities could potentially be contaminated, depending on the nature of the facility. It might be necessary to pipe such waste streams to storage tanks, perhaps for decay, but ultimately for analysis, possible purification and distillation and/or subsequent release to the environment.

10.32. Target and accelerator cooling circuits may become radioactive (excluding the short-lived radionuclide ^{16}N) owing to leaching of activated surfaces or from leakages. Therefore, cooling circuits should be disposed of only after their radioactivity levels are checked.

10.33. Dedicated piping for possibly contaminated or radioactive waste water should be put in place. If acceptable low limits can be ensured for all operating conditions, waste water can be piped directly to the main sewer.

10.34. Workers maintaining such draining installations should be properly trained and should use appropriate personnel protective equipment.

11. PERSONAL PROTECTIVE EQUIPMENT

11.1. The operating organization should ensure that engineering controls are in place to protect workers from exposure due to radioisotopes and other associated hazards. Even when optimized engineering controls have been implemented, additional protective measures such as personal protective equipment will need to be used to keep radiation doses as low as reasonably achievable or to mitigate the consequences of an accident.

11.2. The operating organization should ensure that workers are provided with suitable and adequate personal protective equipment that meets relevant standards and specifications. According to GSR Part 3 [3], the operating organization is required to ensure that personal protective equipment is provided to workers. Personal protective equipment for routine operations may include:

(a) Protective clothing, including gloves, overalls and caps for contamination hazards;

(b) Protective respiratory equipment suitable for protecting the respiratory tract from contamination hazards;

(c) Protective aprons and gloves and organ shields for external radiation hazards;

(d) Safety glasses or face shields for protection against splashes involving radioactive material and against beta radiation and leaded glasses for protection against external radiation hazards.

11.3. Personal protective equipment for emergency operations may include:

(a) Full body covered air suits with air lines or breathing apparatus for entering contaminated areas;

(b) Lead aprons, critical organ protectors and gloves for situations with high dose rates.

11.4. Workers should receive adequate training and refresher training in the use of personal protective equipment. All personal protective equipment should be maintained in working order and tested at regular intervals.

11.5. The reliance on personal protective equipment for protection and safety should be minimized by the operating organization during normal operations by means of appropriate protective measures and safety provisions, including well engineered controls and satisfactory working conditions.

11.6. The safety assessment should provide information for the job specification for each area and process. A medical examination carried out for health surveillance purposes should be used to determine whether a worker is capable of safely using the prescribed personal protective equipment for the job. Aspects to be covered for such medical examinations include the possibility of impaired or reduced lung function, allergies, claustrophobia and hypertension, which could limit the use of some personal protective equipment.

11.7. Contaminated re-usable personal protective equipment, such as clothing and overalls, should be left to decay, and if necessary, decontaminated in a decontamination room. Highly contaminated personal protective equipment should be left to decay before sending for washing. In cases where long-lived radionuclides are present, the radiation protection officer should decide whether such personal protective equipment needs to be considered as radioactive waste.

11.8. If the use of personal protective equipment is being considered for a task, any additional exposure that could result owing to the additional time or inconvenience, and any additional non-radiological risks, should be assessed against the risks associated with performing the task without using personal protective equipment.

12. **NUCLEAR SECURITY CONSIDERATIONS**

12.1. The nuclear security policy of the organization should aim to deter, detect, delay, and respond to any attempt to gain or actual unauthorized access to radioactive sources. The following paragraphs are intended to raise awareness about the nuclear security issues that need to be addressed. Such issues are covered in detail in the IAEA Nuclear Security Series of publications. In particular, IAEA Nuclear Security Series No. 14 [6] provides recommendations to States and competent authorities on how to develop or enhance, to implement, and to maintain a nuclear security regime for radioactive material, associated facilities and associated activities. IAEA Nuclear Security Series No. 11 [7] contains more specific guidance to assist States in the development of regulatory requirements for the security of radioactive sources. IAEA Nuclear Security Series No. 9 [8] provides guidance on the security of radioactive material during transport.

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

12.3. To ensure that safety measures and security measures are implemented in a compatible manner, the government may have designated a responsible body for managing the interfaces between safety and security in relation to radioactive sources. This might be the regulatory body if the regulatory body has responsibility for both the safety and security of radioactive sources under the regulatory infrastructure.

12.4. In radioisotope production, there may be an interface between security and safety measures with regard to access to information. For safety purposes, information on the locations and characteristics of radioactive sources and the safety measures in place may need to be readily accessible. However, this information may also be of potential value to an adversary, and therefore security considerations may require that some sensitive information be protected. Guidance on the protection and confidentiality of sensitive information in nuclear security is provided in IAEA Nuclear Security Series No. 23-G [9]. An appropriate balance should be maintained between the availability of information for safety reasons and the need to protect sensitive information for security reasons.

12.5. Safety measures designed to prevent the loss of radioactive sources or for protection of people from radiation exposure can also provide some benefit in protection against the theft of such sources. For Category 4 to 5 sources, for example, it is recommended that measures described in GSR Part 3 [3] be used. However, the element of intent involved in unauthorized access means that additional considerations apply for higher activity sources (Category 1 to 3), and additional and/or different security measures may be necessary to protect against unauthorized access.

12.6. The IAEA Nuclear Security Series provides guidance on how to define the requirements for the security of radioactive sources using a graded approach, based on considerations of threat, the nature of the sources, and the relative attractiveness of the material for use in a malicious act. IAEA Nuclear Security Series No. 11 [7] suggests using the IAEA's categorization system in order to assign a particular security level to sources and to help define the necessary security measures. Radioisotope production sources are typically assigned to Security Level C, and not higher than Security Level B. The security measures required for each security function for Security Levels B and C are described in detail in Ref. [7].

12.7. Due to their small size and portability, radioisotope sources may need additional security measures or procedures to ensure they remain adequately protected and under control during use, during transport incidental to their use, and while they are not in use. The specific details of such additional measures will depend on the threat assessment. Reference [7] contains illustrative security measures, including measures for mobile operations where measures applicable to a fixed installation are not practicable, which can be adapted for mobile Security Level C operations.

13. TESTING AND MAINTENANCE OF EQUIPMENT

13.1. To ensure the continued safe operation of the radioisotope production facility, the operating organization should set up a formal programme of maintenance and testing to test all safety functions regularly, as follows:

(a) Particular attention should be paid to regular testing of components of the safety interlock system for correct operation, in accordance with the instructions of the equipment manufacturer. These tests should be carried out by appropriately qualified persons and endorsed by the radiation protection officer.

(b) Periodic leak tests of radioactive sources should be carried out in a manner and at a frequency recommended by the source supplier and in accordance with regulatory requirements.

PERIODIC TESTS

13.2. The ventilation system (buildings, hot cells, fume hoods) should be maintained on a regular basis (at least annually).

13.3. The heating and cooling systems, generators, radiation monitoring equipment, interlocks, freezers, building monitoring system, HEPA filters in clean rooms and dose calibrators should be maintained on a regular basis. All equipment used in measuring radiation levels and weights, as well as other equipment as required by the regulatory body, should be tested, calibrated and maintained on a regular basis.

13.4. The following additional tests should be carried out on a monthly basis:

(a) Check, in accordance with the manufacturer's instructions, that access to the facility is prevented when the radiation monitor alarm sounds. Check the emergency exit procedure by ensuring that the personnel access door can be opened from the inside and that other means of exit in an emergency are functioning properly.

(b) Check all visual warning signals and alarms for correct operation. Check all control indicator lights to ensure that they illuminate.

(c) Verify that the uninteruptible power supply[9] is functioning within specification. It is a good practice to use an uninteruptible power supply as a backup power supply for the cyclotron or linear accelerator control system, as power failure can affect the operation of control units.

(d) Verify that the heat detectors and smoke detectors are functioning properly.

(e) Verify all safety interlocks on removable shield plugs (or self shield) in the cyclclotron room.

(f) Verify that posted notices are in place and that all the details are correct.

13.5. If any of the checks indicate a fault or that a safety interlock is not functioning properly, the facility should not be operated until the system has been returned to a validated safe state. The return of the facility to normal operation should be subject to approval by the radiation protection officer.

RECORDS

13.6. The results of all tests described above should be recorded on a formal checklist signed by the radiation protection officer .

13.7. Maintenance records should be kept for such periods of time as are prescribed by the regulatory body.

13.8. Records should be kept of the radioisotope inventory, and of information on the storage and transfer of radioisotopes.

FACILITY MAINTENANCE AND MODIFICATION

13.9. Maintenance operations at the facility should be coordinated with the manufacturer of the various items of equipment in the facility to ensure that appropriate repairs, modifications and system upgrades are completed in accordance with approved protocols.

13.10. Bypassing or disabling a safety interlock should be done only with the express, written approval of the radiation protection officer, and should be ~~restricted~~controlled by a code or key

[9] An uninterruptible power supply is a backup power supply that, in the event of power failure or power fluctuations, allows enough time for an orderly shutdown of the system or for a standby generator to start up.

that is available to ~~only for~~ a limited number of persons. All circumstances necessitating any component of a safety interlock to be bypassed or disabled should be documented with a description of the circumstances and the actions taken, and with the specific approval of the radiation protection officer.

13.11. If it becomes necessary to bypass or disable a safety interlock, independent verification should be obtained that the accelerator is switched off (e.g. the ion source is not on). The affected component of the safety interlock system should be bypassed or disabled only long enough to allow entry to the radiation room to remedy the problem (e.g. to repair or replace the monitor), during which time the relevant portion of the facility will not be in operation. Entry to the radiation room should be permitted once a satisfactory survey of the area has been completed.

13.12. If it is necessary to bypass or disable a component of a safety system, the affected component should be tested for proper operation upon being reinstated. The specific test will depend on which component is to be tested, but the test should be a duplicate of the routine test performed to verify proper operation. After verifying that the safety interlocks have been restored to their design function, approval of the radiation protection officer should be obtained for a return of the facility to normal operation.

13.13. Since bypassing or disabling any component of the safety interlock system is to be avoided, except under abnormal circumstances, routine and preventive maintenance functions should be designed to prevent the need for bypassing safety interlocks.

14. **RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING**

14.1. The regulatory body is required to establish requirements ~~and criteria~~ for radioactive waste management [32]. Radioactive waste is radioactive material for which no further use is foreseen and with characteristics that make it unsuitable for recycling or authorized discharge. This may include unsealed and sealed sources [36, ~~39~~40]. Radioactive waste should be addressed in the safety assessment prior to its generation. Non-radiological hazards (e.g. biohazards and chemical hazards) and the need to meet the acceptance criteria of the ultimate waste destination (e.g. a national waste disposal facility or interim storage site) should be also considered. IAEA Safety Standards No. GSG-1, Classification of Radioactive Waste [41] provides detailed guidance on waste classification.

14.2. Radioactive waste is generated at various points in a radioisotope production facility. Low level waste is generated from contamination control procedures (e.g. disposable personal protective equipment, clothes, packages and surface and floor swipes). The waste with the highest activity concentration is generated from activated materials within the cyclotron or linear accelerator, targets, synthesis processes and quality control testing. Archive samples and unsold products are other examples of waste.

14.3. Application of waste management protocols, clearance of materials after processing, storage for decay, and reuse and recycling of material can be effective in reducing the amount of radioactive waste that requires disposal. In accordance with para. 4.9 of IAEA Safety Standards Series No. GSR Part 5, Predisposal Management of Radioactive Waste [32], the operating organization is required to ensure that these processes are in compliance with the conditions and criteria established in regulations or by the regulatory body. The regulatory body is also required to ensure that the operating organization gives due consideration to non-radiological hazards in applying such options [32].

14.4. The control measures are generally applied in the following order: reduce waste generation, reuse items as originally intended, recycle materials and, finally, consider disposal as radioactive waste.

14.5. In accordance with Requirement 10 of IAEA Safety Standards Series No. GSR Part 6, Decommissioning of Facilities [~~40~~42], the operating organization is required to prepare a decommissioning plan for the facility that considers the ultimate disposal of all resultant waste and contaminated and/or activated equipment and materials, including an estimation of cost,

identification of the provision of financial resources and assurances to cover the cost associated with decommissioning. This decommissioning plan is required to be periodically reviewed and updated as necessary in the light of operating experience gained, new or revised safety requirements, lessons learned from the decommissioning of similar facilities, and technological developments relevant to decommissioning [~~39~~40].

14.6. Sealed sources in use at the radioisotope production facility will, in time, become spent or disused sealed sources. A disposal pathway should be established, subject to the approval of the regulatory body, so that sealed sources do not become orphaned. The accounting of sealed sources should meet the requirements of the regulatory body.

14.7. Some radioisotope production facilities fabricate sealed sources and the radioactive material in such facilities is typically in one of three states: raw material, finished product (inventory) or waste. The operating organizations of such radioisotope production facilities should offer customers a disposal pathway as a pre-sale condition. The operating organization is responsible for accounting for their sealed sources, and for documenting returned, spent sources to ensure that the sealed sources do not become orphaned.

14.8. The operating organization should provide the regulatory body with a list of anticipated waste streams and sources to be generated at the facility, including waste forms (e.g. solid, liquid and/or gaseous), estimates of waste volumes, waste categories and plans for storage and disposal.

CHARACTERIZATION OF RADIOACTIVE WASTE

14.9. At a radioisotope production facility, aqueous waste results from chemical processing, mainly the etching and dissolving of target materials. Such waste should be processed only after its precise characterization. In addition to its radiological, physical, mechanical, chemical and biological properties, radionuclide impurities from the production process should be characterized and segregated. Radionuclide impurities in the waste streams should first be estimated from predictive models and then measured. Radioactive material that is produced in cyclotrons or linear accelerators can contain small quantities of radioisotope impurities that are longer lived than the finished product. The operating organization of the radioisotope production facility (in consultation with the operating organizations of the waste disposal facility) is responsible for developing and applying the waste acceptance criteria for disposal.

14.10. The operating organization should meet the clearance criteria established by the regulatory body. Clearance levels establish at which point material under regulatory control can be removed from this control [~~41~~43]. In order to demonstrate that the quantity or concentration of radioactive substances in the material is below the clearance level, the operating organization should first determine the radioisotopes in the waste streams, and then compare their activity concentrations with the clearance levels. The activity concentrations in waste streams can be determined by taking the initial concentrations and calculating for decay and/or by directly measuring and identifying the activities of the radionuclides present. The operating organization should document this evaluation.

WASTE MINIMIZATION

14.11. Minimization of the amount of waste generated is important for waste management and for controlling risk as well as cost. 'Delay and decay' and 'concentrate and contain' are two of the principal approaches to waste minimization [32].

14.12. Segregation is an important step in waste minimization within the controlled area. Waste should be first segregated into two categories: waste that is known to be or is suspected of being radioactive, and waste that is believed to be non-radioactive. It should be verified that the latter category meets the clearance criteria.

14.13. Segregation is also applied to biological waste that needs to be treated (by autoclaving, sterilizing or incinerating) or to liquids that need chemical treatment (e.g. to maintain an alkaline pH value for radioiodine) for safe storage, transport or disposal.

HANDLING AND PROCESSING OF RADIOACTIVE WASTE

14.14. Depending on regulatory approval, it may be acceptable to 'dilute and disperse' radioactive material [32]. An example of the use of 'dilute and disperse' might involve a filtered ventilation exhaust where the activity concentrations of airborne effluents have been pre-determined (in accordance with regulatory approval) not to endanger people or the environment. Liquid waste should be safely stored in proper storage tanks, contained and subsequently treated and disposed.

14.15. The operating organization is required to ensure that radioactive material is not discharged to the environment unless:

(a) Such discharges are within the limits specified in the authorization for discharges issued by the regulatory body; or

(b) The exposures due to the discharge are excluded from regulatory control or the discharges can be exempted from the requirement for an authorization.

14.16. Control measures for the handling and processing of radioactive waste may include sampling of each batch of waste prior to its removal from control. If, in accordance with the national policy and strategy, radioactive waste is to be stored in a centralized storage facility, the operating organization should adopt provisions to ensure the prompt transfer of waste and disused sources to that facility.

14.17. Other guidelines for handling radioactive waste in a radioisotope production facility include the following:

— Radioactive waste should be characterized in terms of its physical, mechanical, chemical, radiological and biological properties.
— Containers for solid wastes should be lined with a durable plastic bag that can be sealed (e.g. tied with plastic adhesive tape or heat-sealed with a radio-frequency welder).
— If drums of waste are to be compacted at the radioisotope production facility, the compactor should be enclosed to prevent the spread of contamination. The safety of the compactor should be evaluated to avoid any ‘pinch points’ or the use compacting material that could damage the drum.
— Sharps should be collected separately and stored in rigid, puncture-resistant containers that have been clearly labelled ‘sharps’.
— Refuse cans with lids should be lifted by foot pedals to minimize contamination.
— Liquids might need chemical treatment (e.g. to maintain an alkaline pH value for radioiodine) and immobilization prior to transport.
— Special precautions might be necessary for used target foils, target blanks, target bodies and collimators. The area where target reconditioning is performed should be shielded to protect the worker’s whole body and extremities.

ON-SITE STORAGE OF RADIOACTIVE WASTE

14.18. In most radioisotope production facilities, it will be necessary to have a dedicated storage room for waste and contaminated equipment. Access to this room should be secure and

ventilated. In some radioisotope production facilities, sealed waste containers are placed in air sampling boxes to ensure that there is no airborne contamination present prior to disposal.

14.19. Contamination and dose rate surveys should be carried out routinely in the storage room. An alarming continuous air monitor and respiratory protection might also be used to control internal exposures in this room.

14.20. Waste storage locations should be planned and designed to minimize the need for handling and transport and exposure of the public (if the storage room is external to the building).

PREPARATION OF WASTE SHIPMENTS

14.21. It should be ensured that radioactive waste is in a safe and passive form (with regard to radiological, physical, chemical and biological hazards) before it is placed in an approved transport container to be transferred to a centralized waste storage facility. Waste acceptance criteria for the storage facility should be met regarding the acceptability of packages, package contents and configurations.

14.22. All floor drains and sinks should discharge into delay tanks or holding tanks and activity concentrations in the runoff should be monitored. The discharge port of the main floor drains should have a removable bladder type plug to contain the liquid in the drainage system until it has been assessed for disposal.

14.23. The recommendations provided in Section 16 also apply to waste shipments.

14.24. . The operating organization should verify that the recipient has an authorization or a regulatory permit to receive radioactive waste for storage or disposal.

15. TRANSPORT OF RADIOACTIVE MATERIAL

TRANSPORT REQUIREMENTS

15.1. Transport of radioactive material should conform to national regulations with the State and to the IAEA Transport Regulations [22].

Movement of radioactive material within the site

15.2. When radioactive material and sources are to be moved within a site for radioisotope production operations, they should be kept in the storage facility until they are ready to be moved to the new location.

15.3. Sources should be moved only in shielded containers, and these should be locked and the keys should be removed and held only by authorized personnel. If a vehicle or trolley is to be used to move the container, the container should be securely fastened inside a separate compartment of the vehicle or trolley. The shielded container should be kept under surveillance for the duration of the movement on the site.

Transport to another site

15.4. When radioactive material is to be transported from the radioisotope production facility to another location, it should be kept in the storage facility until it is ready to be moved to the new site.

15.5. Sources should be moved only in shielded containers, and these should be locked and the keys should be removed. The operating organization should ensure that the transport and the transport packages comply with the IAEA Transport Regulations [22] or equivalent national or international regulations.

15.6. Where applicable, consideration should also be given to binding international instruments for specific modes of transport, such as by air [~~42~~44] and by sea [~~43~~45].

15.7. Regional agreements such as the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [~~44~~46], the European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) [~~45~~47] and the Agreement of Partial Reach to Facilitate the Transport of Dangerous Goods, signed by the Governments of Argentina, Brazil, Paraguay and Uruguay (MERCOSUR/MERCOSUL) [~~46~~48] might also apply.

15.8. The IAEA Transport Regulations [22] assign responsibilities for individuals involved in the transport of radioactive material:

(a) The consignor (the person, organization or government that prepares a consignment for transport);

(b) The carrier (the person, organization or government that undertakes transport of radioactive material);

(c) The consignee (the person, organization or government that receives a consignment).

In some cases, for an operating radioisotope production facility, the operating organization performs all three functions and as such is required to discharge the responsibilities associated with each function.

15.9. Transport of radioactive material is a complex activity, and a comprehensive overview of the IAEA Transport Regulations [22] is outside the scope of this Safety Guide. Guidance on how to meet these requirements is provided in IAEA Safety Standards Series No. SSG-26, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition) [~~47~~49].

15.10. Comprehensive guidance on nuclear security in the transport of radioactive material is provided in Ref. [8].

16. EMERGENCY PREPAREDNESS AND RESPONSE

GENERAL

16.1. An emergency is

> "A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human life, health, property or the environment.
>
> This includes nuclear and radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes.
>
> This includes situations for which prompt action is warranted to mitigate the adverse effects of a perceived hazard."

16.2. As defined in GSR Part 7 [15], a nuclear or radiological emergency is:

> "An emergency in which there is, or is perceived to be, a hazard due to:
>
> (a) The energy resulting from a nuclear chain reaction or from the decay of the products of a chain reaction;
> (b) Radiation exposure."

16.3. Incidents at a radioisotope production facility can occur mainly as a result of operator error or equipment failure and may lead to a radiological emergency. Typical incidents include:

— Breach of a target package;

— Abnormal or higher dose rate than expected;

— A dropped source;

— A leaking source;

— Fire inside the hot cell, clean rooms or other production areas;

— A loss of supply air to the facility and/or a loss of exhaust air from the hot cells;

— Loss of off-site power supply;

— Breakage of the cooling line for the cyclotron and the target transfer system and consequent flooding in the facility;

— A natural disaster (e.g. a hurricane) affecting the facility;

— A nuclear security event resulting in a loss of control of radioactive material or of the facility, such as theft of radioactive material or sabotage.

16.4. The hazards associated with the operation of a radioisotope production facility and the consequences of a nuclear or radiological emergency are required to be assessed as a means to provide a basis for establishing emergency arrangements [15, ~~48~~50]. Emergencies that could affect workers, the public or the environment and could warrant emergency response actions should be identified in the hazard assessment for the radioisotope production facility [14, ~~48~~50].

16.5. Based on the assessed hazards and the potential consequences, emergency arrangements for the radioisotope production facility should be established in accordance with Refs [~~49~~51–~~51~~53]. Radioisotope production facilities generally fall into emergency preparedness category III, as set out in GSR Part 7 [15]. Emergency arrangements that correspond to this category should be established for any ~~the~~ radioisotope production facility. Some radioisotope production facilities may pose limited on-site and off-site hazards. However, addressing the perceived hazards or other non-radiological hazards in these circumstances may warrant implementing parts of emergency arrangements.

16.6. The applicability of paragraphs in GSR Part 7 to facilities in emergency preparedness category III is set out in the annex to GSR Part 7 [15] and these should be used during the preparation of emergency plans for the radioisotope production facility.

EMERGENCY PLANS AND PROCEDURES

16.7. Although the prevention of incidents and accidents is the first line of defence, events could still occur that would necessitate protective actions or other response actions. The operating organization is required to have in place an emergency plan and procedures prepared in advance, for the goals of emergency response to be achieved and for the emergency response to be effective [15].

16.8. An outline for a facility (on-site) emergency plan can be found in Ref. [~~50~~52]; this should be used for developing the emergency plan for the radioisotope production facility. Notices

outlining the procedures for notification of an emergency and activation of an emergency response should be clearly and visibly posted inside the facility at locations where they might be needed, and staff should be trained in these procedures (see section 4.2.18 of Ref. [~~50~~52]).

16.9. The emergency plan for the radioisotope production facility should address, but not be limited to, scenarios such as theft of sources, on-site contamination or leaking due to damage of the source, accidental radioactive releases to the environment and overexposures of workers. Emergency procedures should include, but not be limited to:

— Protocols for notification of an emergency and activation of an emergency response;

— Communication and coordination arrangements;

— Provisions for obtaining support from off-site emergency services;

— Provision of instructions to the site personnel and provisions for accounting the site personnel;

— Delineation of the affected area and access control;

— Measures and actions to protect site personnel and emergency workers;

— Arrangements for communication with the public.

A qualified expert or radiation protection adviser should be consulted, where possible, when drawing up emergency plans and procedures. Examples of immediate on-site actions to be taken in case of an emergency at a radioisotope production facility are given in Annex II.

16.10. Recommendations on developing adequate emergency arrangements at the organizational, local and national levels on a step by step basis are also provided in GS-G-2.1 [~~48~~50]. Further practical guidance regarding generic procedures for assessment and response during a radiological emergency is provided in Ref. [~~51~~53].

16.11. Implementation of the on-site emergency plan and procedures may require off-site support (e.g. off-site response organizations, emergency services and radiation protection specialists), as addressed in GSR Part 7 [15] and GS-G-2.1 [~~48~~50]. The emergency plan should set out detailed arrangements for obtaining such off-site support.

16.12. The operating organization is required to submit its on-site emergency plan to the regulatory body for approval [15]. This is required to be done when applying for an authorization.

16.13. Arrangements are required to be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons from research, operating experience (such as in the response to emergencies) and emergency exercises. [15].~~Emergency plans and procedures are required to be periodically reviewed and updated with the aim of incorporating lessons from research, operating experience (such as response to emergencies) and exercises [15].~~

EMERGENCY EQUIPMENT

16.14. The operating organization is required to ensure that all necessary tools, instruments, supplies, equipment, communication systems, facilities and documentation for responding to emergencies are made available and are subject to a quality management programme that includes arrangements for inventory control, resupplies, testing and calibrations [15]. All necessary tools, instruments, supplies, equipment, communication systems, facilities and documentation should be maintained in a manner that is readily available and functional for use under emergency conditions.

16.15. For emergencies involving radioisotope production sources, the following equipment should be considered, as appropriate:

—Appropriate and functional survey meters to measure both high and low dose rates;

—Personal alarm dosimeters and direct reading dosimeters (preferably electronic personal dosimeters);

—Additional personal dosimeters (optically stimulated luminescence dosimeters, thermoluminescent dosimeters and/or film badges);

—Personal protective equipment;

—Barrier materials and notices;

—Lead bricks;

—Suitable tool kits and source recovery equipment (long handled tongs, pliers, screwdrivers, bolt cutters, adjustable spanner, torch, lead storage container for sources);

—Materials and agents for decontamination [~~52~~54];

—A spare shielded container;

—Plastic sheets, air tight bags for rupture of gaseous sources, a swipe test kit and a measuring tape;

—Communication equipment (e.g. mobile phones);

—Spare batteries for survey meters, electronic personal dosimeters, mobile phones and torches;

—Pens, paper, calculator and an incident log book with first responder sheets;

—Equipment manuals, procedures and instructions.

16.16. If it is suspected that a radioactive source might have been damaged, it should be ensured that the leak is detected promptly and the extent of the contamination is assessed.

TRAINING AND EXERCISES

16.17. Personnel who will participate in implementing the emergency plans are required to be adequately qualified and trained for the effective fulfilment of their duties [15]. This should include familiarization with and understanding of the plans, procedures, analytical tools and other arrangements, together with specific training on implementing specific emergency procedures and on the use of the emergency equipment, as appropriate. Provisions for training should be reviewed periodically to ensure the continued proficiency of emergency workers.

16.18. Emergency workers should implement only those parts of the emergency plans or those emergency procedures for which they have been authorized and trained.

16.19. Exercise programmes are required to be developed and implemented to ensure that all specified functions required to be performed for emergency response as well as organizational interfaces are tested at suitable intervals [15]. Guidance on the preparation, conduct and evaluation of exercises including guidance on various types of exercises, their purpose, as well as examples of scenarios for category III facilities, is provided in Ref. [~~49~~51].

16.20. Training should cover the following:

(i) Recognizing the circumstances indicative of an emergency;

(ii) Procedures for notification of an emergency and activation of an emergency response, including provisions for obtaining assistance from off-site emergency services;

(iii) Implementation of necessary on-site mitigatory actions and protective actions, including provision of immediate first aid, and procedures for evacuation of non-essential personnel from facility;

(iv) Assessment of the situation;

(v) Use of emergency response tools and equipment including firefighting equipment;

(vi) Use of personnel protective equipment;

~~(v)~~(vii) Use of ~~radiological~~workplace monitoring equipment;

~~(vi)~~(viii) Implementation of recovery actions, including decontamination;

~~(vii)~~(ix) Measures to be followed for their protection during the emergency response.

~~16.21. Arrangements are required to be made to maintain, review and update emergency plans, procedures and other arrangements and to incorporate lessons from research, operating experience (such as in the response to emergencies) and emergency exercises. [15].~~

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REPORTING

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~~16.22.~~16.21. Arrangements are required to be made to undertake a timely and comprehensive analysis of the emergency and the emergency response [15]. A comprehensive report on the findings of the analysis should be prepared by the radiation protection officer in consultation, as appropriate, with relevant interested parties and, if necessary, with qualified expert(s) or radiation protection adviser(s).

~~16.23.~~16.22. The report should be submitted to senior management as well as to the regulatory body and, as appropriate, to other relevant authorities at local, regional or national level. If the emergency was caused by an equipment malfunction, the supplier and other users of similar equipment should be promptly informed so that the equipment can be evaluated and appropriate action taken and similar emergencies can be avoided.

~~16.24.~~16.23. The report should, inter alia, include the following:

(a) A detailed description of the emergency, including specifics of the equipment and sources involved;

(b) Environmental and working conditions at the time of the emergency, with particular reference to whether or not these conditions played any significant part in causing the emergency or affecting the outcome;

(c) The root causes of the emergency;

(d) A detailed description of the emergency response taken;

(e) The personnel involved, the work they carried out, and their skills and qualifications;

(f) An assessment and summary of the doses received by all affected individuals;

(g) Corrective actions identified with the aim of preventing similar emergencies in the future and necessary for improving overall radiation safety, security and emergency arrangements;

(h) Proposed means and timeframes for implementation of the corrective actions identified and responsible staff.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Research Reactor Database (RRDB), IAEA, Vienna (2017), https://nucleus.iaea.org/RRDB/RR/ReactorSearch.aspx

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Directory of Radiotherapy Centres (DIRAC), IAEA, Vienna (2017), https://dirac.iaea.org/

[3] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIROMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Glossary: 2018 Edition, IAEA, Vienna (in preparation).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Standards Series No. SSR-3, Safety of Research Reactors, IAEA, Vienna (2016).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Security Recommendations on Radioactive Material and Associated Facilities, IAEA Nuclear Security Series No. 14, IAEA, Vienna (2011).

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Security of Radioactive Sources, IAEA Nuclear Security Series No. 11, IAEA, Vienna (2009).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Security in the Transport of Radioactive Material, IAEA Nuclear Security Series No. 9, IAEA, Vienna (2008).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Security of Nuclear Information, IAEA Nuclear Security Series No. 23-G, IAEA, Vienna (2015).

[10] EUROPEAN ATOMIC ENERGY COMMUNITY, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Fundamental Safety Principles, IAEA Safety Standards Series No. SF-1, IAEA, Vienna (2006).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, Categorization of Radioactive Sources, IAEA Safety Standards Series No. RS-G-1.9, IAEA, Vienna (2005).

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Dangerous Quantities of Radioactive Material (D-Values), EPR-D-Values (2006), IAEA, Vienna (2006).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Cyclotron Produced Radionuclides: Guidelines for Setting Up a Facility, Technical Reports Series No. 471, IAEA, Vienna (2009).

[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Governmental, Legal and Regulatory Framework for Safety, IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), IAEA, Vienna (2016).

[15] COMPREHENSIVE NUCLEAR-TEST-BAN TREATY ORGANIZATION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL CIVIL AVIATION ORGANIZATION, INTERNATIONAL LABOUR ORGANIZATION, INTERNATIONAL MARITIME ORGANIZATION, INTERPOL, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN

HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, UNITED NATIONS OFFICE FOR THE CO-ORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, WORLD METEOROLOGICAL ORGANIZATION, Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSR Part 7, IAEA, Vienna (2015).

[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[17] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, ISO 9001:2015 Quality Management Systems – Requirements, ISO (2015).

[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, Vienna (2006).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Functions and Processes of the Regulatory Body for Safety, IAEA Safety Standards Series No. GSG-13, IAEA, Vienna (in preparation).

[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Occupational Radiation Protection, IAEA Safety Standards Series No. GSG-7, IAEA, Vienna (in preparation).

[21] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016).

[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, IAEA Safety Standards Series No. SSR-6 (Rev. 1), IAEA, Vienna (~~in preparation~~2018).

[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Radioisotope Handling Facilities and Automation of Radioisotope Production, IAEA-TECDOC-1430, IAEA, Vienna (2004).

[24] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Radiation Protection for Particle Accelerator Facilities, Report No. 144, NCRP, Washington, DC (2003).

[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological Safety Aspects of the Operation of Electron Linear Accelerators, Technical Reports Series No. 188, IAEA, Vienna (1979).

[26] BRITISH STANDARDS INSTITUTION, Recommendation for Data on Shielding from Ionizing Radiation, Part 1: 1966, Shielding from Gamma Radiation, BS 4094, BSI, London (1988).

[27] BRITISH STANDARDS INSTITUTION, Recommendation for Data on Shielding from Ionizing Radiation, Part 2: 1971, Shielding from X radiation, BS 4094, BSI, London (1988).

[28] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Structural Shielding Design for Medical X-Ray Imaging Facilities, Report No. 147, NCRP, Bethesda, MD (2004).

[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in the Design of Radiotherapy Facilities, Safety Reports Series No. 47, IAEA, Vienna (2006).

[30] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities, Report No. 151, NCRP, Washington, DC (2005).

[31] INTERNATIONAL ATOMIC ENERGY AGENCY, Site Survey and Site Selection for Nuclear Installations, IAEA Safety Standards Series No. SSG-35, Vienna (2015).

[32] INTERNATIONAL ATOMIC ENERGY AGENCY, Predisposal Management of Radioactive Waste, IAEA Safety Standards Series No. GSR Part 5, IAEA, Vienna (2009).

[33] INTERNATIONAL ATOMIC ENERGY AGENCY, Implications for Occupational Radiation Protection of the New Dose Limit for the Lens of the Eye, IAEA-TECDOC-1731, IAEA, Vienna (2013).

[34] INTERNATIONAL COMMISSION ON RADIATION PROTECTION, Dose Coefficients for Intakes of Radionuclides by Workers, ICRP Publication 68, Pergamon (1994).

[35] INTERNATIONAL ATOMIC ENERGY AGENCY, Calibration of Radiation Protection Monitoring Instruments, Safety Reports Series No. 16, IAEA, Vienna (2000).
[36] INTERNATIONAL ATOMIC ENERGY AGENCY, Regulatory Control of Radioactive Discharges to the Environment, IAEA Safety Standards Series No. GSG-9, IAEA, Vienna (in preparation).
[37] INTERNATIONAL ATOMIC ENERGY AGENCY, Environmental and Source Monitoring for Purposes of Radiation Protection, IAEA Safety Standards Series No. RS-G-1.8, IAEA, Vienna (2005).
~~[37]~~[38] INTERNATIONAL ATOMIC ENERGY AGENCY, Programmes and Systems for Source and Environmental Radiation Monitoring, Safety Reports Series No. 64, IAEA, Vienna (2010).
~~[38]~~[39] INTERNATIONAL ATOMIC ENERGY AGENCY, Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment, Safety Reports Series No. 19, IAEA, Vienna (2001).
[40] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Medical, Industrial and Research Facilities, IAEA Safety Standards Series No. SSG-49, IAEA, Vienna. (in preparation)
~~[39]~~[41] INTERNATIONAL ATOMIC ENERGY AGENCY, Classification of Radioactive Waste, IAEA Safety Standards Series No. GSG-1, IAEA, Vienna (2009).
~~[40]~~[42] INTERNATIONAL ATOMIC ENERGY AGENCY, Decommissioning of Facilities, IAEA Safety Standards Series No. GSR Part 6, IAEA, Vienna (2014).
~~[41]~~[43] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Concepts of Exclusion, Exemption and Clearance, IAEA Safety Standards Series No. RS-G-1.7, IAEA, Vienna (2004).
~~[42]~~[44] INTERNATIONAL CIVIL AVIATION ORGANIZATION, Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2015–2016 Edition, ICAO, Montreal (2014).
~~[43]~~[45] INTERNATIONAL MARITIME ORGANIZATION, International Maritime Dangerous Goods (IMDG) Code, 2014 Edition including Amendment 37–14, IMO, London (2014).
~~[44]~~[46] UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE, INLAND TRANSPORT COMMITTEE, European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), 2011 Edition, UNECE, Geneva (2011).
~~[45]~~[47] UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE, INLAND TRANSPORT COMMITTEE, European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN), 2011 Edition, UNECE, Geneva (2011).
~~[46]~~[48] The MERCOSUR/MERCOSUL Agreement of Partial Reach to Facilitate the Transport of Dangerous Goods, Signed by the Governments of Argentina, Brazil, Paraguay and Uruguay (1994).
~~[47]~~[49] INTERNATIONAL ATOMIC ENERGY AGENCY, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition), IAEA Safety Standards Series No. SSG-26, IAEA, Vienna (2012). (A revision of this publication is in preparation.)
~~[48]~~[50] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS OFFICE FOR THE COORDINATION OF HUMANITARIAN AFFAIRS, WORLD HEALTH ORGANIZATION, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).
~~[49]~~[51] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE,

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PAN AMERICAN HEALTH ORGANIZATION AND WORLD HEALTH ORGANIZATION, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

~~[50]~~[52] INTERNATIONAL ATOMIC ENERGY AGENCY, Method for Developing Arrangements for Response to a Nuclear or Radiological Emergency, EPR-Method (2003), IAEA, Vienna (2003).

~~[51]~~[53] INTERNATIONAL ATOMIC ENERGY AGENCY, Generic Procedures for Assessment and Response during a Radiological Emergency, IAEA-TECDOC-1162, IAEA, Vienna (2000).

~~[52]~~[54] INTERNATIONAL ATOMIC ENERGY AGENCY, State of the Art Technology for Decontamination and Dismantling of Nuclear Facilities, Technical Reports Series No. 395, IAEA, Vienna (1999).

ANNEX I

KEY RADIATION SAFETY ISSUES TO BE TAKEN INTO ACCOUNT WHEN PLANNING THE PRODUCTION OF ACCELERATOR BASED RADIOISOTOPES

I–1. The production of radioisotopes has to comply with radiation safety requirements for protection of workers and the public. Some of the key aspects to be taken into account in planning the production of radioisotopes are listed in the following:

(a) Material, process and personnel flow diagrams that are appropriate for the design of the facility;
(b) Appropriate shielding;
(c) Carefully designed mechanical, electrical and utility equipment for the operation of the cyclotron in the vault;
(d) Doors to high radiation areas with interlocks;
(e) Negative pressure in the cyclotron vault;
(f) Adequately shielded hot cells;
(g) Air handling equipment for the facility;
(h) Air pressure regimes in rooms and hot cells;
(i) Radiation monitoring provisions;
(j) An automated response system for engineering controls in the building;
(k) Provisions for security of radioactive material;
(l) A decommissioning plan and financial assurance for decommissioning;
(m) Application of health and safety requirements (e.g. fire protection requirements);
(n) Utility capacity (e.g. electric power, coolant, medical gases);
(o) Research and development needs ;
(p) Application of good manufacturing practice requirements;
(q) Provision for quarantine of materials on receipt ;
(r) Verification that recipients of transferred radioactive material are authorized to receive such material;
(s) Emergency planning and response;
(t) IT capacities and networks;
(u) Redundancy;
(v) Quality control laboratories.

ANNEX II
EXAMPLE OF IMMEDIATE ON-SITE RESPONSE ACTIONS IN CASE OF AN EMERGENCY AT A RADIOISOTOPE PRODUCTION FACILITY

II–1. This Annex provides practical guidance for immediate on-site response actions that might be warranted in case of an emergency at a radioisotope production facility. Although the actions are listed in the sequence in which they can be expected to generally be performed, it may be necessary to implement these actions in another sequence or simultaneously. These actions are generic and focused only on those that are immediately warranted on-site. They do not take into account all the emergency response actions that might be warranted off the site and those actions that might be warranted beyond these immediate actions on the site, as stated in related IAEA Safety Standards and practical guidance [II–1] to[II–4].

II–2. Operating personnel:

(a) Recognize promptly abnormal conditions at the site that are indicative of an emergency and activate the pre-planned emergency response;

(b) Take lifesaving actions and give first aid;

(c) Evacuate non-essential personnel and visitors from the potentially hazardous area;

(d) Establish an inner cordoned off area and prevents any access;

(e) Notify relevant authorities (on the site and off the site), including the radiation protection officer;

(f) Measure the radiation dose rates and record any doses measured by direct reading dosimeters;

(g) Re-adjust the inner cordoned off area if necessary;

(h) Keep the area always attended until the designated emergency workers and the radiation protection officer -arrive.

II–3. The radiation protection officer:

(a) Monitors on-site personnel and visitors for contamination and ensures that contaminated individuals do not leave the site undetected and contaminated items are not removed from the site undetected;

(b) Recommends decontamination of individuals and items, as appropriate, in accordance with emergency procedures;

(c) Confirms whether off-site protective actions are needed;

(d) Ensures a unified command and control system is established as pre-planned to manage the emergency response;

(e) Recommends a specific course of action on the basis of previously established emergency procedures, taking care to adequately protect emergency workers and on-site personnel as well as to minimize their doses;

(f) If necessary, rehearses the planned course of action with respective emergency workers before entering the inner cordoned off area to implement the emergency plan;

(g) Implements, along with designated emergency workers, the planned course of action;

(h) If necessary, calls for technical assistance from a qualified expert or radiation protection adviser and/or from the manufacturer of equipment;

(i) Ensures that the access control to the inner cordoned-off area is in place at all times;

(j) As appropriate, notifies senior management and the regulatory body and ensures continuous communication with off-site authorities.

REFERENCES TO ANNEX II

[II–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Arrangements for Preparedness for a Nuclear or Radiological Emergency, IAEA Safety Standards Series No. GS-G-2.1, IAEA, Vienna (2007).

[II–2] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OFFICE, PAN AMERICAN HEALTH ORGANIZATION AND WORLD HEALTH ORGANIZATION, Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency: General Safety Guide, IAEA Safety Standards Series No. GSG-2, IAEA, Vienna (2011).

[II–3] INTERNATIONAL ATOMIC ENERGY AGENCY, Method for Developing Arrangements for Response to a Nuclear or Radiological Emergency, EPR-Method (2003), IAEA, Vienna (2003).

[II–4] INTERNATIONAL ATOMIC ENERGY AGENCY, Generic Procedures for Assessment and Response during a Radiological Emergency, IAEA-TECDOC-1162, IAEA, Vienna (2000).

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