



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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June 9, 2017

ALL AGREEMENT AND NON-AGREEMENT STATES
STATE LIAISON OFFICERS

OPPORTUNITY TO REVIEW AND COMMENT ON INTERNATIONAL ATOMIC ENERGY
AGENCY DRAFT SAFETY GUIDE DS434, "RADIATION SAFETY OF ACCELERATOR
RADIOISOTOPE PRODUCTION FACILITIES" (STC-17-050)

Purpose: To provide States with the opportunity to review and comment on the Draft Safety Guide DS434, "Radiation Safety of Accelerator Radioisotope Production Facilities,"¹ by August 8, 2017, to the contact listed.

Background: The International Atomic Energy Agency (IAEA) has made available the Draft Safety Guide DS434, "Radiation Safety of Accelerator Radioisotope Production Facilities," for Member State review and comment. Proposed changes from Member State review will be taken into account in the finalization of the safety standard. The objective of Draft Safety Guide DS434 is to provide recommendations on how to meet the requirements of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards with regard to radioisotope production facilities. This Safety Guide provides specific, practical recommendations on the safe design and operation of these facilities for use by operating organizations and the designers of these facilities, and by regulatory bodies.

Discussion: The U.S. Nuclear Regulatory Commission (NRC) is coordinating the U.S. review of this safety guide. Consolidated comments will be submitted to the IAEA by the NRC through established official channels. Please provide your comments to Cindy Flannery (cindy.flannery@nrc.gov) by August 8, 2017. The attached IAEA comment template is provided for your use. Any comments provided should refer to the relevant paragraph number in the draft text being reviewed and should propose alternative text, as appropriate.

The review should focus on the following:

- 1) Are there any safety issues that may be inconsistent with States' regulations or common practices?
- 2) Relevance and usefulness of this document — Are the stated objectives appropriate, and are they met by the draft text? Do you have any suggestions to include in the document?
- 3) Scope and completeness — Is the stated scope appropriate and is it adequately covered by the draft text?

¹ This information request has been approved by OMB under clearance numbers 3150-0029 and 3150-0200, expiration 1/31/2019 and 10/31/2018. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

- 4) Quality and clarity — Do the requirements and guidance in the document represent the current consensus among specialists in the field, and are they expressed clearly and coherently?
- 5) Are the requirements and guidance expressed clearly and coherently? If you have any questions regarding this correspondence?

Comments of an editorial nature will be considered; however, it should be noted that the draft text will be comprehensively edited by the IAEA Secretariat.

Enclosed is: (1) communication from the IAEA concerning Draft Safety Guide DS434 and its review, including an “Explanatory Note” regarding this document; (2) Draft Safety Guide DS434, “Radiation Safety of Accelerator Radioisotope Production Facilities;” and (3) blank template for comment preparation.

If you have any questions regarding this communication, please contact the individual named below:

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Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Explanatory Note from IAEA
2. Draft Safety Guide DS434
3. IAEA Comment Template



Atoms for Peace

الوكالة الدولية للطاقة الذرية

国际原子能机构

International Atomic Energy Agency

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The Secretariat of the International Atomic Energy Agency (IAEA) presents its compliments to the IAEA's Member States and has the honour to draw their attention to the following draft safety standard:

***Radiation Safety of Accelerator Radioisotope Production Facilities
(DS434)***

Member States and their experts are hereby provided with an opportunity to review and evaluate this draft safety standard, which is available online at:

<http://www-ns.iaea.org/standards/documents/draft-ms-posted.asp>

A hard copy of the draft text will be sent out upon request.

Any proposed changes to this draft text resulting from the review by Member States will be taken into account in the finalization of the safety standard.

Member States are kindly requested to provide comments on the draft text following the guidance given in the attached Explanatory Note.

The Secretariat of the International Atomic Energy Agency avails itself of this opportunity to assure the IAEA's Member States of its highest consideration.



2017-04-20

Enclosures: Explanatory Note

Form for Comments

Statement by the Commission on Safety Standards

Explanatory Note

Radiation Safety of Accelerator Radioisotope Production Facilities (DS434)

The draft text for review, entitled *Radiation Safety of Accelerator Radioisotope Production Facilities*, was prepared as a draft Safety Guide to be issued in the IAEA Safety Standards Series.

The draft text has already been reviewed through consultants' meetings, as well as by the Radiation Safety Standards Committee (RASSC), the Nuclear Safety Standards Committee (NUSSC), the Transport Safety Standards Committee (TRANSSC), the Waste Safety Standards Committee (WASSC), the Emergency Preparedness and Response Committee (EPReSC) and by the Nuclear Security Guidance Committee (NSGC).

The objective of this draft text, as accepted by the Commission on Safety Standards (CSS), is to provide guidance on the safety measures to be taken in those facilities that produce radioisotopes in both sealed and unsealed form in order to adequately protect workers, the public and the environment from radiation risks, consistently with the requirements established in *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* (IAEA Safety Standards Series No. GSR Part 3).

Comments are requested in relation to:

- Relevance and usefulness — Are the stated objectives appropriate, and are they met by the draft text?
- Scope and completeness — Is the stated scope appropriate, and is it adequately covered by the draft text?
- Quality and clarity — Does the guidance in the draft text represent the current consensus among specialists in the field, and is this guidance expressed clearly and coherently?

Comments of an editorial nature will be considered; however, it should be noted that the draft text will be comprehensively edited by the IAEA Secretariat.

Any comments should be made in English, should refer to the relevant paragraph number in the draft text being reviewed, and should propose alternative text where appropriate. Please use the attached Form for Comments to record all comments.

The responsible IAEA officer is Mr Tony Colgan of the Department of Nuclear Safety and Security, who may be contacted for further information in connection with this subject by telephone at: +43 1 2600 24271 or via email at: T.Colgan@iaea.org.

Any comments should be sent through the established official channels to the responsible IAEA officer by **18 August 2017**.

Form for Comments
Radiation Safety of Accelerator Radioisotope Production Facilities (DS434)

COMMENTS BY REVIEWER				RESOLUTION			
Reviewer: Page.... of.... Country/Organization: Date:							
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection

Statement by the Commission on Safety Standards

Publications in the IAEA Safety Standards Series are prepared and reviewed in accordance with a uniform process. To this end, the Commission on Safety Standards (CSS) and five committees with harmonized terms of reference — the Emergency Preparedness and Response Standards Committee (EPRaSC), the Nuclear Safety Standards Committee (NUSSC), the Radiation Safety Standards Committee (RASSC), the Transport Safety Standards Committee (TRANSSC) and the Waste Safety Standards Committee (WASSC) — have been established. The CSS has a special overview role with regard to the IAEA's safety standards and provides advice to the Director General on the IAEA's overall programme with regard to regulatory aspects of safety.

The uniform preparation and review process involves organizing expert group meetings; arranging at different stages of preparation for the internal review of draft texts; submitting the texts to the relevant Committee(s) for review; submitting draft texts to the IAEA's Member States for comment; and submitting the approved final draft of the safety standard¹ for endorsement by the CSS before publication.

The CSS stresses the importance of Member States' comments to the preparation and review process for safety standards. Publications in the IAEA Safety Standards Series not only should be of the requisite quality but also should represent the consensus view of the Member States and should address the issues of importance to the Member States. While the CSS, the Committees and the Secretariat strive to provide safety standards that satisfy these criteria, the review of draft standards by experts in the Member States is an essential stage in obtaining the broadest possible technical consensus and the highest possible quality and relevance.

Member States are also encouraged to provide the IAEA with feedback on their use of the safety standards. The status of safety standards extant and in preparation can be seen on the IAEA's website, where there are also links to electronic files for existing publications, including those in other official languages.² The responsible IAEA officer is Mr Dominique Delattre, Head of the Safety and Security Publications Unit of the Department of Nuclear Safety and Security. He may be contacted for further information in connection with this subject by telephone at: + 43 1 2600 22696 or via email at: D.Delattre@iaea.org.

¹ Safety Guides are published under the authority of the Director General. Safety Fundamentals and Safety Requirements publications require the approval of the Board of Governors, after endorsement by the CSS.

² See <http://www-ns.iaea.org/committees/files/CSS/205/status.pdf>.

DS434

April 2017

IAEA SAFETY STANDARDS

for protecting people and the environment

Status: Step 8 - for submission to Members
States for 120-day comment

Deadline for comments: 18 August 2017

Radiation Safety of Accelerator Radioisotope Production Facilities

DRAFT SAFETY GUIDE No. SSG-

DS434

IAEA

International Atomic Energy Agency

DRAFT

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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. The facilities which produce radionuclides and the 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, members of the public, and the environment unless they are properly controlled.

1.2. In 2003, there were 278 research reactors in operation, of which approximately 70 were deemed useful for regular radioisotope production [1]. In 2006, it was estimated that there were approximately 350 cyclotrons in operation worldwide that were 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. The IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [3] establish the basic requirements for protection of people against exposure to ionizing radiation and for the safety of radiation sources². The implementation of these requirements at 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 social factors being taken into account.

1.4. Unless otherwise stated, terms are used with the meanings ascribed to them in the IAEA Safety Glossary (2007 Edition) [4].

¹ The word ‘radioisotope’ is commonly used in the context of the facilities considered in this Safety Guide and is therefore retained here. Strictly, the word ‘radionuclide’ should be used or the word qualified by the name of the element to which it relates, for example, 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.

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 these facilities for use by operating organizations and the designers of these facilities, and by regulatory bodies.

SCOPE

1.6. This Safety Guide addresses the radiation safety and protection aspects of the process whereby radioisotopes that have been produced in accelerators (principally cyclotrons), or purified from other sources are processed into radioactive products for subsequent use, for example, in 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 facilities 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 document addresses these in the following four categories of accelerators:
 - (i) Low energy (<20 MeV /nucleon) cyclotrons for medical radioisotope production;
 - (ii) 20 – 40 MeV/ nucleon isotope production cyclotrons;
 - (iii) > 40 MeV/ nucleon cyclotrons for mixed research and radioisotope production;
 - (iv) Linear accelerators used for radioisotope production.

1.8. The use of radioactive material following its manufacture, and standards and quality assurance procedures that pertain to its production are outside the scope of this document. The production of fissile material is outside the scope of this document.

1.9. The design and operation of reactors is outside the scope of this document to avoid duplication with a number of IAEA publications on research reactors.

1.10. Centralized radiopharmacies that formulate radiopharmaceuticals from bulk quantities of radioisotopes or generators are outside the scope of this document.

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 document.

1.12. Consideration of non-radiological related 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 also 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 security guidance can be found in the IAEA's Nuclear Security Series [5, 6, 7, 8].

STRUCTURE

1.14. The justification of radioisotope production facilities is discussed in Section 2. Designs of irradiation facilities are categorized according to radiation type and methods of accessibility and shielding, as described in Section 3 of this Safety Guide. The authorization of irradiation practices, the responsibilities of the operating organization and general radiation safety issues are discussed in Section 4. The safety assessment duties and radiation protection programme are described in Sections 5 and 6 respectively.

1.15. Section 7 provides a description of training and education of personnel of radioisotope production facilities. Section 8 deals with individual monitoring of workers of isotope production facilities. Section 9 discusses the workplace monitoring.

1.16. Section 10 focuses on the environmental monitoring and radioactive effluent discharge. Section 11 addresses the personal protective equipment being used by the personnel.

1.17. Sections 12 to 16 are devoted to the control of radioactive material, facility and equipment design, testing and maintenance of the equipment, radioactive waste management, transport of radioactive material, and emergency preparedness and response.

1.18. Examples of a safety assessment structure and emergency response procedures can be found in the Annexes I and II respectively.

2. JUSTIFICATION OF PRACTICES

2.1. The IAEA Fundamental Safety Principles [9] state that the fundamental safety objective is to protect people and the environment from harmful effects of ionizing radiation. Principle 4, Justification of facilities and activities, states that “Facilities and activities that give rise to radiation risks must yield an overall benefit”. This may be taken as equivalent to the well-established principle of justification of practices, the operation of radioisotope production facilities being one example [3].

2.2. The basic requirements for radiation protection for practices established in GSR Part 3 [3] are: justification of practices; individual dose limits; and optimization of protection and safety.

2.3. When the principle 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]. The operation of radioisotope production facilities can on occasion result in doses to workers and releases of radioactive material to the environment that may be in excess of authorized limits. Furthermore, the operation of inadequately designed facilities may result in elevated dose rates in both uncontrolled areas and unsupervised areas that 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 material.

2.4. IAEA Safety Guide RS-G-1.9 [10] 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 [11].

2.5. Within this categorization system [10], 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 may be

fatal. At the lower end of the categorization system, sources in Category 5 are the least dangerous; however, even these sources could give rise to doses in excess of the dose limits if not properly controlled, and therefore need to be kept under appropriate regulatory control. The finished products of radioisotope production fall into source categories 3–5.

2.6. The decision as to whether the operation of radioisotope production facilities is justified is specific to the circumstances and benefits of their use, including national priorities, so definitive recommendations regarding justification cannot be provided. Ultimately, the decision as to whether the operation of such facilities is justified should be made on a case by case basis by the appropriate governmental authority, which should weigh the various benefits and risks associated with their operation in determining whether specific practices are justified. The governmental authority's 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 FACILITIES

3.1. For the purposes of this Safety Guide, general categories of radioisotope production facilities are defined on the basis of the design of the facility and the resultant radiation protection provisions necessary:

- Facilities that process targets that have been irradiated by a charged particle beam of an accelerator to produce radioisotopes;
- Accelerator facilities with energies of less than 70 MeV/nucleon that are operated principally to produce radioisotopes. This document addresses these four categories of accelerators:
 - Low energy (<20 MeV /nucleon) cyclotrons for medical radioisotope production;
 - 20–40 MeV/nucleon isotope production cyclotrons;
 - >40 MeV /nucleon cyclotrons for mixed research and radioisotope production; and
 - Linear accelerators used for radioisotope production.

When recommendations in this Safety Guide only apply to specific categories of radioisotope production facilities, those categories are identified.

Irradiation of targets in accelerators

3.2. Accelerators for the production of radioisotopes are generally located in the same building as where the radioisotope containing products are synthesized.

3.3. Accelerators can be used for the activation of isotopes for research and radiopharmaceutical usage. For the production of ^{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 are used for activation of isotopes for research and radiopharmaceutical usage. Such accelerators are designed and sold to isotope production facilities or hospitals. Some accelerators are designed specifically for positron emission tomography (PET) radiopharmaceuticals, e.g. ^{18}F . Examples of accelerator types I–V can be found in Section 6 of Ref. [12].

4. DUTIES AND RESPONSIBILITIES

GENERAL

4.1. The person or organization responsible for facilities and activities that give rise to radiation risks should have the prime responsibility for protection and safety. Other parties should have specified responsibilities for protection and safety. In line with para. 3.6 of the IAEA Fundamental Safety Principles [9], 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 and

(g) Establishing plans and procedures to respond to any radiological emergency that may arise at the facility and coordinating exercises to test the same [13].

4.2. Specific duties and the day to day responsibilities for the design, operation and eventual decommissioning of the facility will, however, lie with a range of people, including senior management, the radiation protection officer (RPO), workers who operate the facility and handle radioactive material, and qualified experts/radiation protection advisers (RPAs).

MANAGEMENT OF RADIATION SAFETY AND SAFETY CULTURE

4.3. The operating organization, through its managers, 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/RPA should be appointed to take responsibility, for radiation safety and regulatory compliance.

4.4. A senior manager should be designated as having overall responsibility for overseeing radiation safety, and verifying that all activities involving radioactive material are carried out in accordance with regulatory requirements. Responsibilities for radiation safety are required to be established, and they should be agreed to by all relevant parties and recorded in written form. Managers should ensure that procedures are in place for the protection of workers, the public and the environment, and for ensuring that doses are kept as low as reasonably achievable (the principle of optimization). All policies and procedures should be documented, and should be made available to all staff and the regulatory body as appropriate.

4.5. 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, and to discourage complacency with regard to safety [14]. A strong 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.

4.6. In cases where there is a potential conflict between operational responsibilities, such as responsibilities for meeting a production schedule and responsibilities for radiation safety, radiation safety requirements should always take priority.

4.7. Operating organizations with a strong safety culture do not assign blame when incidents occur; they should learn from their mistakes, foster a questioning attitude and seek continuous improvement in the safety of work processes. For each incident, the question of acceptable behavior should be answered on a case by case basis and, in some cases, disciplinary measures may be taken.

4.8. As stated in GSR Part 2 [14], the operating organization is required to establish, implement, assess and continually improve an integrated management system that defines the responsibilities of all relevant persons and that details the key radiological requirements for personnel, equipment and the facility. The management system should be based on national or international standards [14, 15, 16]. It should incorporate mechanisms for routine internal inspections and audits, as well as third party audits, as appropriate. The radiation protection programme should be integrated into the management system.

Facilities and resources

4.9. The operating organization should ensure that suitable safety systems have been installed and equipment is available to enable work to be carried out safely and in accordance with regulatory requirements.

Notification and authorization

4.10. An application for a license should contain information that demonstrates the safety of the practice. Guidance relating to the preparation of an application for the authorization of a radioisotope production facility, and its subsequent review by the regulatory body is included in a GS-G-1.5 [17].

4.11. When applying for an authorization, the operating organization should provide the regulatory body with the appropriate documentary evidence to demonstrate that an adequate level of radiation safety will be afforded and maintained.

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

- (a) Identification of the operating organization and the individual(s) representing the operating organization;
- (b) Radioisotopes and chemical forms of the material to be possessed;

- (c) Characteristics of the particle accelerator, i.e. type (cyclotron, linear accelerator), energy, current, beam characteristics and layout;
- (d) Facility in which particle accelerators and/or radioactive material will be processed and stored with particular attention paid to associated safety systems and equipment, e.g., radiation shielding, interlock systems, fume hoods, remote handling tools, effluent exhaust systems, monitoring systems, and warning systems;
- (e) Locations where particle accelerators will be operated and radioactive material will be processed and stored;
- (f) Inventory system to be used to account for radioactive material;
- (g) Identification and details of qualifications of the radiation protection officer (RPO) and, where appropriate, qualified experts or radiation protection advisers (RPAs);
- (h) Operating organization's requirements for the training and qualification of all relevant staff;
- (i) Justification for the operation of the facility;
- (j) Safety assessment covering the operation of the facility;
- (k) Radiation protection programme;
- (l) Arrangements for the management of radioactive waste; and
- (m) Arrangements for responding to a radiological emergency within the facility premises (see Section 16).

4.13. The operating organization should obtain the approval of the regulatory body before commencing 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, the principal radiation protection officer and qualified experts/radiation protection advisers.

RADIATION PROTECTION OFFICER

4.14. The operating organization should appoint at least one employee as a radiation protection officer (RPO) to oversee the day to day implementation of the radiation protection

programme and to carry out the duties required by the programme. While the RPO oversees the application of the safety standards, the prime responsibility for safety remains with the operating organization. The RPO should be technically competent in radiation protection matters of relevance for a given type of radioisotope production facility. The RPO should report directly to senior management and should have sufficient authority to discharge his/her duties. Where there is a conflict between safety and operations, the RPO should have the authority to stop work that is at risk.

4.15. During times when the RPO 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/RPAs or the designation of deputy RPOs who are present at the facility during times of operation.

4.16. The duties of the RPO 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 to comply with regulatory requirements;
- (b) Optimizing exposure controls and maintaining safety systems and other equipment that contributes to controlling exposure of workers and members of the public;
- (c) Oversight of the inspection and maintenance of safety systems, radiation monitoring equipment and warning features;
- (d) Establishment of controlled areas and supervised areas and oversight of access control for controlled areas;
- (e) Periodic review of arrangements for individual monitoring of workers;
- (f) Investigation of high, unexpected or reportable exposures and overexposures;
- (g) Ensuring that workers are suitably trained in the use of equipment and in radiation protection, and that they receive regular refresher training;
- (h) Ensuring that emergency plans and procedures are established and maintained and exercises are conducted as appropriate (see Section 16);

- (i) Oversight of arrangements for environmental monitoring, including review of the results of such monitoring;
- (j) Establishment, issue and periodic review of local rules (including work permits where appropriate);
- (k) Investigation and reporting of incidents and accidents;
- (l) Liaising with contractors, designers and suppliers with regard to radiation protection matters and significant changes to physical or operational aspects of the facility;
- (m) Ensuring the adequacy of safety assessments and emergency plans for any reasonably foreseeable incidents with consequences for radiation protection;
- (n) Oversight of issues related to the safe transport of sources including the receipt of packages containing radioactive material and the preparation of packages for shipment, and
- (o) Maintaining records relevant to the radiation protection programme including records concerning the radioactive material inventory, workplace monitoring, individual monitoring, environmental monitoring and radioactive waste.

QUALIFIED EXPERTS/RADIATION PROTECTION ADVISER

4.17. A qualified expert/RPA is an individual who is duly recognized, by virtue of certification by appropriate boards or societies, professional licenses or academic qualifications and experience, as having expertise in a relevant field of specialization. The qualifications of a qualified expert are described in paras 3.65–3.71 of Ref. [18].

4.18. The operating organization may identify one or more qualified experts/RPA to provide advice on various matters concerning radiation safety in the design and operation of the facility. A qualified expert/RPA 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/RPA to be available when necessary. As with the RPO, the operating organization cannot delegate its responsibility for safety to a qualified expert.

4.19. A qualified expert/RPA should be experienced in radiation protection matters and should have had:

- (a) Theoretical training that includes training in radiation protection and the properties of radiation as used in the radioisotope production facility;
- (b) A thorough knowledge of the hazards associated with the radiation present and the ways in which the hazards can be controlled and minimized;
- (c) A knowledge of the emergency preparedness category of the facility in the context of the emergency preparedness and response (EPR) plans conforming to relevant requirements of the international standards [13];
- (d) An understanding and detailed knowledge of the working practices used in the facility, as well as general knowledge of the working practices in other similar facilities;
- (e) 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 by the operating organization;
- (f) An awareness of regulatory requirements that could affect the work with radiation on which the qualified expert/RPA gives advice;
- (g) The ability to give advice so that the operating organization can comply with regulatory requirements and follow good radiation protection practices;
- (h) The personal qualities to be able to communicate with workers and their representatives;
- (i) The ability to keep up-to-date with developments in the use of radiation in the field in which the qualified expert/RPA gives advice and with developments in radiation protection.

4.20. The operating organization should provide the qualified expert/RPA 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.

4.21. The operating organization may consult the qualified expert/RPA 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, individual and environmental radiation monitoring;
- (d) Investigation of high exposures and overexposures;
- (e) Staff training;
- (f) Safety assessment and emergency arrangements³;
- (g) Examination of any plans for a facility or for modifications of an existing facility;
- (h) Independent audits related to radiation safety matters;
- (i) Quality management;
- (j) Emergency preparedness and response (see Section 16).

WORKERS

4.22. While the primary responsibility for radiation 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 to other individuals or the environment such as process operators, operators working with product shipment, operators working with waste, research scientists, pharmacists, laboratory technicians, personnel with housekeeping duties and personnel who perform routine maintenance activities. The

³ In line with Ref. [13], emergency arrangements are “the integrated set of infrastructural elements, put in place at the preparedness stage, that are necessary to provide the capability for performing a specified function or task required in response to a nuclear or radiological emergency” and include: assignment of authorities and responsibilities, organization, coordination, personnel, plans, procedures, facilities, equipment, training, exercises, quality management programme etc.

competence of these workers to perform their duties in a safe manner should be verified by a RPO. Workers should:

- (a) Follow the local rules (para 4.26) and any relevant procedures;
- (b) Wear their individual dosimeters in the correct place at all times during radiation work and record their daily doses. If the dose exceeded the level set by the local rules they should report it to the responsible (senior) manager or RPO (see Section 6);
- (c) Use radiation monitors properly and in a systematic manner (see Section 8);
- (d) Cooperate with the RPO and qualified experts on all radiation safety issues;
- (e) Participate in any training concerning radiation safety including emergency drills and exercises;
- (f) Abstain from any willful action that could put themselves or others in contravention of regulatory requirements or of the operating organization's own requirements.

4.23. Workers should promptly inform the RPO of any incident or circumstances that could result in higher than usual radiation doses to themselves or to other persons. This 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 RPO as soon as practicable after the incident or observation.

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

4.25. Temporary workers should comply with work practices and local rules within the facility.

LOCAL RULES AND PROCEDURES

4.26. The operating organization should ensure that local rules and procedures are fully understood by the workers and should, as a minimum, include (see also [18], paras 3.87–3.92):

- (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 with regard to radiation safety of key individuals within the operating organization, including the qualified expert/RPA and RPO;
- (d) The method 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 procedure 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 design documentation. Written instructions to require that the worker call for assistance from the RPO when a hot cell or particle accelerator shielding is opened;
- (h) Written instructions describing the wearing of suitable personal protective clothing in supervisory and controlled areas;
- (i) Written instructions to require that the workers check with the RPO that the plant is safe before entrance.

5. SAFETY ASSESSMENT

GENERAL

5.1. General safety requirements on safety assessment for facilities and activities are provided by GSR Part 4 (Rev. 1) [19] which includes the necessary arrangements for:

- (a) scope, purpose, and responsibilities (overall requirements 2–4),
- (b) specific requirements (5–12),
- (c) defence in depth and safety margins (requirement 13),
- (d) safety analysis (requirements 14–19),
- (e) documentation, independent verification, management, use and maintenance (requirements 20–24).

5.2. Requirements of GSR Part 4 (Rev. 1) [19] mentioned above in para. 5.1 and requirement 13 on safety assessment in GSR Part 3 [3] are addressed in this Section in respect of radioisotope production facilities.

PURPOSE AND DEVELOPMENT PROCEDURE

5.3. Requirement 4 (Purpose of the safety assessment) of GSR Part 4 (Rev. 1) [19] requires that the primary purposes of the safety assessment is 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 SAFETY ASSESSMENT DEVELOPMENT

5.4. GSR Part 3 [3] states that the person or organization, or registrants and licensees, as appropriate, 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.

5.5. 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 a detailed description in paras 4.18 (a)–(d) [19].

5.6. The operating organization of the radioisotope production facility should be responsible for the fulfilment of requirements mentioned above in paras 5.4–5.5 [3, 19].

5.7. An example schematic of a safety assessment for a radioisotope production facility is illustrated in Figure 1. This figure outlines the key aspects of the radioisotope production facility which should be addressed in a safety assessment. Thereafter, each of the individual risk assessments (e.g. shielding, emissions, engineering controls, decommissioning, etc.) should be collated into a safety assessment report for the facility. The same approach should be adopted whether it is for a new standalone facility or a modification to an existing and approved facility. The relevant requirements for performing the appropriate risk assessments are provided in para. 5.1. Some specific examples of safety requirements (e.g. shielding, interlocks, transfer lines, remote handling, fume hood, ventilation etc.) are provided in paras 5.13–5.45.

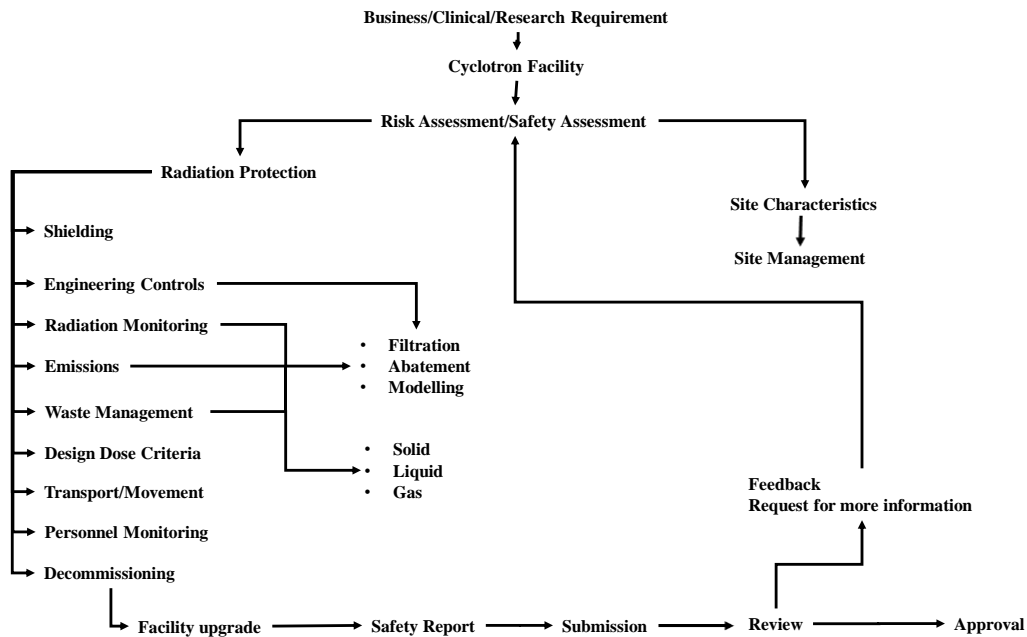


FIG. 1. Example schematic of a safety assessment for a radioisotope production facility.

5.8. Requirement 6 of GSR Part 4 (Rev. 1) [19] states that the possible radiation risks associated with the facility or activity shall be identified and assessed. An example schematic of the key radiological risks associated with a radioisotope production facility is presented in Figure 2.

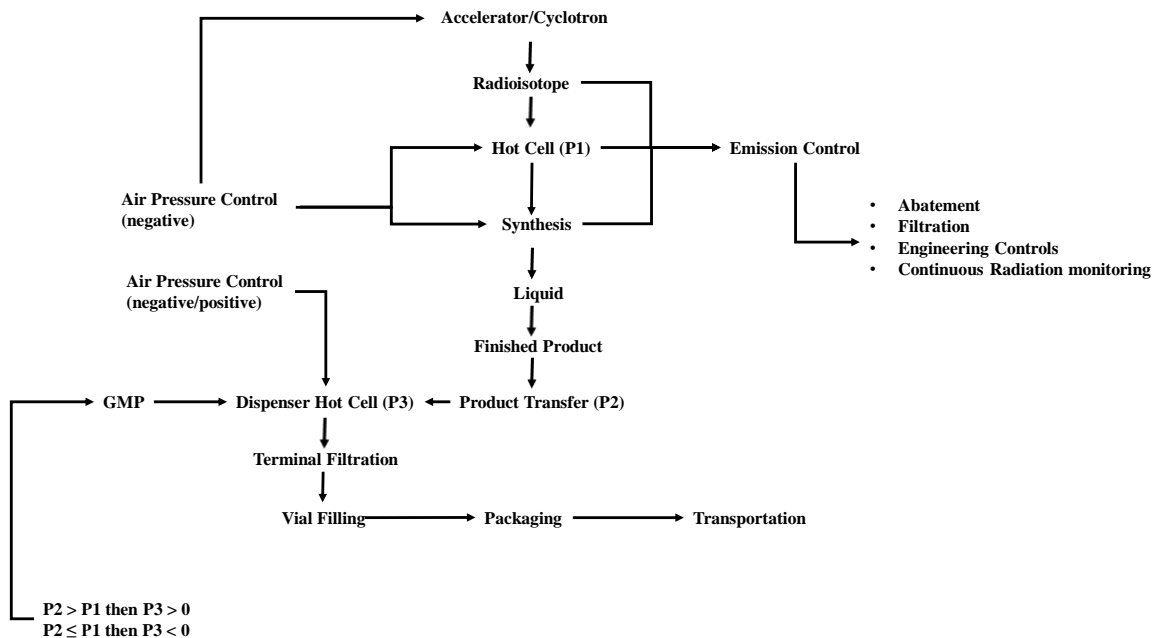


FIG. 2. Key radiological risks associated with the isotope production facility.

5.9. 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.

5.10. During synthesis in the hot cell, there is a potential risk of radioactive contamination of the environment outside and inside the building which could result in potential exposure of operational staff 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 this contamination should be minimized by an appropriate negative pressure regime in the hot cell. The risk of release to the atmosphere should be controlled by the appropriate engineering controls (e.g. filtration, motorized damper, abatement system, etc.).

5.11. During filling of the finished product in the dispenser hot cell, the appropriate engineering controls should be in place (good medical practices (GMP) or other aseptic standards) to ensure that the operator and the product are protected. Specifically, it is important that any potential 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. laminar flow, filtration).⁴

5.12. Transport of the finished product in the shielded container should comply with the IAEA Transport Regulations [20].

SAFETY ARRANGEMENTS

Shielding

5.13. Direct radiation exposure of workers and members of the public due to the operation of radioisotope production facilities should be attenuated to optimized levels by the use of appropriate shielding. Concrete is often used to construct the radiation room shield, but other materials such as earth fill, steel and lead may also be used in its construction. The shielding properties of particular materials are well established [21–28], but experience deriving from existing radioisotope production facilities should be taken into account. The shielding should provide adequate reductions in radiation levels to keep doses within the dose constraints established or agreed to by the regulatory body.

5.14. Penetrations of the shield are necessary for entry and exit ports for personnel and product and for the ventilation system and other ducting. These penetrations can potentially

⁴ It is important to note that the dispensing of the finished product for use in humans should comply to local GMP requirements, which may include dispensing in positive pressure regimes.

create particular problems for the shielding designer, who should ensure that there is no direct radiation leakage path, and should ensure that the use of maze entrances and shield plugs are sufficient to reduce external radiation fields to optimized levels. Care should be taken to ensure that all significant radiation paths are fully shielded. 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.

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

Remote handling tongs, master/slave manipulators

5.16. Handling of radioactive materials in the hot cells may require a remote handling tool, 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 the hot cell should have a leak tight liner that can provide air tightness to prevent the release of radioactive materials from the hot cells. It should also be suitable for the process inside of the hot-cell (acid fume resistant coatings in solid target dissolution stations where hot acid can be present). Edges of the liner should be rounded with an appropriate radius to prevent the accumulation of contaminated dust. The surface should have unnecessary protruded 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 classification and air flow requirements (sometimes in laminar flow when open radiopharmaceuticals are handled like in filling machines).

Fume hoods

5.18. Fume hoods are appropriate for the handling of hazardous and radioactive materials when the potential for contamination control is low and when external dose rates are low. Partial-enclosure fume hoods allow high 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 (0.5 to 0.75 m s^{-1}) 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.

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

5.20. The inspection/maintenance of the fume hood should be done on a scheduled frequency. The face velocity should be checked prior to use.⁵

5.21. The exhaust air should be routed through an appropriate filtration system. This exhaust air should be monitored based on the concentration of the effluent. The volume of exhaust air can be determined if the face velocity and sash area is known. The exhaust air should be routed through an appropriate filtration system to limit releases of radioactive material to external environments.

Glove boxes

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

5.23. Glove boxes are constructed using mild steel, stainless steel, or aluminium coated on the interior surfaces with chemical-resistant epoxy paint, laminated safety glass panels for viewing work activities inside the box, and heavy neoprene gloves (glove port) that allow the operator to handle materials safely inside the glove box. Glove boxes should be equipped with adequate lighting.

Clean environment considerations

5.24. In order to maintain a clean environment for the production facility, the production line should be in a clean room or isolator to ensure the required air classification is achieved. If cleaning agents are used to achieve a sterile/aseptic environment in the hot cell (e.g. H₂O₂), a risk assessment should be carried out to ensure that it does not adversely affect the extraction filtration system.

⁵ Fume hoods require a large volume of air and this may have design implications on the volume of air required in the production facility.

5.25. Secondary neutrons generated during radioisotope production give rise to neutron activation of the cyclotron components and vault room wall. Additional forms of shielding may be required to attenuate and shield the neutrons.

Interlocks

5.26. An interlock should be installed at the access door to controlled areas such as cyclotron rooms and target rooms to protect the workers from ionizing radiation.

5.27. Access by personnel to the radiation field following an 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 so designed that any attempt to pre-empt the controls or to apply them out of sequence will automatically prevent the intended operation.

Transfer systems

5.28. Transfer systems for the radioactive materials vary depending on what types of materials are transferred.

5.29. Transferring of radioisotopes from the cyclotron 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.

5.30. Transferring of the radioactive materials between hot cells can be done either through a simple shield door and/or a pass box installed between hot cells. Also, a conveyor can be employed to transfer the radioactive materials. In cases of a liquid, it 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. Specially, the gas transfer should be done in a closed system to ensure that there is no risk of release of radioactivity to the environment.

5.31. Transferring of 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 requires more physical and robust transfer systems, utilising pneumatic systems as opposed to inert gases.

5.32. Transport of a bulk source, dispensed vials, and sealed sources to outside of the building should follow the protocol for the transport of radioactive material described in section 15.

Ventilation

5.33. For facilities within larger organizations (for example production sites within a hospital environment) systems/procedures should be put in place to ensure that no technical personnel can access the ventilation system or power distribution cabinet of the facility without prior information and consent of the facility management and the radiation safety officer. The operating organisation needs to enforce appropriate standard operating procedures (SOPs) for the maintenance of all shared and interfacing infrastructure.

5.34. Air pressure within radioisotope production facilities 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.

5.35. Redundancy of critical ventilators should be in place to:

- (i) Ensure the safety of the site during ventilation maintenance.
- (ii) Ensure back-up power for critical ventilation systems.

5.36. Redundancy of power to critical parts of the ventilation should be in place. Use of diesel/gas generators and Uninterruptible Power Supply (UPS) should be considered.

5.37. Appropriate filters should be in place for:

- (a) incoming air,
- (b) outgoing air.

This is largely dependent of the chemical compounds produced and the nuclides used. The filter selection needs to be appropriate for the products being used. Appropriate measures to contain gases which cannot be trapped by filters should be put in place.

5.38. The ducting (piping) for the intake/exhaust air should be constructed of stainless steel/mild steel epoxy lined or galvanize: designed as per industry standard.

5.39. The supply air to all 'clean rooms' should have terminal HEPA filters which should be tested as per 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 (exhaust stack) prior to leaving the facility.

SITE SELECTION

5.40. During the processes of site selection and site evaluation, particular consideration should be given to potential hazards that cannot be addressed by means of engineering measures, such as hazards relating to flooding and hazards relating to geological phenomena in areas of potential or actual subsidence, uplift, collapse, faulting, volcanic activity [29], hurricanes, tornadoes and tsunamis.

Safety assessment of waste management

5.41. A safety assessment of waste management at the production facility 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 considered throughout the lifetime of a facility, beginning with the design phase, 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, including:

- (i) Potentially radioactive liquid waste handling system with liquid waste decay tank and chemical waste from QC operation or target processing (solid target dissolution);
- (ii) Solid waste containment and storage room;
- (iii) Gaseous waste; and
- (iv) Evaluation of national procedures and availability of a long-term storage facility for solid waste.

Safety assessment report

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

analyses should include the consideration of combinations of such malfunctions, failures, errors and external events.

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

Facility and Equipment Design Specification

5.44. An integral part of the safety assessment is the design specification of the facility and the equipment to be utilised therein. Each facility design will be unique to the user requirement specifications, the proposed site and the local regulatory requirements. In addition to the specific design requirements referred to in the previous section on safety assessment, some of the key issues which should also be considered when setting up a new radioisotope production facility or modifying an existing production facility are listed in Annex I of this document.

6. RADIATION PROTECTION PROGRAMME

GENERAL

6.1. The general objective of a radiation protection programme is to discharge the management's responsibility for radiation protection and safety through the adoption of management structures, policies, procedures and organizational arrangements that are commensurate with the nature and extent of the radiation risks. The radiation protection programme represents the totality of actions undertaken to achieve the declared aims of the operating organization for radiation protection and safety. The radiation protection programme is a key factor in relation to the development and maintenance of the safety culture within an organization [18], and it should meet the regulatory requirements. The operating organization should always strive to minimize doses to workers and members of the public.

6.2. The operating organization should develop, document and implement a radiation protection programme [18]. This 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 radiation protection programmes, including in many cases measures to prevent or reduce potential exposures and to mitigate the consequences of accidents if they were to 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. Detailed guidance for establishing and maintaining a radiation protection programme that focuses on the protection of workers is provided in an IAEA Safety Guide [18].

6.4. The programme should be based on the operating organization's safety assessment, and it should address planned exposure situations.

6.5. The operating organization should ensure that information on both normal and abnormal operations that are relevant to radiation protection and safety be 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, corrective actions, etc. 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. The guidance on the radiation protection programme is provided in Section 3 of Ref. [18]. 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 (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 radiation safety. This structure, which may 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 duty holders (e.g. the RPO). The chart should clearly show the line of reporting, from the worker through to the senior manager 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. All posts for which responsibilities are allocated should include the senior managers of the operating organization (which has the prime responsibility for safety), the RPO, the qualified expert/RPA and other workers who have responsibility towards radiation safety, as described in Section 2. Personnel must be informed of their responsibility towards radiation safety. Specific responsibilities towards 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 known by the people who will follow them. 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). 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. Management should ensure that all relevant persons have read and understood the local rules. A copy should be provided to all workers and other relevant persons, and additional copies should be available 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.

6.12. In larger organizations, it might be appropriate to have several sets of specific local rules. A facility specific procedure should be established. Workers should be informed on such procedures.

6.13. A short version of the local rules should be approved for visitors to review and understand.

6.14. Visiting workers should be made aware and trained in relevant sections of the local rules.

6.15. The operating organization should appoint at least one employee as a RPO to oversee the day to day implementation of the radiation protection programme and to carry out duties as required by the programme. Details of the duties of the RPO are given in Section 4.

6.16. Operating organizations should ensure that female employees who enter controlled or supervised areas are provided with information regarding the risks to an embryo or foetus from exposure to radiation and the importance of notifying their employer as soon as pregnancy is suspected.

Designation of controlled areas or supervised areas

6.17. The radiation protection programme should describe how controlled areas⁶ and supervised areas⁷ are to be designated for the isotope production facility. Controlled areas should be established with the goal of restricting exposures of workers in isotope production facilities. The designation of such areas should be based on the safety assessment.

6.18. 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 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 have a higher probability for contamination and radiation and should therefore be a controlled area.

⁶ A controlled area is a defined area in which specific protection measures and safety provisions are or could be required for: (a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and (b) preventing or limiting the extent of potential exposures.

⁷ 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.

6.21. In the accelerator room there should be low probability of contamination and radiation and therefore can be operated as a supervised area.

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

6.22. 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 identify problems to be addressed and any modifications that could improve the effectiveness of the radiation protection programme.

6.23. A key part of this periodic review process is a routine series of workplace audits, including the description and qualifications of the persons who will conduct them, their frequency, the expectations of the audit team, and the reporting of results and their follow-up.

Quality assurance and process improvement

6.24. 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 brought to the attention of the management and are promptly remedied.

6.25. The management should also ensure that the correct operational procedures are being followed, and that the quality assurance programme 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 quality assurance programme.

6.26. The management system should include a mechanism for the collection and feedback of lessons learned from day to day operations, emergencies and incidents (including those reported both within the organization and in external reports), and how these lessons can be used to enhance safety.

HEALTH SURVEILLANCE PROGRAMME

6.27. The radiation protection programme should include details of a programme for periodic health surveillance of radionuclide production personnel and other employees as appropriate. This should include a requirement to assess the initial and continuing fitness of workers for their intended tasks. A qualified expert/RPA and/or an appropriately qualified medical doctor

should be consulted in the drawing up of the programme for health surveillance, and it should be consistent with regulatory requirements. No special medical/health surveillance programme is necessary relating to routine work at an isotope production facility.

RADIATION SAFETY COMMITTEE

6.28. A radiation safety committee should be established for the purpose of regularly reviewing the performance of the radiation protection programme. In a hospital, the radiation safety committee for the hospital should also look at the radiological safety aspects of the cyclotron. In the case where the hospital doesn't have a radiation safety committee such a committee should be established. This committee may be dedicated to radiation safety or it may have other (conventional) safety related responsibilities. The committee should include the senior manager(s) responsible for radiation safety, the RPO(s), qualified experts/RPA and representatives of the workforce. The responsibilities of the radiation safety committee should include, but not be limited to:

- (a) Regular reviews of all aspects of the radiation protection programme;
- (b) Reviews of occupational radiation doses and any accident reports prepared by the RPO;
- (c) Making recommendations for improvements in the radiation protection programme;
- (d) Provision of guidance and direction on the performance of the RPO's duties;
- (e) Preparation and dissemination of regular reports to all staff about relevant radiation safety issues.

7. TRAINING AND EDUCATION

GENERAL

7.1. Persons performing work in controlled areas within an isotope production facility are responsible for ensuring that their work is carried out safely and in compliance with all relevant regulations and safety standards. Operating organizations should, therefore, ensure that radiation work is carried out only by workers who are trained, and who are competent and trained in radiation protection and safety.

7.2. The workers in isotope production facilities should have training and qualifications that are specifically related to their area of responsibility. Some of this training may include only a limited amount of training in radiation protection and safety. In this case, they 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. Emergency workers should be qualified and trained in arrangements for preparedness and response for 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 employees directly involved in routine isotope production activities and emergency response. It should include a radiation 'awareness' programme, where appropriate, for other staff, including managers, research scientists, laboratory technicians, trainees, workers such as cleaners and maintenance staff who may 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 RPO, hot cell or cyclotron operators, and pharmacists in accordance with regulatory requirements.

7.5. The requirements for keeping training records should be consistent with regulatory requirements and recommendations, 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.. 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 on the basis of the workers' training and experience. In the case where an operating organization does not have the capability or resources to establish a training programme, the 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 operators
- Pharmacists
- Radiation protection officers
- Laboratory technicians
- Research scientists
- Maintenance personnel, packaging personnel and decontamination workers.

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 THE TRAINING COURSE

7.10. Each training course should be structured around specific aims and objectives and should be customized to the needs of the target audience. Fundamental concepts and measurements include:

- Basic ionizing radiation concepts;
- Ionizing radiation quantities and units;
- Ionizing radiation detecting instruments;
- Biological effects of radiation;
- System of radiation protection (radiation protection principles of justification, optimization and dose limitation);
- Regulatory requirements;
- Designation of controlled areas and of supervised areas;
- Dose limits, dose constraints and investigation levels;

- Effects of time, distance and shielding;
- Individual monitoring, external and internal monitoring and how to interpret their doses;
- Working practices to limit doses and maintain them as low as reasonably achievable;
- Radiation protection programme;
- Emergency preparedness and response.

Practical radiation protection

- handling of radioactive materials including those in unsealed forms;
- implementation of emergency arrangements;
- Specific task related issues.

Hot cell operators

- Operation of hot cell (opening hot-cells for operation or maintenance etc.);
- Manipulator handling (e.g. tongs).

Research scientists

- Specific training on radiation protection without standard working procedures.

Maintenance services

- Maintenance on target system, isotope transfer system, hot cells and manipulators and operations significant to radiation safety.

Decontamination services

- Decontamination after radioactive contamination incidents.

Waste operators

- Handling instructions for radioactive waste.

Shipping clerks

- IATA training on shipment of radioactive material;

- Storage of radioactive materials;
- Access control procedures;
- Security procedures;
- Local rules;
- Management of radiation protection;
- Transport of radioactive materials;
- Measurement of radiation fields and the units of measurement;
- Accidents and other incidents involving the production, use and transport of radioisotope, their consequences and lessons learned.

7.11. The training should provide practical exercises, including the rehearsal of dealing with abnormal events (e.g. a broken vial with a medical isotope during dispensing). However, radioactive sources, unless they are exempt, should never be used in such rehearsals. Not-in-use cells can also be used for training in the use of manipulators and coupling and uncoupling of transfer containers.

7.12. A RPO and a qualified expert/RPA should provide advice on staff training needs and on how those needs may best be satisfied. In many cases, a RPO should be able to provide much of the necessary training.

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

REFRESHER TRAINING

7.14. Management should ensure that their 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 possible changes in regulatory requirements.

7.15. 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 notifications of safety issues should be disseminated as written instructions as soon as practicable, and then followed up by inclusion in refresher training.

8. INDIVIDUAL MONITORING OF WORKERS

INDIVIDUAL DOSE ASSESSMENT AND RECORD KEEPING

8.1. 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. For radiation safety and regulatory compliance, all workers at a radioisotope production facility with potential for radiation exposure in controlled areas should be monitored to assess external and internal radiation dose.

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 [18].

8.4. The designation of controlled 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. All visitors should be supplied with individual dosimeters. The isotope production facility should record the dose received by the visitor.

8.6. Dosimetry records provide the means for tracking individual radiation exposures and internal dose from sources of ionizing radiation for both routine work and inadvertent or accidental exposures. Radiation dose records should be used to demonstrate regulatory compliance and support radiation safety planning. These records should include the results of individual worker monitoring for both external radiation 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. Personal exposure and dosimetry records should be permanently maintained in retrievable forms.

8.7. States should establish a national dose register for workers in order to accumulate all doses workers received at different facilities.

EXTERNAL DOSIMETRY

8.8. Individual monitoring tracks individual cumulative exposure, demonstrates the current level of the occupational radiation safety at a radioisotope production facility and provides essential information for record keeping. Guidance for establishing external radiation monitoring for individual workers is given in [18].

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

8.10. A programme for individual monitoring of external radiation exposure is intended to demonstrate that workers' exposures are being monitored, to provide information for the optimization of protection and to verify the adequacy of work procedures. Guidance on establishing monitoring programmes for external exposure, selection of appropriate dosimeters, interpretation of results, record keeping and quality management is given in [18].

Types of external monitoring

8.11. Each worker should wear an above-the-waist, whole-body dosimeter (film, thermoluminescent chip, or optically stimulated luminescence crystal) capable of accurately recording and integrating cumulative exposure to gamma radiation.

8.12. Hot cell operators, RPOs, pharmacists, decontamination workers, laboratory technicians and maintenance staff who routinely enter controlled areas should be subject to individual dose monitoring. These individuals should wear whole body monitors (e.g. a film badge, thermoluminescent dosimeter or optically stimulated luminescent dosimeter) and an electronic personal dosimeter to ensure effective dose management.

8.13. 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. Finger rings should be worn for situations requiring the monitoring of exposure to the hands.

8.15. Eye dosimeters should be worn on forehead for situations requiring the monitoring of the eye doses. In some cases, it might not be possible to wear eye dosimeters on the forehead [30].

8.16. The worker should wear the dosimeters under the lab coat, apron or overalls in order to reflect the dose to the body. It will also prevent the radioactive contamination of the dosimeter.

8.17. The dosimeters should be processed (or evaluated or read) at least quarterly or more frequent depending on the nature of work and technical specification of the dosimeter.

8.18. The electronic dosimeters should be used in an isotope production environment whenever multiple or variable work activities are performed, such as equipment maintenance or hot cell modifications, involving potentially hazardous radiation levels.

8.19. The tools and procedures for individual monitoring for exposure of workers, including the type of dosimeter required and the necessary frequency of replacement, should be chosen in consultation with a RPO or qualified expert or RPA, in accordance with the requirements of the regulatory body. The dosimeters should be provided 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. The operating organization should make arrangements to ensure that dose records are maintained for each worker in the manner specified in regulatory requirements. Operating organizations should ensure that personal dose records are provided to workers upon termination of their employment and are available to the individual at other times.

8.21. Operating organizations should prepare procedures describing the way in which individual dosimeters are to be administered, and these procedures should include the following:

- (i) Ordering and receiving dosimeters from the dosimetry laboratory;
- (ii) Distribution of dosimeters to monitored workers;
- (iii) Collection and dispatch of dosimeters to the dosimetry laboratory for processing;
- (iv) Review and maintenance of dose records.

8.22. Operating organizations 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. Dosimeters should not be put through mail inspection systems that utilize X rays.

8.23. Monitored workers should be required to take good care of their dosimeters, and to 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 RPO 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. If a dosimeter is lost, all reasonable steps should be taken to recover it. If the dosimeter cannot be located, operating organizations 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 regulatory bodies may be required prior to the entry of such estimates into a person's dose record.

INTERNAL DOSIMETRY

8.25. The probability for internal intake of radioactive substances should be established during the safety assessment of the isotope production facility. A monitoring programme should be established in cases where there is a probability of intake. The frequency of the monitoring and the type of monitoring should be determined from the level of probability for the intake. Guidance on internal dosimetry is established in Ref. [18].

Types of internal dosimetry

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

8.27. Methods used to assess radioactivity intakes and uptakes should be appropriate for the radioisotopes under consideration, e.g. for beta emitters a 24-hour urine sample should be taken and sent for analysis for the isotope in the urine. From the result, internal doses should

be calculated for intakes of radioactive materials by workers at isotope production and processing facilities.

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

Criteria for internal monitoring

8.29. Under normal conditions the contamination level in the air should be $<1/10$ DAC (derived air concentrations) of the isotope ^{131}I . DAC values are available in the IAEA Safety Guide on occupational exposure [18].

8.30. In cases where there is a probability that contamination in the air could exceed $1/10$ of DAC of the applicable isotope, a routine internal monitoring programme should be established for the workers that would be appropriate for this isotope.

INVESTIGATION OF DOSES

8.31. The operating organization should instruct workers to notify a RPO immediately if they know or suspect that they have been exposed to high level radiation or airborne contamination. If the individual(s) concerned was wearing a personal dosimeter, it should be sent immediately to the dosimetry laboratory and the laboratory should be informed of the urgency of the case. In the case of exposure to airborne contamination, the person should be monitored for the appropriate isotope.

8.32. The operating organization should conduct a formal investigation, as required by the regulatory body, whenever the recorded dose exceeds the investigation level. The investigation should be initiated as soon as possible following the event, and a written report should be prepared concerning its cause. This report should include a determination or verification of any doses received, details of corrective or mitigating actions, and instructions or recommendations on how to avoid a recurrence.

8.33. The report should be provided to all concerned parties within the appropriate time frame as required by the regulatory body.

9. WORKPLACE MONITORING

9.1. Paragraph 3.96 of GSR Part 3 [3] states that 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 RPO or qualified expert/RPA.

9.2. The type and frequency of workplace monitoring shall:

(a) 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) 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. GSR Part 3 should be consulted for further details on general requirements. Production facilities have some specific requirements regarding workplace monitoring on fixed and portable radiation dose rate meters, contamination control and air sampling.

9.4. Dosimetry should be performed by calibrated and suitable instrumentation. Details of the guidance on the selection of the proper radiation survey instrument for a given application are provided in Refs [17, 18]. The following subsection summarizes information in regard to the radiation meters and monitors that are normally employed in the radioisotope production facilities.

RADIATION METERS AND MONITORS

Fixed and Portable Radiation Dose Rate Meters

9.5. For both fixed and portable dose rate monitors, the detector probes and detector windows should be carefully selected to suit the type of radiation being emitted. Under production conditions in the hot cell it is possible to measure beta emitting product 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 production facility, a range of radiation detectors may be required.

9.6. Fixed radiation 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. Alarm levels are set to alert the worker of an elevated radiation dose rate. Both audible and visual alarm signals should be available to warn personnel on the abnormal situation in the monitored area. The requirement for the number and location of fixed radiation dose rate meters should be based upon the safety assessment. Locations for fixed dose rate monitors can include:

- (a) door openings from hot cells, cyclotron 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 hot cells, shielding covering filtration, ventilation plant room, waste room, etc.

9.7. A final consideration in determining the location and alarm presets of area monitors is the avoidance of nuisance alarms. In a production facility, loaded 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. If these steps are not followed, workers may not be alerted to an irregular condition.

Considerations for Portable Dose Rate Meters

9.8. Since ionizing radiation cannot be noticed by the human senses, work at production facilities can only proceed if trained people have working detection equipment. Therefore, the number of portable detectors in a production facility is a crucial matter. The production facility may need a variety of different dose rate meters, for example:

- Large volume, thin end window open air ion chambers for beta, and low energy gamma ($< \sim 50$ keV) dose rate evaluation (chambers that have desiccants inside are important considerations as humidity fluctuations may render the chamber inoperable). These detectors are useful for obtaining a reliable dose rate at 1 meter 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 very useful at localizing high energy beta activity/contamination in production hot cells.

- Large volume pressurized ion chambers, though they are not capable of beta or low energy gamma detection, are useful for providing stable dose rate measurements and do not suffer from humidity fluctuations as they must be sealed in order to maintain their pressurized gas. 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.
- Proportional detectors 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 detectors will normally be sealed and not suffer the effects of humidity.
- Geiger-Mueller (GM) type detectors are available in a variety of sizes and configurations. Larger probes have increased dead times and are not suited to higher dose rate measurements, smaller volume probes are best suited for big dose rates and in evaluating dose rates produced by small diameter beams. GM probes smaller than an ion chamber provide better evaluation for the dose rates near contact on surfaces. Thin end window GM probes may be suited for beta detection, though they typically over respond to low energy gamma rays via the thin window. Thin end window GM probes often have greater directional dependence than other detectors, which is an important consideration in training of staff in their use. GM 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 are not best suited to all types of radiation.
- A useful type of portable dose meter in a production facility is one that has an extending pole. Distance can be maximized using an extender type detector to protect the employee when encountering high or unknown dose rates. Extending detectors are essential tools at many 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 extended detector will inform radiation safety staff whether it is safe to proceed with work at a closer distance and will be able to estimate the length of time permissible to perform the planned work.

Surface Contamination Detection in the production premises

9.9. Contamination surveys can sometimes be performed using direct measurement but when there are varying or elevated radiation backgrounds in the production facility they are more frequently performed by swiping. Routine surveys include checks of equipment and personnel at barrier doors, and routine floor and surface checks. Minimal frequencies for routine floor and surface checks should be defined by the operating organization, but the practice should be commensurate with the risks at the production facility and may vary from weekly at a small facility, to daily or multiple times a day at large production facilities.

9.10. Contamination monitoring should be performed when utilising glove-boxes and fume hoods or when non-routine work is being carried out.

9.11. Surface contamination surveys fall into two categories at a production facility: routine and as needed. Contamination surveys can sometimes be performed using direct measurement but when there are varying or elevated backgrounds in the production facility they are more frequently performed by swiping or other means. Routine contamination survey frequencies and acceptable activity/unit area (Bq/cm^2) criteria are defined by the radiation protection programme. If necessary these values can be conservatively converted to units in which the detector reports (cps or cpm) for ease of use by the operator. Factors to consider when stabilising these values are swipe efficiency, efficiency of the contamination meter at the swipe to detector distance it will be used (geometry + detector efficiency for the radioisotope), and the length of time that is required for the reading to stabilize.

9.12. It is normal practice to assume that 10% of loose contamination is removed on a swipe. This value can be used in calculations to demonstrate compliance for indirect contamination surveys.

9.13. Routine contamination surveys are an essential part of the defence in depth concept. Routine surveys include checks of equipment and personnel at barrier doors, and routine floor and surface checks. Minimal frequencies for routine floor and surface checks may be defined by the regulator, but the practice should be commensurate with the risks at the production facility and may vary from weekly at a small facility, to daily or multiple times a day at large production facilities. Routine floor surveys in general areas and hallways provide an indication if contamination is being tracked from processing areas. Indirect floor surveys can

be performed by swiping with a dry mop with replaceable cloth and direct checking the mop for contamination ea.

9.14. As needed, contamination surveys happen whenever processing work is performed, such as when items enter or exit, cells, glove-boxes and fume hoods or when the potential to perform intervention work is being evaluated in areas which may have non-fixed contamination (cyclotron bunkers and caves, cell, etc. work) and also on packages which are being prepared for shipment.

Room Air Contamination Monitoring

9.15. Typically, there are two methods to assess air concentration in production facilities: either by a fixed/portable continuous air monitor with a shielded contaminant probe (CAM) or by performing a grab sample on a filter then removing the filter media for measurement at another location.

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 a worker to wear. Personal air samplers (PAS) which can be worn on a worker's lapel normally operate at low flow rates (for example 2 L/min), are more directly placed in the workers breathing zone, but may get covered by the workers clothing or have issues with battery life.

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

9.18. Set levels at which a room may not be entered or respiratory protection must or may be used based upon filter efficiency, detector efficiency, line losses, pump flow rate and dose conversion factors [31] for inhalation.

9.19. Place alarming CAMs in locations of high risk (radioiodine processing areas, waste, cyclotron bunker and caves) and have the alarm register at a secondary location.

9.20. The number of bends in tubing for CAMs needs to be minimized to avoid line losses. Tubing material for CAMs needs to be correctly chosen so that the radioactivity is minimally deposited on tubing. Tubing runs to CAMs must be as short as possible.

9.21. As CAMs are optimally placed as close as possible to the source of airborne, 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 caused by movement of product, waste, raw materials, etc. Otherwise packages placed near an insufficiently shielded CAM will appear to cause an increase in airborne, or mask airborne activities. If the CAM has two detectors, one can be used to correct the variations in the background. Filter material should be optimally suited to catch the airbornes. Filter materials include paper and fiberglass for particulate, activated charcoal and silver zeolite for radioiodine, etc.

Maintenance and calibration

9.22. Following calibration, a label should be attached to the instrument to provide information, including the organization performing 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 a national standards body.

9.23. Fixed radiation monitoring instruments are not calibrated in the same sense as radiation survey meters. Since their operation is 'pass-fail', fixed 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 the radiation room monitor respond appropriately. In some applications, such as in using a single channel analyzer for air effluent monitoring, the instrument should be calibrated periodically to ensure that the detector voltage and window settings are still applicable.

9.24. Further information on the establishment and operation of calibration facilities for radiation survey instruments and recommended calibration procedures is provided in Ref. [32].

Records of radiation and contamination surveys

9.25. 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, background subtraction, conversions or other calculations for the survey instrument if used;
- Name of the person performing the survey;
- Radiation levels and the corresponding locations are best to record and communicate on sketches of the section of the building which 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. Environmental monitoring of foodstuffs, plants and animals is not a requirement for the processing facilities covered under this Safety Guide. The environmental monitoring required is limited to performing and documenting dose rate surveys external to the controlled area, with the objective to demonstrate that members of the public are receiving effective doses <1 mSv in a year. In some cases, the boundary to perform 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 until the facility is deemed safe to operate under the conditions where maximum dose rates can occur. Once the facility is operational, routine environmental dose rate surveys should be carried out continuously.

10.2. The environmental verification should be periodically confirmed by measurement of groundwater or soil samples. Soil samples will always contain trace natural amounts of radioactivity radioactive isotopes, e.g. ^{137}Cs , due to atmospheric weapons testing or the naturally occurring ^{40}K , therefore soil samples should be compared to background soil away from the discharge stack.

EFFLUENT DISCHARGE

10.3. Radioisotope production and processing inherently poses risk of dispersal of radioactive materials to the environment which can be the primary product or a mixture of decay products.

10.4. The production technology, the adopted practices and the facility design should all aim to control the amount of activity routinely discharged and to minimize the risk of discharges.

10.5. Effluent discharges for production facilities should be regulated, based on authorized discharge limits which should be developed by the operating organization and approved by the regulatory body. The IAEA publication [33] provides more detailed guidance on methodology and procedures to develop such authorized discharge limits.

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

10.7. Effective means should be available for containing releases of activity before they leave the facility. Best practices include in-process means of capturing and securing gaseous, liquid and dispersed solid waste. Filtration and trapping systems should be designed to be as close as possible to the source production in order to minimize the unnecessary contamination of ducts, piping, etc. 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 release of other toxic chemicals).

AIR EFFLUENT MONITORING

10.8. The IAEA publications [33] and [34] have established standards for monitoring air effluent emissions.

10.9. Quantitative on-line air effluent monitoring should be performed using:

- A well shielded detector which views a cross-section of the stack and is oriented not to detect other sources of radiation;
- A well shielded continuous air monitor (CAM) sampling the stack;
- A gas flow through chamber detector for inert gases, or other means.

However, in all cases a representative sample of the effluent should be taken.

10.10. Off-line measurements should be taken using filters (cartridge or otherwise) which are replaced daily or weekly (as necessary) and measured.

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

10.12. Experimental evidence should sometimes be used to validate sampling systems. One such example is to release an approved activity of ^{11}C labelled carbon dioxide ($^{11}\text{CO}_2$) to calibrate systems at PET facilities.

10.13. The stability of sampling pump and stack flow rates should be taken into account and variations may need to be logged.

10.14. Other points should be considered with respect to monitoring of air emissions:

- (a) The emitted activity is product of concentration and air flow.
- (b) The monitor should be capable of measuring relevant radionuclides at 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.

LIQUID EFFLUENT MONITORING

10.15. National, regional and municipal regulations should apply to limit the discharge to liquid effluent streams, in terms of chemical and biological composition, suspended solids, radioactivity and other hazards.

10.16. Liquid effluent should be monitored on-line or a sample may be taken from a delay tank. Procedures should be developed to ensure that the delay tank contents are adequately mixed so that a representative sample may be taken. If an aliquot is to be taken of the sample (for example for liquid scintillation counting), then the sample also should be agitated to ensure adequate mixing before the aliquot is taken.

MINIMIZING EFFLUENT DISCHARGES

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

10.18. The process water should be kept and treated separately. Coolant should only be diluted with inactive water prior to ultimate disposal. The control of radioactive discharges is discussed in the IAEA publication [33] including its minimization options.

10.19. Water used for washing and cleaning in isotope 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/distillation and/or subsequent disposal into the general environment.

10.20. Target and accelerator cooling circuits may become radioactive (excluding the short-lived radionuclide ^{16}N) due to leaching of activated surfaces or from leakages. Therefore, they should be disposed of only after check of activity.

10.21. Dedicated piping for possibly contaminated/radioactive waste water should be in place. In case acceptable low limits can be assured under all operating conditions, direct piping to main sewer can be recommended.

10.22. Workers maintaining such draining installations should be properly protected and instructed.

10.23. All airstreams in the facility that might contain activity should be considered. This could include all of the controlled area as well as storage areas, target loading/unloading areas and potentially also radioisotope generation equipment.

AIR EMISSIONS

10.24. Air monitoring filters should be suitably placed in the ventilation system prior to exiting the building. If the filter (e.g. charcoal) is in an uncontrolled area, it should be adequately shielded to minimise the risk of exposure to personnel.

10.25. Corrosive substances (e.g. acids) should not be ventilated through the air monitoring control system.

10.26. The filters in the filtration system should be changed on a regular scheduled basis (e.g. annually). The frequency of change may need to be increased if an elevated trend in emissions is observed.

10.27. If radioactive materials are produced that cannot be trapped by the air filtration system, abatement systems (e.g. exhaust bags) should be utilised to store radioactive materials until they have decayed to background levels.

10.28. General principles of placement, height of stack, assured ejection speeds and meteorological considerations should take into account occupied areas and worst case scenarios, the need for calculation of worst case committed radiation dose to most exposed member of the public, and the reference to suitable guidelines for this, and possible general dose constraints (1/10 of annual dose limit to members of the public). Compliance with this is the responsibility of the facility operator, and could be part of an operation permit.

10.29. Channels, filters and other components should not be attacked by components of the air stream, nor yield unnecessary particle burdens by themselves (stainless steel or epoxy). Description of the abundant use of boiling with strong mineral acids should be included as well as good practices to minimize corrosion risks from the acid fumes (gaswashers/scrubbers).

10.30. Filters bound to contain large activities at any point in time should be placed in controlled areas and, if appropriate, also shielded or separated from areas of any occupancy.

10.31. Pressure drops and integrity of critical filters should be kept under control by suitable measures.

10.32. Filters should be removable under radiologically safe conditions (bagging provisions).

10.33. Practices for removal of non-filterable contaminants may include:

- (i) Placement of filters as close as possible to the source, at points of lowest airflow.
- (ii) Use of activated charcoal filters.
- (iii) Use of acid filters/scrubbers.
- (iv) Pressure drops and integrity of critical filters should be kept under control by suitable measures.

- (v) Filters should be removable under radiologically safe conditions (bagging provisions).
- (vi) Ways of testing the efficacy of such filters.

10.34. Considerations concerning non-filterable, non-condensable airborne contaminants should include:

- (i) Radioactive noble gases.
- (ii) Some PET cyclotron products (examples [^{11}C]- CH_4/CO_2 , [^{18}F]- FCH_3 or F_2 , [^{13}N]- NH_3) cannot be removed from air stream.
- (iii) Tritium, and some tritiated and ^{14}C labelled compounds.

10.35. In case such contaminants pose any significant dose risk/contribution to either workers or members of the public, measures should be taken to limit and control the release of such contaminants.

10.36. The most efficient ways is to control the release of contaminants are to contain and trap the contaminants at the source itself with using gas bags or traps (liquid nitrogen or cartridges). Another possibility could be tank storage for decay (in case of the PET gases).

11. PERSONAL PROTECTIVE EQUIPMENT

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

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

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

- (b) Protective respiratory equipment suitable to protect the respiratory tract from the contamination hazards;
- (c) Protective aprons and gloves and organ shields for external radiation hazards;
- (d) Safety glasses or face shields for splash protection involving radiological liquids.

11.3. The PPE for emergency operations may include:

- (a) Full air suits with air lines or breathing apparatus for entering contaminated areas,
- (b) Lead aprons, critical organ protectors and gloves for handling situations with high radiation.

11.4. Where appropriate, workers should receive adequate training and refresher training in the use of PPE. All PPE should be maintained in working order, tested at regular intervals if appropriate and be maintained for use in the event of usage.

11.5. The reliance on PPE for protection and safety should be minimised by the operating organisation during normal operations by providing 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, and during the medical examination it must be determined if a person is medically fit to use the prescribed PPE for the job. Some of the aspects to be covered for medical examinations are the possibility of claustrophobia and hypertension, for example, that would limit the use of some of the PPE.

11.7. Contaminated re-usable PPE like expensive apparels and washed overalls, should be decayed, and if necessary, decontaminated in a decontamination room. Highly contaminated PPE should be left to decay before sending for washing. In cases where long-lived radionuclides are present, the RPO should decide if it can be considered as radioactive waste.

11.8. If the use of PPE 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 performing the task without using PPE.

12. NUCLEAR SECURITY CONSIDERATIONS

12.1. The 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 security issues that need to be addressed and which are covered in detail in the IAEA Nuclear Security Series (NSS) publications. In particular, NSS No. 14 [5] 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. NSS No. 11 [6] contains more specific guidance to assist States in the development of regulatory requirements for the security of radioactive sources. NSS No. 9 [7] provides guidance on the security of radioactive material during transportation.

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

12.3. To ensure that safety and security 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 may 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 the confidentiality of some sensitive information be protected. Guidance on the protection and confidentiality of sensitive information in nuclear security is provided in [8]. An appropriate balance needs to 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 against radiation incidents can also provide some benefit against the theft of those sources.

For Category 1 sources, for example, it is recommended that measures described in GSR Part 3 [3] are used. However, the element of intent involved in unauthorized access means that additional considerations apply for higher activity sources, and additional and/or different security measures may be needed to protect against unauthorized access.

12.6. The IAEA Nuclear Security Series (NSS) provide 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. NSS No. 11 [6] 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 [6].

12.7. It should be noted that, due to their small size, portability and the fact they are most often used far from any secure facility, radioisotope sources may need additional security measures or procedures to ensure they remain adequately protected and under control both during use, transport incidental to use, and while they are not in use. The specific details of such additional measures will depend on the threat assessment. Reference [6] also contains illustrative security measures including those for mobile operation 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 radiation production facility, the operating organization should set up a formal programme of maintenance and testing to test all safety functions regularly. The following actions should be performed periodically (or as otherwise specified below):

- (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 in the presence of a RPO.

- (b) Periodic leak tests of radioactive sources should be carried out in a manner and at a frequency as 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 (annually).

13.3. The heating/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, weights and as required by regulatory agencies should be tested/calibrated/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 radiation room is prevented when the radiation room 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 operating 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 all uninterruptible power supplies (UPS)⁸ are functioning within specification. It is good to practice a UPS on the cyclotron control system as power 'dips' can affect the operation of control units.
- (d) Verify the proper operation of the heat detectors and smoke detectors.
- (e) Verify all safety interlocks on removable shield plugs (or self shield) in the cyclotron room.
- (f) Verify that posted notices are in place and that all the details are correct.

⁸ 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(s) to start up.

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 its validated operational state. The return of the facility to normal operation should be subject to approval by a RPO.

RECORDS

13.6. The results of all tests described above should be recorded on a formal checklist signed by a RPO who has witnessed the tests.

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

FACILITY MAINTENANCE AND MODIFICATION

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

13.9. Bypassing or disabling a safety interlock should be done only with the express, written approval of a RPO. 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 a RPO.

13.10. If it becomes necessary to bypass or disable a safety interlock, independent verification should be obtained either that the accelerator is not on (e.g. ion source is not on). The affected component of the safety interlock system should only 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.

13.11. If it is necessary to bypass or disable a component of a safety system, the affected component should be tested for specified 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 specified operation. After verifying that the safety interlocks

have been restored to their design function, approval of a RPO should be obtained for a return to normal operations.

13.12. 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 obviate the necessity for bypassing safety interlocks.

14. RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING

14.1. The Regulatory Body should establish requirements and criteria for radioactive waste. 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 [33, 35]. Radioactive waste should be examined in the safety assessment prior to its generation and needs to have considered non-radiological hazards (biohazards, chemical content) and the acceptance criteria of the ultimate waste destination (e.g. national waste site, interim storage site).

14.2. Radioactive waste is generated at certain points in a radioisotope production facility. Low-level waste is created from contamination control procedures (disposable PPE, cloths, package, surface and floor swipes, etc.). The waste with the highest concentration is generated from activated materials within the cyclotron, targets, synthesis processes and quality control testing. Archive samples and unsold product are other examples of waste.

14.3. The waste management protocols and clearance of materials after processing, storage, reuse and recycling of material can be effective in reducing the amount of radioactive waste that requires disposal. The operator has to ensure that these processes are in compliance with the conditions and criteria established in regulations or by the regulatory body. The regulatory body also has to ensure that the operator gives due consideration to non-radiological hazards in applying such options [34].

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 line with Requirement 10 of GSR Part 6 [36], the production facility is required to prepare a decommissioning plan ('from the cradle to the grave') for their facility which considers ultimate disposal of all resultant waste, contaminated and/or activated equipment and materials. This decommissioning plan is required to be periodically reviewed and updated as necessary in the light of operational experience gained, new or revised safety requirements, available lessons learned from the decommissioning of similar facilities, and technological developments relevant to decommissioning [35].

14.6. The production facility may possess sealed sources that will, in time, become spent or disused sealed sources. They then need to have an approved disposal pathway so that sealed sources do not become orphaned. The accounting of sealed sources must follow the requirements of the regulatory body.

14.7. Some production facilities fabricate sealed sources and the radioactive material is typically in one of three states: raw material, finished product (inventory) or waste. These production facilities should offer their customers a disposal pathway as a pre-sale condition. The production facility is responsible for accounting for their sealed sources, and returned, spent customer sources to document that the sealed sources have not been orphaned.

CHARACTERIZATION OF RADIOACTIVE WASTE

14.8. At radioisotope production facilities, aqueous waste results from chemical processing, mainly the etching and dissolving of target materials. The waste should only be processed 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 shall first be estimated from predictive models and then measured. Radioactive materials that are produced in cyclotrons can contain small quantities of longer lived radioisotope impurities other than the finished product. The production facility is responsible for developing the waste acceptance criteria for approval by the regulatory body.

14.9. The production facility should follow the clearance criteria established by the regulatory body. Clearance levels establish at which point material under regulatory control can be removed from this control [37]. In order to demonstrate that the material in their possession contains radioactivity below the clearance level, the production facility should first establish 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 understanding the initial concentrations and calculating for decay and/or by directly measuring and identifying the activities of the radionuclides present. The production facility should document this evaluation.

PRINCIPLES OF WASTE MINIMIZATION

14.10. Waste minimization is an important step in waste management and controlling potential risk as well as cost. The principles of ‘delay and decay’, and ‘concentrate and contain’ [38] are important in waste minimization.

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

14.12. Another form of segregation is for biological waste that needs to be treated (by either autoclaving, sterilizing or incinerating) or pH adjusted of liquids to render them safe (e.g. iodines must be alkaline).

HANDLING AND PROCESSING OF RADIOACTIVE WASTE

14.13. Depending on local regulatory approval, it may be acceptable to ‘dilute and disperse’ [39] radioactive material. An example of ‘dilute and disperse’ might involve filtered ventilation exhaust where the activity concentrations of gaseous effluents concentrations that have been pre-determined (by regulatory approval) not to endanger people or the environment.

14.14. The facility operator should ensure that radioactive materials and sources from authorized practices are not discharged to the environment unless:

- (a) Such discharge is within the limits specified in the licence and is carried out in a controlled manner according to the regulation in force and the authorization issued by the regulatory body methods; or
- (b) The activity discharged is confirmed to be below clearance or other disposal levels established by the regulatory body.

14.15. Control measures for release of radioactive materials may include:

- (a) Sampling of each batch of waste prior to removal from control.
- (b) If, according to the national policy and strategy, radioactive waste is to be stored in a centralized storage facility, the operator should adopt provisions to ensure the prompt transfer of above waste and disused sources to that facility.

OTHER HANDLING GUIDELINES

- Radioactive waste is 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 (tied with plastic adhesive tape or heat-sealed with a radio-frequency welder).
- If drums of waste are to be compacted at the production facility, the compactor shall be enclosed to prevent the spread of contamination. Compactor safety must be evaluated to avoid pinch points, compacting material which could damage the drum, etc.
- Sharps should be collected separately and stored in rigid, puncture-resistant containers (preferably metal) that have been clearly labelled 'sharps'.
- Refuse cans with lids should be lifted by foot pedals to minimize contamination.
- Liquids can require chemical adjustment (pH important for radioiodines must remain alkaline) and immobilization prior to transport.
- Special precaution may be required on used target foils, target blanks, target bodies and collimators. The area where target reconditioning is performed needs to shield the operator's body and extremities.

ON-SITE STORAGE OF RADIOACTIVE WASTE

14.16. In most production facilities, it is necessary to have a dedicated waste and contaminated equipment storage room. Access to this room should be secure and ventilated. Some production facilities place sealed waste containers in air sampling boxes to ensure there is no volatile radioactivity present prior to disposal.

14.17. Routine contamination and dose rate survey should be performed in the storage room. An alarming continuous air monitor and respiratory protection may also be used to optimize safety in this room.

14.18. Waste storage locations should be planned and designed to minimize handling, transport and potential doses to members of the public (if the store room is external to the building).

PREPARATION OF WASTE SHIPMENTS

14.19. Radioactive waste should be prepared by the production facility to ensure that it 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 the centralized waste storage facility. This facility should be consulted to determine what type of package, package contents and configurations are acceptable to be received by them. If the production facility desires to design, build and test [17] a new waste container, such container has to be compatible with the handling capabilities of the centralized waste storage facility.

14.20. All floor drains and sinks should discharge into delay/holding tanks and water quality monitored prior to disposal. The discharge port of the main floor drains should have a removable bladder type plug to contain the spilled liquid in the drain pipes until it has been assessed for disposal.

14.21. The contents of section 16 equally apply to waste shipments and should be observed.

15. TRANSPORT OF RADIOACTIVE MATERIAL

TRANSPORT REQUIREMENTS

15.1. Transport of radioactive materials should conform to national regulations inside the State and IAEA regulations for international transport [20].

Movement within the worksite

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

15.3. The sources should be moved only in shielded containers, and these should be locked and the keys removed. If a vehicle or trolley is used to move the container, it should be securely fastened inside the separate compartment of the vehicle. The shielded container

should be kept under surveillance for the duration of the movement on the worksite. The keys of the container should be kept by the authorized person.

Transport to another site

15.4. When radioactive materials are to be transported from the production facility, they should be kept in the storage facility until they are to be moved to the new site.

15.5. The sources should be moved only in shielded containers, and these should be locked and the keys removed. The operating organizations should ensure that the transport and the transport packages comply with the IAEA Regulations for the Safe Transport of Radioactive Material [20] 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 [40] and by sea [41].

15.7. Regional agreements such as the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) [42], the European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) [43] 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) [44] may also apply.

15.8. The IAEA Transport Regulations [20] assign responsibilities for individuals involved in the transport of radioactive material: the consignor (a person, organization or government that prepares a consignment for transport), the carrier (the person, organization or government that undertakes transport of radioactive material) and the consignee (the person, organization or government that receives a consignment). In some cases, for an operating radioisotope production facility, the operating organization will perform all three functions and 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 relevant requirements is outside the scope of this Safety Guide. Guidance on how to meet transport related requirements is provided in [45].

15.10. Comprehensive recommendations on nuclear security in the transport of radioactive material are provided in [7].

16. EMERGENCY PREPAREDNESS AND RESPONSE

GENERAL

16.1. According to GSR Part 3 [3] and GSR Part 7 [13], an emergency is a non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear or radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the adverse effects of a perceived hazard.

16.2. As defined in GSR Part 3 [3] and GSR Part 7 [13], 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; or
- (b) Radiation exposure.

16.3. Incidents and accidents at a radioisotope production can occur mainly as a result of operator error or equipment failure and may lead to a radiological emergency. Typical incidents and accidents include: (1) target package breach; (2) higher dose rate than expected; (3) dropped source; (4) leaking source; (5) fire inside the hot cell/clean rooms/other production areas; (6) loss of supply air to the facility and/or loss of exhaust air from the hot cells; (7) breakage of the cooling line for the cyclotron and the targetary system and consequent flooding in the facility; (8) natural disasters (e.g. hurricane) affecting the facility; and (9) nuclear security events resulting in loss of control over radioactive material or the facility, such as theft or sabotage of radioactive material.

16.4. The hazards associated with the operation of a radioisotope production facility and the potential consequences of a radiological emergency are required to be assessed as a means to provide a basis for establishing adequate arrangements for emergency preparedness and response [13, 44]. Potential emergencies that could affect workers, members of the public or the environment and could warrant emergency response actions should be identified in the operating organization's hazard assessment [13, 46].

16.5. Based on the assessed hazards and potential consequences, emergency arrangements should be established for the radioisotope production facility in accordance with Refs [47–

49]. Radioisotope production facilities generally fall into emergency preparedness category III described in [13, 47]. Emergency arrangements that correspond to this category should be established for preparedness and response for a radiological emergency involving the radioisotope production facility. Some radioisotope production facilities may pose limited hazards on-site and off-site. 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 various sections of GSR Part 7 to Emergency Preparedness Category III is listed in the Table in Annex 1 to GSR Part 7 and these should be used during the preparation of EPR plans for the facility.

EMERGENCY PLANS AND PROCEDURES

16.7. Although prevention of incidents and accidents is the first line of defence, emergencies still may occur. Operating organizations are required to have in place an emergency plan and procedures developed at the preparedness stage [13], so as to be able to respond effectively to an emergency involving the facility under their responsibility.

16.8. An outline for facility (on-site) emergency plan that should be used for developing an emergency plan of the radioisotope production facility can be found in Ref. [48]. Notices outlining the notification and activation procedures in case of an emergency may be clearly and visibly posted inside the facility at locations where they might be needed, and staff should be trained in these procedures (see para. 4.2.18 of Ref. [48]).

16.9. The emergency plan for a radioisotope production facility should include, but not be limited to, scenarios such as theft of sources, on-site contamination or leaking due to damage of the source, accidental releases into the environment and overexposures of workers. Emergency procedures should include, but not be limited to: (a) notification and activation protocols; (b) communication and coordination arrangements; (c) provisions for obtaining support from off-site emergency services; (d) provision of instructions to the site personnel and provisions for accounting the site personnel; (e) delineation of the affected area and access control; (f) measures and actions to protect site personnel and emergency workers; and (g) arrangements for communication with the public etc. A qualified expert/RPA may be consulted, where possible, when drawing up emergency plans and procedures. Examples of

immediate actions to be taken in case of a radiological emergency at a radioisotope production facility are given in Annex II.

16.10. Requirements and recommendations for on-site and off-site emergency preparedness and response are given in the IAEA safety standards [13, 46, 47] and Schedule IV of Ref. [3]. Technical guidance on developing adequate emergency arrangements at the organizational, local and national levels on a step by step basis is also available from the IAEA [46]. Technical guidance regarding generic procedures for assessment and response during a radiological emergency is also available [49].

16.11. Implementation of the on-site emergency plan and procedures may require off-site support (e.g. off-site response organizations, emergency services, radiation protection specialists) as addressed in Refs [13, 46]. The emergency plan should elaborate arrangements for obtaining such off-site support.

16.12. Operating organizations are required to submit for approval their on-site emergency plans to the regulatory body [13]. This is to be done when applying for an authorization.

16.13. Emergency plans and procedures are required to be periodically reviewed and updated with the aim to incorporate lessons from research, operating experience (such as response to emergencies) and from exercises [13].

EMERGENCY EQUIPMENT

16.14. Operators are required to ensure that all necessary tools, supplies, equipment, communication systems, facilities and documentation for responding to emergencies is made available and are subjected to a quality management programme which includes inventories, resupplies, tests and calibrations [13]. All necessary tools, 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 (OSL dosimeters, thermoluminescent dosimeters and/or film badges);
- Barrier materials and notices;
- Lead bricks;
- Suitable tool kit and source recovery equipment (long handling tongs, pliers, screwdrivers, bolt cutters, adjustable spanner, torch, lead source storage container);
- Materials and agents for decontamination [50];
- Spare shielded container;
- Plastic sheets, air tight bags for rupture of gaseous sources, swipe test kit, 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, instructions.

16.16. If it is suspected that a radioactive source might have been damaged, consideration should be given to detect the leak promptly and to assess the contamination before being further spread out.

TRAINING AND EXERCISES

16.17. All personnel who have role and responsibilities in an emergency response are required to be designated emergency workers and to be adequately qualified and trained for the effective fulfilment of their duties [13]. This should include both 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. This is required to include guidance and training on the approximate radius of the inner cordoned off area in which urgent protective actions would initially be taken, and on the adjustment of this area on the basis of observed or assessed

conditions on the site [13]. Provisions for training should be reviewed periodically to ensure the continued proficiency of emergency workers.

16.18. Designated emergency workers should implement only those parts of the emergency plans or those emergency procedures for which they have been given authority and responsibility and for which they have been trained.

16.19. Exercise programmes are required to be developed and implemented to ensure that all specified functions in an emergency response as well as organizational interfaces are tested at suitable intervals [13]. Technical guidance on preparation, conduct and evaluation of exercises including technical guidance on various types of exercises, their purpose as well as examples of scenarios for category III facilities can be found in Ref. [47].

16.20. Staff should be trained appropriately in emergency response, including:

- (i) Recognizing the circumstances indicative of an emergency situation;
- (ii) Notification and activation procedures including provisions for obtaining assistance from off-site emergency services;
- (iii) Implementation of necessary on-site mitigatory actions and protective actions on-site including provision of first aid and evacuation procedures for non-essential personnel;
- (iv) Assessment of the situation;
- (v) Use of emergency response tools and equipment including fire extinguishing gear and the rules of engagement;
- (vi) Implementation of recovery actions including decontamination;
- (vii) Measures to be followed for their protection during the emergency response.

16.21. Any lessons learned are required to be fed back into reviews and, as necessary, revisions of the emergency plans and procedures [13].

REPORTING

16.22. Arrangements are required to be made to undertake a timely and comprehensive analysis of an emergency and the emergency response [13]. A comprehensive report on the

findings of the analysis should be prepared by the RPO in consultation, as appropriate, with relevant interested parties and, if necessary, with qualified expert(s)/RPA(s).

16.23. 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 could have been 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 avoided.

16.24. The report should, inter alia, include:

- (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) Personnel involved, the work they carried out, 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; and
- (h) Proposed means and timeframes for implementation of the corrective actions identified and responsible staff.

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ANNEX I

KEY RADIATION PROTECTION ISSUES TO BE TAKEN INTO ACCOUNT WHEN PLANNING THE PRODUCTION OF CYCLOTRON RADIOISOTOPES

At the outset, the accelerator building design should comply with radiation safety requirements on protection of workers and public. Some of the key requirements are listed below:

1. Material, process, and personnel flow diagrams are important for the design of the facility
2. Appropriate shielding
3. Carefully designed mechanical, electrical, and utility requirements for the operation of the cyclotron in the vault
4. Negative pressure in the cyclotron vault
5. Adequately shielded hot cells
6. Air handling requirements for the facility
7. Air pressure regimes in rooms and hot cells
8. Radiation monitoring
9. Automated response system for engineering controls in the building
10. Security of radioactive materials
11. Decommissioning plan
12. Health and safety requirements (fire protection, etc.)
13. Utility capacity (e.g. electric power, coolant, medical gases etc.)
14. R&D requirements
15. GMP requirements
16. Receipt quarantine of materials
17. Emergency planning and response
18. IT capacities and networking
19. Redundancy
20. Quality control laboratories

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

II.I. This Annex provides practical guidance for immediate on-site response actions that may be warranted to be taken in case of an emergency at a radioisotope production facility by operating personnel and/or the RPO. Although the actions are listed in the sequence in which they can be expected to generally be performed, it may be necessary that they be implemented in another sequence or simultaneously. These actions are generic and focused only on those that are immediately warranted on-site. They do not account for all the emergency response actions that may be warranted off-site and for those actions that may be warranted beyond these immediate actions on-site as required in EPR related Safety Standards [II-1–II-IV].

Gamma and neutrons

II.II. Operating personnel:

- (a) Recognizes promptly abnormal conditions at the site that is indicative of an emergency and activates the pre-planned emergency response;
- (b) Takes lifesaving actions and gives first aid;
- (c) Evacuates non-essential personnel and visitors from the potentially hazardous area;
- (d) Establishes inner cordoned off area and prevents any access;
- (e) Notifies relevant authorities (on-site and off-site) including the radiation protection officer (RPO);
- (f) Measures the radiation dose rates and records any doses measured by direct reading dosimeters;
- (g) Re-adjusts the inner cordoned off area;
- (h) Keeps the area always attended until the respective emergency workers arrive.

II.III. The RPO:

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

- (b) Recommends decontamination of individuals and items, as appropriate, following respective emergency procedures;
- (c) Confirms that off-site protective actions are not needed;
- (d) Ensures 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 needed, 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/RPA 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.

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COMMENTS BY REVIEWER				RESOLUTION			
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Country/Organization:		Date:					
Comment No.	Para/Line No.	Proposed new text	Reason	Accepted	Accepted, but modified as follows	Rejected	Reason for modification/rejection
1.							
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