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Practice specific model regulations: Radiation safety of non-medical irradiation facilities

Interim report for comment

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PRACTICE SPECIFIC MODEL REGULATIONS: RADIATION SAFETY OF NON-MEDICAL IRRADIATION FACILITIES
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FOREWORD

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (Standards or BSS), along with national regulations, cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users must apply these basic requirements to their own particular practices. This requires a degree of 'interpretation' by the user, which can result in varying levels of regulatory compliance (or non-compliance) and inconsistencies between applications of the BSS to similar practices. In order to assist the user to achieve a good standard of protection and to facilitate a consistent national approach to licensing and inspection procedures, some countries have developed practice specific regulatory documents such as practice specific regulations or codes of practice.

Full and proper implementation of the standards requires that an independent regulatory authority be established by a government, through legislation, to regulate the introduction and conduct of any practice involving sources of radiation. The legislation should empower and require the regulatory authority to issue, among other things, regulations governing radiation safety and supporting guides as may be appropriate to assist in implementing the regulations. The principal purpose of regulations is to codify the overall safety requirements and basic operational parameters. The supporting guides are prescriptive regulations which are more specific and state how to achieve safety within a given practice.

A number of draft regulatory documents for the main practices involving the use of ionizing radiation have already been prepared. This initiative is to be commended and indicates that there is a global demand for this type of publication. In particular, it is felt that Model Project countries would benefit significantly from the availability of practice specific guidance. Member States could then more readily develop their own guidance tailored to their own national requirements and national needs. This idea led to the development of this publication.

A national regulatory report is tailored to a country's own legislation and regulations for obvious reasons. This can lead to problems if the guidance is used in other States without appropriate modification to take local requirements into account. However, the need for producing harmonized guidance remains.

This TECDOC provides organizations intending to purchase and operate industrial irradiation facilities with information and guidance regarding the design and safe operation of such facilities. It is not intended to repeat basic requirements such as those spelled out in the standards or equivalent national regulations. The set of model regulations is intended for use by both users and regulators. Registrants/licensees may choose to follow the guidance or may propose alternative measures that provide an equivalent level of protection and safety. Regulators can use the guidance for reviewing applications for authorization and during the inspection of facilities.

Moreover, experts recruited on IAEA missions to advise on the implementation of the BSS for irradiation facilities are expected to use the model regulatory document rather than their own national guidance. This will result in consistent advice and a harmonized application of the BSS in Member States, which in turn will give greater credibility to regulatory authorities and the international radiation protection community including the IAEA.

The present report is to be circulated to regulatory authorities and professional associations and tested as an interim report pending the comments of these organizations. Feedback on applicability, enforceability and correctness will be requested and subsequently implemented in later versions of the publication.

The IAEA officer responsible for this publication was M.M. Oresegun of the Division of Radiation and Waste Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. Background

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (Standards or BSS) were published as IAEA Safety Series No. 115 in 1996 [1]. This publication is the culmination of efforts over the past decades towards harmonization of radiation protection and safety standards internationally, and is jointly sponsored by the Food and Agriculture Organisation of the United Nations (FAO), the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organisation (PAHO) and the World Health Organisation (WHO). The purpose of the Standards is to establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure (hereinafter called 'radiation safety'). The requirements are based on the principles set out in the Safety Fundamentals, published as IAEA Safety Series Nos 110 and 120 [2, 3].

The Standards can be implemented only through an effective radiation safety infrastructure that includes adequate laws and regulations, an efficient regulatory system, supporting experts and services, and a 'safety culture' shared by all those with responsibilities for protection, including both management and workers.

IAEA-TECDOC-1067, Organization and Implementation of a National Regulatory Infrastructure Governing Protection against Ionizing Radiation and the Safety of Radiation Sources [4], provides detailed guidance on how to establish or improve national radiation safety infrastructure in order to implement the requirements of the Standards. The TECDOC covers the elements of a radiation safety infrastructure at the national level needed to apply the Standards to radiation sources such as those used in medicine, agriculture, research, industry and education. It also provides advice on approaches to the organization and operation of the infrastructure aimed at achieving its maximum efficiency, and extensively covers performance regulations.

The BSS cover the application of ionizing radiation for all practices and interventions and are, therefore, basic and general in nature. Users must apply these basic requirements to their own particular practices. In this context, the preamble of the BSS states that:

"The Regulatory Authority may need to provide guidance on how certain regulatory requirements are to be fulfilled for various practices, for example in regulatory guideline documents."

There are certain requirements that, when applied to specific practices, can be fulfilled through virtually only one practical solution. In these cases, the regulatory authority would use a 'shall' statement for this solution. To meet other requirements, there may be more than one option. In these cases the regulatory authority would usually indicate the recommended option with a 'should' statement, which implies that licensees may choose another alternative provided that the level of safety is equivalent. This distinction has been maintained in this "model regulations" for irradiation facilities in order to facilitate the decision of regulatory authorities on the degree of obligation. Any explanatory notes, advice or points of clarification are also needed and are indicated by the use of double indented smaller text.

This model regulatory publication is designed to focus on three main objectives, namely:

– establishing regulatory control over possession and use of radiation sources in non-medical irradiation facilities;
– maintaining doses to workers and the public from normal operations within regulatory limits and as low as reasonably achievable (ALARA), economic and social factors being taken into account;
– avoiding accidents or incidents.

Several IAEA publications give further guidance on radiation protection and safety in irradiation facilities. Safety Series No. 107, Radiation Safety of Gamma and Electron Irradiation Facilities [5], provides device specific guidance regarding design, operation and regulation of industrial irradiators. A training manual on radiation protection facilities is in preparation. It will be able to be used as resource material at national training courses in Member States.

1.2. Objective

The objective of this publication is to assist regulatory authorities in preparing regulatory documents for non-medical irradiation facilities, for ensuring proper and consistent application of basic requirements of the BSS. As one of a series of practice specific model regulatory publications, it provides information and guidance regarding design and safe operation of facilities to organizations intending to purchase and operate industrial irradiation facilities. The information satisfies the requirements of the BSS in that a code is provided to ensure that, during normal operation, maintenance and decommissioning and in emergency situations, radiation exposure of the workers and the public is kept ALARA.

1.3. Scope

This model practice specific regulations given in this publication apply to all types of non-medical irradiation facilities (see Section 1.4), whether operated on a commercial basis or for research and development purposes. This publication is solely concerned with radiation safety and does not deal with the irradiation techniques or the products that are irradiatede..

The target audience for this publication includes both operating organizations and regulatory authorities.

1.4. Types of irradiators

Two general types of radiation sources are used in industrial irradiators:

– Gamma irradiators containing sealed radioactive sources, usually cobalt-60 or caesium-137.
– Radiation generators that emit either particulate radiation (e.g. electron beams) or X rays.

1.4.1. Classification of gamma irradiation facilities

For the purposes of this publication, four general categories of gamma irradiators are defined, as in IAEA Safety Series No. 107 [5], according to the design of the facility and,

particularly, the accessibility and shielding of the radioactive source (schematic diagrams are given in Appendix I). The four categories are:

Category I: An irradiator in which the sealed source is completely enclosed in a dry container constructed of solid materials and is shielded at all times, and where human access to the sealed source and the volume undergoing irradiation is not physically possible in the designed configuration.

Category II: A controlled human access irradiator in which the sealed source is enclosed in a dry container constructed of solid materials, is fully shielded when not in use and is exposed within a radiation volume that, during use, is kept inaccessible by an entry control system.

Category III: An irradiator in which the sealed source is contained in a water-filled storage pool and is shielded at all times and where human access to the sealed source and the volume undergoing irradiation is physically restricted in the designed configuration and proper mode of use.

Category IV. A controlled human access irradiator in which the sealed source is contained in a water-filled storage pool, is fully shielded when not in use and is exposed within a radiation volume that, during use, is kept inaccessible by an entry control system.

1.4.2. Classification of electron beam facilities

In this publication, only electron accelerators of energies less than or equal to 10 MeV are considered. For these energies, there is no induced radioactivity in any part of the equipment. (For electron accelerators of energies above 10 MeV, the effects of induced radioactivity need to be considered for materials used in construction and for materials in the product being processed). Electron irradiation facilities are divided into two categories [5] (schematic diagrams are shown in Appendix I). These two categories are:

Category I: An integrally shielded unit with interlocks, where human access during operation is not physically possible owing to the configuration of the shielding.

Category II: A unit housed in shielded rooms that during operation, are maintained inaccessible by an entry interlock system.

1.5. Structure

Section 1 provides a preamble on the legal framework for regulatory infrastructure needed at the national level and a categorization of irradiation facilities. The remainder of the publication provides guidance and examples of material appropriate for inclusion in model regulations or a code of practice: Section 2 outlines administrative and managerial requirements and suppliers' responsibilities for radiation protection and safety of facilities; Section 3 deals with the design and operational safety of facilities and with security of sources; Section 4 discusses occupational radiation protection, involving the control and monitoring of exposure, investigating potential or actual overexposures, implementing local rules, and training and supervising staff; Section 5 covers the licensee's responsibilities with regard to public exposure, controlling access to facilities, and transferring and disposing of sources; Section 6 focuses on the safe transport of radioactive material; and Section 7 sets out requirements for emergency planning, covering safety assessment and accident prevention, mitigation and response. Finally, the appendices provide models for checklists and application forms, describe procedures, outline training programmes and reproduce relevant requirements from the BSS. Notes are indicated by the use of double indented smaller text, to explain the rationale for a particular requirement or simply to give more information or advice.

2. GENERAL REQUIREMENTS

2.1. Administrative requirements

2.1.1. Authorization of the practice

Any legal person intending to build or operate a non-medical irradiation facility shall notify this intention to the regulatory authority and shall apply for an authorization submitting the relevant information necessary to demonstrate the safety of the practice.

Given the risk involved in the operation of a non-medical irradiation facility, demonstration of safety requires a detailed safety assessment and, therefore, the authorization shall take the form of a license rather than a registration (see BSS 2.11 and 2.12 and footnote reproduced below)[1].

> Examples of information that should be provided to the regulatory authority by an applicant in support of a license application are provided in Appendix II. These are taken from IAEA-TECDOC-1113 [6].
>
> As non-medical irradiation facility involves construction of facilities which may be difficult to modify retrospectively, regulatory authorities may choose a two-stage process of authorization, i.e. an initial application to approve the design before construction begins. A good way to implement the two-stage process is for the regulatory authority to get an almost complete picture in the initial application: facility design, equipment description. The regulatory authority may also wish to prohibit or to condition procurement of radiation sources (including import) until a particular stage of construction has been completed and safe storage of the sources can be ensured. The sequence may be subdivided in various steps (acceptance tests, commissioning, operational use) for which additional information may be required by the regulatory authority as a condition to allow continuation of the process or inspections to be performed.

2.1.2. Personal accreditation

Individuals who hold key positions with the licensee, i.e. those with responsibility for radiation protection or whose actions or decisions could affect safety or lead to an incident or accidental exposure, shall have documented evidence of relevant education and training.

With regard to a non-medical irradiation facility these key individuals are:

- radiation protection officer;
- qualified operator;
- staff undertaking maintenance and source changing;
- qualified expert; and
- facility manager.

> Such training should be carried out in a systematic manner and, where appropriate, should involve accreditation to recognized local, national, or international standards.

[1] Typical practices that are amenable to registration are those for which: (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the safety training requirements are minimal; and (d) there is a history of few problems with safety in operations. Registration is best suited to those practices for which operations do not vary significantly.

2.1.2.1. Radiation protection officer

No person shall be appointed as a radiation protection officer (RPO) unless he or she:

– has the necessary theoretical training and practical experience, as recognized by the regulatory authority, covering practical radiation protection and regulatory requirements with respect to the irradiation facility for which they are appointed.
– commands sufficient respect from the people doing the work to be able to exercise the necessary supervision of radiation protection and to stop unsafe practices.

A training programme for RPOs is outlined in Appendix III.

2.1.2.2. Qualified operator

A qualified operator shall be at least 18 years old and hold a certificate of competence, having passed an examination following approved training recognized by the regulatory authority (see Appendix IV). The examination shall test knowledge and understanding, and should cover at least the following:

– knowledge of the basic design, operation and preventive maintenance of the irradiator;
– understanding of radiation safety and security systems such as locks, posting of signs, warning lights, audible and visible signals, and interlock systems;
– principles and practices of radiation protection; biological effects of radiation; written procedures for routine and emergency irradiator operation;
– knowledge of the principal requirements of legislation, regulations and codes of practice as laid down by the regulatory authority and relevant to the operation of the irradiation facility; and
– knowledge of 'normal' radiation levels at all areas around the irradiator, the radiation detection instrumentation used and the requirements for personal dose monitoring as specified by the regulatory authority.

Each operator shall demonstrate competence to use the irradiation facility and its related components, and to maintain the required operation logs and records. Operators shall understand the overall organizational structure pertaining to management of the irradiator, including specific delegations of authority and responsibility for operation of the irradiator.

2.1.2.3. Qualified expert

Sometimes additional specialist assistance is needed where insufficient expertise is available from the licensee's own staff. For example, a qualified expert in radiological protection may be required for safety assessments and hazard analysis.

The qualified expert for radiation protection shall have appropriate experience, including:

– such theoretical training as would ensure the necessary knowledge of the properties of the ionizing radiation used in the work undertaken by the licensee;
– thorough knowledge of the hazards of the ionizing radiation present and the ways in which they should be controlled and minimized;
– general knowledge of the working practices in other establishments of the same type; and
– knowledge of all relevant regulatory provisions, codes of practice, international and national protection standards, guidance material and other information needed for the provision of advice with regard to irradiation facilities.

2.1.3. Authorization of other practices related to irradiation facilities

According to the BSS, the activities listed below also require authorization. Theregulatory authority may therefore require the licensee to contract any of the following services only to enterprises authorized by the regulatory authority:

– Import, distribution, sale or transfer of radioactive sources;
– Construction, installation and maintenance, including source change, and decommissioning;
– Disposal of radioactive sources.

The requirements to carry out these practices would have been established by national regulations complemented by regulatory guidance documents.

2.1.4. Authorization of facility modification

The licensee shall notify the regulatory authority, and supplier where appropriate, and obtain approval from the regulatory authority prior to any modifications which may have radiological protection implications. These include:

– modifying operating procedures;
– modifying the safety control system;
– major modifications of the irradiator;
– source loading, replenishment, removal or redistribution, or electron beam orientation, in any way at variance with the agreed approval; and
– changes in supervisory personnel or advisers.

> The licensee is not required to notify the competent authority when performing routine maintenance procedures, including the changing of components, which will not cause a radiation hazard.

2.1.5. Inspection

The licensee shall permit inspection by the regulatory authority of the facilities and records.

2.1.6. Radiation protection requirements

The radiation protection requirements for justification of a practice, dose limitation, optimization of protection, and dose constraints (BSS 2.20 to 2.26) shall be applied to irradiation facilities. The dose limits for occupational and public exposure are reproduced in Appendix V.

2.2. Managerial requirements

2.2.1. Managerial commitment and policy statement

The licensee shall foster and maintain a positive attitude to safety and radiation protection and seek to discourage complacency, which has been shown to contribute directly to a number of serious, indeed fatal, radiation accidents at irradiation facilities.

> A written safety policy is a crucial element in the promotion and maintenance of a positive safety culture within an organization and of high standards of safety awareness in the minds of both management and workers.

The written safety policy should:

- identify the individual (director or key senior manager) with overall responsibility for safety;
- clearly state that safety is one of the organization principal objectives, and of equal status to all other principal objectives, e.g. commercial or research;
- clearly state that the organization's approach to safety is directed towards prevention;
- identify staff below director or key senior manager level that have safety responsibilities;
- indicate the primary communication links and organizational structure between those in (d) above;
- indicate the roles, responsibilities and authority of those individuals with specialist safety functions, e.g. for radiation safety, and their reporting lines and communication links with other management functions;
- provide the framework within which the necessary resources of both time and money will be made available for the implementation of safety policy;
- describe how standards for safety will be established, how prevention strategies will be chosen, and which procedures and criteria will be used to monitor compliance with standards;
- explain how the workforce and its representatives will be involved in the promotion of safety in the organization;
- provide the framework for the provision of training in safety for the whole range of employees, including managers, workers and others, e.g. contractors; and
- provide a mechanism for regular reviews of safety performance and of the safety policy itself.

There shall be a system for audit and review of the level of performance achieved in order to maximize learning and to ensure that appropriate action is taken to improve the control of hazards, which in turn furthers the development of safety policy.

> The safety policy should provide the basis for a positive approach to the management of safety. Its purpose should be to establish the organization's attitude to safety and the structural framework through which the safety objectives can be achieved.
> In order to be effective, the safety policy needs the support and commitment of all members of staff in the organization. Senior managers should "lead by example" to demonstrate their commitment to safety and provide clear direction.
> All individuals with specific safety duties should be aware of those duties and responsibilities, and should be provided with appropriate training and instruction to ensure that they are competent to carry out those duties. All employees should have a clear job description, know how they will be supervised and held accountable for their actions.
> There should be regular and meaningful consultation with staff and their representatives. Information about the hazards, risks and preventative measures should be routinely communicated to all staff.
> The organization's performance should be measured against safety policy objectives and regulatory and license requirements. This monitoring should be of two types: active systems which monitor the achievement of objectives and the extent of compliance with standards; and reactive systems which monitor accidents and incidents and other evidence of deficient safety performance. Thus, effective safety policy is not a fixed and unchanging document but an evolving and developing attitude to safety. This is what is meant by a safety culture.

2.2.2. Organization and responsibilities

The licensee's management shall be responsible for possession and use of the irradiator and shall obtain a license for the design, construction, acquisition, storage and use of

the irradiator from the regulatory authority. The licensee shall be responsible for the operation of the irradiator in accordance with the conditions of the license.

The licensee shall notify the regulatory authority of any proposed modifications to the irradiator or changes to the key personnel, in particular senior managers, the radiation protection officer and qualified operators.

The company management may delegate responsibility for various parts of the radiation protection programme to qualified individuals such as the qualified expert or radiation protection officer, in order to manage the business effectively but must always accept full responsibility for the results of the programme. Therefore, management should set up a quality assurance programme to define the elements of the radiation protection programme and hold delegated employees responsible for its successful implementation.

2.2.2.1. Radiation protection officer

In order to ensure that a radiation protection officer (RPO) is either on duty or otherwise readily available, the licensee shall appoint a sufficient number of RPOs, whose duties shall include ensuring that the written administrative procedures are implemented. The licensee shall notify the regulatory authority of the appointment of a radiation protection officer.

The RPO should report directly to senior management and have sufficient authority to discharge his/her duties. The RPO should not have other responsibilities which could compromise radiation safety interests.

The licensee shall carry the general responsibility of compliance with the regulations and with the terms of the license issued by the regulatory authority. This responsibility cannot be delegated to the radiation protection officer or the qualified expert.

The duties of the RPO should include the following, some of which may require consultation or assistance from the qualified expert:

- ensuring that all operators, maintenance staff, contractors and other relevant individuals and organizations are provided with copies of the operating instructions, that they have read and understood these instructions and are complying with them;
- identification of controlled and supervised areas;
- control of access to controlled areas;
- restriction of exposure and maintenance of engineering controls and other equipment provided for such restriction;
- deciding whether any special restrictions are required with regard to the exposure of pregnant employees;
- arranging the testing of radiation monitoring instruments;
- maintaining source and other relevant records;
- routine radiation surveys and environmental monitoring;
- supervision of issue and return of personal dosimeters;
- arranging statutory tests for leakage of radioactive material;
- undertaking a programme of periodic safety checks on safety and warning systems, general conditions of the facility etc. A sample checklist is provided in Appendix VI;
- together with the qualified expert, liaison with contractors, designers and suppliers with regard to radiation protection matters and significant changes to physical or operational aspects of the facility;

– arranging suitable radiation protection training for operators, maintenance staff, contractors and others as appropriate;
– ensuring the adequacy of safety assessments and contingency plans for any reasonably foreseeable incident with radiation protection consequences;
– arranging periodic exercises to test the effective implementation of these contingency plans; and
– initiating investigation of any incident or near miss involving the facility.

The radiation protection officers play a supervisory role in assisting the licensee to comply with the requirements of the approval or regulations. In cases where there is a potential conflict between operational responsibilities, e.g. for meeting production targets and radiation safety, the radiation safety requirements must always take priority. At least one officer must be available, though not necessarily present, at all times. In some large establishments, the officer may not be the immediate line manager or supervisor overseeing the work with ionizing radiation. In all cases, a system involving more than one person should operate to ensure that adequate supervision is maintained.

2.2.2.2. Qualified operator

Only qualified operators shall be authorized to be responsible for the routine operation of the irradiator and shall ensure that the established safety procedures are observed.

Qualified operators are those who work most closely with a particular irradiator and generally have day-to-day responsibility for safe operation. The operators' training, experience, attitude and competence will establish the degree of safety associated with operation of the irradiator.

2.2.2.3. Qualified expert

The licensee shall identify one or more suitably qualified persons as qualified experts to advise on all matters concerning radiation protection in the use and operation of the facility, on technical requirements such as source security and good engineering practice, and on safety assessment. Arrangements shall be made to ensure that advice from the qualified expert will be available at any time as such advice may be required urgently, for example following an accident or major repair.

The licensee cannot delegate the responsibility for compliance with the regulations to the qualified expert.

The licensee shall consult the qualified expert, as required, about radiation safety matters, including:
– restriction of exposure and attainment of ALARA;
– maintenance of engineering controls and other equipment provided;
– dosimetry and monitoring;
– investigation of abnormally high exposures and overexposures;
– training;
– safety assessment and contingency arrangements;
– prior examination of any plans for new plant or premises or for modifications of existing plant or premises from a radiation safety aspect;
– independent audits;
– quality assurance; and
– assistance following an emergency.

The licensee should give the qualified expert adequate information, facilities and support services as may be needed for the expert to work effectively. The information should include a clear statement of the scope of the advice the expert is required to give.
The appointment of the qualified expert can be on a part-time basis. He/she need not necessarily be an employee of the organization but should be available to give advice and help when required.
The qualified expert should undertake independent audits of radiation protection systems in place at the facility. Example audit check lists are included in Appendix VII. These are taken from IAEA-TECDOC-1113 [6] and are also suitable for use by the regulatory authority.
Copies of all reports and correspondence from the qualified expert should be received by both the radiation protection officer and a senior manager of the licensee with responsibility for radiation protection at the facility. This manager should not have responsibility for operational matters or production at the facility in order not to have conflict of interest and avoid compromising radiation safety.

2.2.3. Quality assurance

The licensee shall establish a comprehensive quality assurance programme for radiation protection and safety to ensure that all necessary procedures are developed and implemented in order to comply with the regulations for radiation protection within the terms and conditions of the authorization(s). This is the radiation protection programme (RPP).

The RPP should include documented policies and procedures and also requires a commitment to an effective safety culture from management and employees of the licensee, together with the allocation of adequate resources of time, personnel and equipment.
Feedback from operational experience, and lessons learned from accidents or near misses can help identify potential problems and correct deficiencies, and should be used systematically, as part of the RPP.
The maintenance of records is an important part of the RPP and a list of the principal records required to be maintained for a non-medical irradiation facility is provided in this section.

2.2.3.1. Objectives of the RPP

The objectives of the RPP shall be clearly stated and should include the following:

- The licensee is committed to carrying out all aspects of its work in a safe manner which minimizes the risks to its own workers and all other persons who may be at risk from this work.
- In relation to its work with radiation sources, the licensee will take all practicable steps to ensure that the exposure of its workers and all other persons are kept as low as reasonably achievable and below the dose limits set in the national regulations.
- In particular, the licensee will take all necessary steps to ensure the physical safety and security of radiation sources so as to minimize the risk these present to persons not connected with this work.
- The licensee undertakes to comply with national regulations and any local requirements and will ensure that all necessary tests, inspections and records are maintained so as to enable the licensee to demonstrate compliance with these requirements.

2.2.3.2. Structure and content

The RPP represents the totality of the actions undertaken to achieve the objectives of the programme and may include a top level policy document supported by detailed and specific procedures or local rules and a comprehensive system of records. These components may consist of the following:

Policy document specifying:

– objectives;
– responsibilities;
– training;
– safety assessment; and
– quality assurance.

Procedures and local rules covering:

– operation, e.g. access control, startup/shut down procedures;
– maintenance and source changing;
– individual monitoring and health surveillance;
– training;
– leakage testing of sources;
– testing of radiation monitors;
– routine checks by RPO;
– audits and safety assessments by qualified expert; and
– incident reporting and investigation.

2.2.3.3. System of records

A comprehensive system of records collating information of key importance to the maintenance of good standards of radiological protection at the facility shall be maintained by the licensee.

The following are the principal records that should be maintained for a non-medical irradiation facility:

– Authorization certificate and documentation supporting the corresponding applications, and also any correspondence between the licensee and regulatory authority.
– Name of the person authorized and responsible for the radiation protection programme.
– Record of safety assessment reports.
– Operating log book.
– Routine checks of safety systems by RPO.
– Individual doses (current and prior work history).
– Results of workplace monitoring.
– Radiation monitor test reports.
– Results of leakage tests of radioactive sources.
– Inventory of sealed sources.
– Log of sealed source movement.
– Incident and accident investigation reports.
– Audits and reviews of radiation safety programme by qualified expert.
– Installation, maintenance and repair work.
– Facility modification.
– Training provided (initial and refresher).
– Evidence of health surveillance of workers.
– Transportation:

    Package documentation;
    Package surveys;
    Transfer/receipt documents; and
    Details of shipments dispatched.

– Disposal or return of radioactive sources:
– Records of training, which should include the following information:
– Name of the person who delivered the instruction or training;
– Name of the person who received the instruction or training;
– Date and length of the instruction or training;
– List of the topics addressed;
– Copy of the certificates of training.

2.2.4. Human factors

2.2.4.1. Staffing

The licensee shall appoint a number of professionals, with personal accreditation (see Section 2.1.2), sufficient to ensure that all activities are carried out in accordance with national regulations and this practice specific regulatory document. The number of persons should be reviewed, as workload increases, or new techniques and new equipment are incorporated.

2.2.4.2. Education and training

Training, competency and an adequate number of qualified staff are the most important components for the safe and efficient operation of an irradiation facility. All staff working with radiation sources must have an adequate educational background with relevant practical training.

The licensee should ensure that only staff with the appropriate accreditation are appointed to key positions and that they are aware of:

– the conditions and limitations of the license;
– institutional radiation protection policies and procedures (including practice drills);
– review and analysis of incidents and accidents that have occurred in the institution or elsewhere; and
– local quality assurance programme and quality control procedures; use and operation of equipment.

2.3. Responsibilities of suppliers

2.3.1. Designers and manufacturers

The licensee of an irradiation facility shall ensure that the facility is designed to meet the radiation safety objectives given in Section 1 and any more specific safety requirements of the regulatory authority during siting, operation, maintenance and decommissioning. This shall be achieved by:

– contracting to a qualified expert, as accredited by the regulatory authority, who follows the requirements of the BSS to ensure safe design for these facilities; and
– ensuring adequate information is provided so that the facility can be safely installed and operated. This information should consist of:
  (i) a detailed description of the design and operation of the safety systems, including control circuit diagrams;

(ii) detailed operating and maintenance procedures, including the type and frequency of checks for safety control systems, contamination monitoring and radiation surveys;

(iii) safety assessments using formal analysis methods appropriate to the level of risk associated with the facility, (It should be noted that it is also the responsibility of the licensee to carry out a safety assessment based on information from the supplier and the organization's own administrative rules.);

(iv) instructions and procedures to be followed in emergency situations as outlined in Section 7 of this publication.

The licensee shall ensure that all documents provided by the manufacturer, supplier or installer (operating manuals, operating rules and procedures and emergency procedures) shall be available in the local working language, understandable to the users, in order to avoid the risk of misunderstanding.

The licensee shall ensure that any new information discovered about weaknesses of the facility that relates to safety (for example, information regarding defects in material and equipment and weaknesses in operating procedures) is obtained from the manufacturers or suppliers as rapidly as possible. Such information should include any necessary advice on corrective actions that need to be taken.

In order to achieve this, it will be necessary for the licensee to seek this information from the manufacturer or supplier periodically rather than to rely upon them to supply it.

2.3.2. Constructors and installers

The licensees shall ensure that construction and installation work does not compromise the safety aspects of the facility by fully complying with the requirements of the designer, the manufacturer and the regulatory authority. On completion of the installation, or at appropriate stages during the construction, the licensee shall ensure that a qualified expert thoroughly and critically reviews the facility or any component part before it is commissioned to ensure that:

– the safety features and warning devices have been properly installed and operate correctly; and
– there is sufficient radiation protection for all persons and the environment.

The licensee shall ensure that the constructor or installer provides adequate information about proper operation, maintenance and decommissioning of the facility. The licensee should also ensure that designers, manufacturers, constructors and installers co-operate in order to provide employees with the necessary theoretical and practical training to enable them to do their work in a safe manner.

3. SAFETY OF SOURCES AND FACILITIES

3.1. Design safety for gamma irradiation facilities

3.1.1. Design of sealed sources (gamma radiation sources)

Sealed sources used in gamma irradiation facilities shall meet the general requirements for sealed sources given in ISO Standard 2919 [7].

These classification requirements are:

Category I irradiator:	Sealed source classification; 43323
Category II irradiator:	Sealed source classification; 53424
Category III irradiator:	Sealed source classification; 53424
Category IV irradiator:	Sealed source classification; 53424

If the activity of the source exceeds those indicated in Annex I of Ref. [7], a specific evaluation of the use of the sealed source and its design shall be made by the licensee and approved by the regulatory authority.

The licensee shall also take account of the possible effects of fire, explosion, corrosion and any aspects related to the continuous use of the sealed source in addition to those covered by Ref. [6]. The consequences of failure of source integrity must be considered. These are influenced by:

– the quantity of radioactive material contained in the sealed source;
– the radiotoxicity, leachability and solubility of the radioactive material;
– the chemical and physical form of the radioactive material; and
– the environment in which the source is stored, moved and used.

3.1.1.1. Specific requirements for wet storage conditions

When selecting sources, the licensee shall ensure that the outer capsule material is such that it does not significantly corrode under the conditions of storage of the sealed source in the pool. Account shall also be taken of the need to limit thermal fatigue in the selection of the capsule material.

The licensee shall also ensure that the source material is substantially insoluble in water so that the consequences of a breach in the containment are kept to a minimum. In this context, caesium chloride is highly soluble in water and shall not be used.

3.1.1.2. Certification and documentation

The licensee shall maintain records relating to the sealed source. The records shall include the following:

– Model number and identification number of the source, the radionuclide contained, the source activity and the date to which the source activity relates;
– ISO classification certificate;
– Bend test certificate (if required);
– Leak test certificate;
– Contamination test certificate;
– Special form test certificate for transportation purposes (see Ref. [8]).
    - Any other documentation required by the regulatory authority.

3.1.2. Internal design

3.1.2.1. *Source holder and rack*

The sealed source shall be firmly fixed within its holder and rack such that it cannot be readily dislodged. Means shall be provided to position and retain the sealed source in the design position. Devices used for the purpose of positioning and removing sources should be capable of being operated from outside the radiation shields. In the event of failure of the sealed

source holder or rack, it shall not be possible for the source to move into a position that may cause a radiation hazard.

3.1.2.2. Source guard

The radiation source shall be provided with adequate mechanical protection to prevent interference and damage by items such as product boxes or carriers.

Product positioning systems shall not be able to come into contact either directly or indirectly with the radiation source.

For example, this may take the form of a protective shroud, guide bars or floor guides on the product positioning system.

3.1.2.3. Source status and exposure system interlocks

Means shall be provided to ensure that, if a malfunction occurs in the source exposure mechanism, the radiation source will automatically become fully shielded.

If the source cannot be returned to its shielded position, means shall be provided to prevent access and provide a visible and audible alaram signal.

An alarm which is audible both inside the irradiation room and at all access ports shall be provided to indicate when the radiation source is neither fully shielded nor in the 'source in use' status.

3.1.2.4. Product exit monitor

A fixed radiation monitoring system with built-in redundancy and audible alarms shall be located such that the monitors will detect any radioactive source being accidentally brought out on a product carrier. These monitors shall he interlocked with the irradiator controls such that if radiation at the exit port exceeds a predetermined level, the conveyor which carries products from the irradiation room to the exit port will stop and the source will automatically become fully shielded.

3.1.2.5. Source exposure mechanism disconnect for servicing

The motive power (e.g. electrical, pneumatic, hydraulic) used to expose the source shall be provided with a disconnecting mechanism to enable servicing to be carried out without the danger of the source being inadvertently exposed. Means shall also be provided for positively isolating the source control system or for mechanically locking the moving parts.

3.1.3. Wet storage irradiators

3.1.3.1. Pool accessories

An automatic water level control shall he provided to maintain the water above a pre-set level. Except for float switches, all components of the automatic water level control that are placed below water level shall be made of a material that will not float (i.e. with a density greater than 1000 kg m^{-3}). If hollow tubing is used, it shall be fully vented to allow the water to flood the tubing to eliminate the risk of a high radiation beam up the tube.

3.1.3.2. Pool integrity

The containment of the pool shall be watertight and designed to retain the water under all foreseeable circumstances. A non-corrosive stainless steel liner shall be used. The containment shall be designed to support radiation source transport containers used during source transfer operations without compromising the integrity of the pool. There shall be no penetration (e.g. pipes or plugged holes) through the bottom of the pool. There shall be no penetration through the walls of the pool more than 30 cm below normal water level.

3.1.3.3. Pool component material

All permanent pool components shall be made of corrosion resistant materials because corrosion products may affect the integrity of the sealed source. Where practical, stainless steel components (e.g. brackets or pulleys) shall he passivated, particularly after fabrication.

3.1.3.4. Water level control — normal

Means shall be provided to replenish water losses from the pool automatically. The system shall be capable of maintaining the pool water at a level sufficient to provide the radiation shielding necessary. A metering device shall be installed in the make-up water supply line to indicate major changes in water replenishment requirements that may be associated with pool leakage.

Normal water losses are principally due to evaporation.

3.1.3.5. Water level control — abnormal (low)

Means shall be provided to activate audible and visible signals in the control area if the pool water falls to a level more than 30 cm below the normal make-up water level.

3.1.3.6. Water conditioning

To reduce the possibility of source corrosion, the pool shall be equipped with a water conditioning system capable of maintaining the water in a clean condition and at a level of conductance not exceeding 1000 μS/m^2. Care shall be exercised to avoid the introduction of contaminants into the water system (e.g. deionizer regenerates, cleaning materials, corrosive fire extinguishing materials, spilled product).

3.1.3.7. Water cooling

A pool water cooling system shall be provided in wet storage irradiators to remove heat produced by gamma emitting sources.

This is to reduce damage to electrical equipment and product boxes and the product positioning system resulting from high humidity 1evels. Reducing evaporation losses from the pool will also facilitate maintaining the conductance of the water below 1000 μS/m for a longer time before regeneration or replacement of deionizer resins is required.

[2] Siemens is the SI unit of conductance which is the reciprocal of resistance, i.e. 1 S is the reciprocal of 1 Ohm and was formerly called 1 Mho.

3.1.3.8. In–pool piping

Since pipes are used in source storage pools for the water level and water quality systems, suitable siphon breakers shall be provided to prevent the possibility of lowering the pool water to more than 30 cm below the normal make-up water level. All pool water circulation suction pipes shall have intakes no lower than 30 cm below the normal make-up water level.

3.1.3.9. Pool guard and cover

A physical barrier, such as a railing and/or a metal cover, shall be installed to prevent personnel from accidentally falling into the source storage pool. This physical barrier may be removed during maintenance or service operations.

3.1.3.10. Water treatment system monitor

A fixed radiation monitor with an audible alarm shall be located on the deionizer column to detect contamination arising from source leakage. This monitor shall be interlocked with the irradiation controls, such that if the pre-set alarm level is reached the source returns to its shielded position and the water circulation stops.

3.1.4. Fire protection

During extended periods of static irradiation of combustible materials, or when a malfunction prevents the source from becoming fully shielded, heat build-up can lead to combustion. Heat and smoke sensing devices with visible and audible alarms shall be provided to detect combustion in the irradiation room. The triggering of the devices shall cause the source automatically to become fully shielded and the product positioning and ventilation systems to shut down. The design of the facility should be such that damage to any component part will not inhibit the source from returning to the fully shielded position.

A fire extinguishing system shall be provided in the irradiation room. When a water sprinkling system has been installed, provision shall be made to control any overflow of water that may arise from its use. Chemicals and corrosive substances that could adversely affect the integrity of the sealed source shall not be used in fire extinguishing systems.

3.1.5. Power failure

3.1.5.1. Electrical

Means shall be provided to ensure that, if an electrical power failure occurs, the source will automatically be returned to the fully shielded position and the irradiator shut down, and that safety control systems will also not be compromised.

3.1.5.2. Non-electrical

Means shall be provided to ensure that failure of non-electrical power (e.g. pneumatic or hydraulic power) used to control or operate any irradiator safety feature or device will automatically cause the source to become fully shielded and the irradiator to shut down.

3.2. Design safety for both gamma and electron accelerator facilities

3.2.1. Product positioning system

The product positioning system shall be provided with controls that detect any malfunction of the system, and subsequently ensure that the source automatically becomes fully shielded.

3.2.2. Shielding

Direct radiation exposure from the operation of irradiation facilities shall be limited by appropriate shielding. The amount of shielding shall be determined by reference to any dose-rate requirements specified by the regulatory authority.

Once the design of the shield has been established, no subsequent changes affecting radiation safety shall be made unless they have been approved by the regulatory authority.

Penetration of the shield will be necessary for personnel and product entry and exit and for ventilation and other ducting. Measures shall be taken to ensure that all such significant radiation paths are fully evaluated and protected by design, including those that arise during the transit of the source from its shield to its operating position.

All shielding calculations carried out for the purpose of design shall be undertaken by an appropriate qualified expert accredited by the regulatory authority.

Penetration poses particular problems for the shielding designer, who should ensure that there is no direct radiation leakage path and that the use of maze entrances and shield plugs is sufficient to reduce the radiation fields at the point of exit to acceptable levels. Where this is not feasible, access to areas of high dose rate will need to be restricted.

The shielding properties of particular materials are well established [9, 10, 11, 12, 13], and, in addition, the experience from existing irradiation facilities should be taken into account.

3.2.3. Access to the radiation source and interlocked systems

Facilities requiring access shall be designed such that persons cannot enter the irradiation room while the source is in the exposed position, or is energized. Such control relies heavily on the use of interlocked systems.

Sequentially interlocked controls shall be provided for personnel access, locking the irradiation room and irradiation operations. The controls shall be designed such that any attempt to override them or apply them out of sequence will automatically abort the intended operation and require the sequence to be restarted.

3.2.3.1. Personnel access door interlocks

Means shall be provided such that the personnel access door to the irradiation room is closed and secured before the irradiation process can begin.

The door interlocks shall be integrated with the master control system such that violation of the interlock system or use of the door will cause the radiation to be automatically terminated. Any failure of the control system shall generate visible and audible alarm signals.

Opening the access door shall also disable the source hoist control circuit and cut off the motive power to the source hoist operating mechanism in the case of gamma facilities, or

switch off the high voltage supply for electron beam facilities. The disabling of the source hoist control circuit and the cut-off of the motive power to the source hoist operating mechanism shall be accomplished by independent actions.

The door shall not prevent any person in the irradiation room from leaving. In addition, there should be an independent backup access control to detect the entry of personnel while the sources are exposed.

Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate an alarm to warn the individual entering the room of the hazard. The alarm shall also alert at least one other individual on site that an entry has occurred. That individual shall have been trained on how to respond to the alarm and be prepared to render or summon assistance promptly.

3.2.3.2. Product entry and exit port interlocks

Suitable means shall be provided at the product entry and exit ports to prevent inadvertent entry of personnel into high radiation areas The ports shall be interlocked such that a visible or audible alarm indicates when the entry/exit port control mechanism has malfunctioned or been overridden or tampered with. The irradiation shall automatically be terminated when this occurs and shall be prevented from being restarted unless the cause has been remedied.

3.2.3.3. Removable irradiation room shield plugs

Removable irradiation room shield plugs shall be interlocked with the master control system to prevent or abort irradiator operations if a plug is removed. To ensure that the interlock cannot be tampered with, the interlock control shall not be accessible outside the radiation shields.

3.2.3.4. Fixed radiation monitor with alarm

A monitoring system with built-in redundancy shall be provided to detect radiation levels in the irradiation room. The monitor shall be integrated with the personnel access door interlocks to prevent room access when it detects a radiation level in excess of that specified, or when it malfunctions or is turned off. The monitor shall generate visible and audible alarm signals if the radiation level exceeds that specified when the irradiation is indicated to be terminated. If it is necessary to override interlocks or other safety systems, written administrative procedures shall be used to provide detailed guidance for such actions, and shall be undertaken only under the direct control of a radiation protection officer.

The pre-set alarm level must be set sufficiently above the natural background level to avoid an excessive number of false alarms.

3.2.3.5. Fully shielded facilities (Category I and III gamma irradiation facilities and Category I electron beam facilities)

The irradiator shall not be operable until all shielding is in place and all other safety devices are actuated. Movable shielding shall be interlocked so that it cannot be displaced in a manner that results in radiation levels in excess of those specified in the design. An interlocked radiation monitor shall be provided as a backup check that the shielding is in place.

3.2.4. Control console

Each irradiator shall have a master control that shall be used to prevent unauthorized operation.

Means shall be provided to terminate an irradiation and turn the irradiator off at any time.

In power operated irradiators this control may be a key operated switch. In manually operated irradiators a keyed mechanical lock or simple padlock may be used.

3.2.4.1. Access key

Access key control systems shall be designed to ensure that there can be no more than one access key in use at any given time, e.g. the irradiator controls may be designed such that a single multipurpose key operates the irradiator during normal use. This key may be used to operate the control console, gain access to the irradiation room and actuate the safety delay timer. In systems employing two or more keys, one key must remain captive (trapped within the lock) when the other keys are being used.

3.2.4.2. Emergency stop device

In addition to any other means normally available at the control console to shut down the irradiator, a clearly labelled emergency stop device shall be provided at the control console to prevent, quickly interrupt or abort irradiator operations and terminate the irradiation at any time.

3.2.5. Irradiation room

3.2.5.1. Safety delay timer with alarms

The irradiation room shall be equipped with a safety delay timer that will automatically generate visible and audible signals to alert persons in the area that the radiation exposure sequence has begun. The timer shall allow sufficient time for the operator to make a complete search of the area to ensure that no one else is present and then to leave the area. The timer shall be integrated with the master control system such that irradiation cannot begin unless the startup sequence has been properly completed within a pre-set time

3.2.5.2. Emergency exit or shielding

For the protection of anyone inadvertently shut inside the irradiation room, one or more of the following systems shall he provided:

– a means of exit from the irradiation room. This may require a system for opening the personnel access door from inside the irradiation room, thus activating the normal safety interlocks; and
– a clearly marked location where radiation dose rates are sufficiently low.

3.2.5.3. Emergency stop device

Means shall be provided within the irradiation room to prevent, quickly interrupt or abort irradiator operations and terminate the irradiation at any time. The device shall he

clearly labelled and readily accessible to workers in the irradiation room, and shall cause a visible or audible signal to be given outside the room.

3.2.6. Geological site considerations

Geological features that could adversely affect the integrity of the radiation shields shall be evaluated and the physical properties of materials underlying the irradiator site or its environs shall be taken into account. Areas of potential or actual surface or subsurface subsidence, uplift or collapse shall be taken into consideration when assessing the suitability of a site. Other factors that are not necessarily due to natural features (e.g. underground mining) but that could result in instability shall also be considered.

3.2.6.1. Seismic detector

In areas with a significant potential for severe seismic disturbance[3], each Category II or IV gamma irradiator shall he equipped with a seismic detector that causes the radiation source automatically to become fully shielded should the detector be actuated. The seismic detector may be a horizontal omniaxial or a vertical uniaxial type and shall be set to be actuated at an acceleration above 0.05 g.

3.2.6.2. Design basis earthquake

In seismic areas, the radiation shields shall be designed to retain their integrity for the 'design basis earthquake' (DBE). The DBE is based upon an evaluation of the maximum earthquake potential, for which the regional and local geology and seismology and the specific characteristics of local subsurface materials are taken into consideration.

3.2.7. Ventilation

3.2.7.1. Noxious gas control

Ozone (O_3), oxides of nitrogen and other noxious gases (e.g. those from certain plastics) are produced by radiolysis. Measures shall be taken to protect personnel against exposure to concentrations of such gases above the threshold limit values prescribed by the health authority.

Ventilation shall be installed to prevent the migration of the ozone produced in an irradiator into areas that may be occupied and where the concentration could build up to exceed the accepted limit. This can be achieved by using a ventilation system that creates a negative pressure in the irradiation room.

Where forced air systems are utilized, the flow of air shall be continuously monitored such that failure of the system will automatically terminate irradiation.

> Ozone, being very reactive, is readily reduced to the normal form of oxygen (O_2) and, when a large capacity, continuously operated ventilation system is used, the irradiation room can normally be entered a few minutes after the termination of irradiation. One method of controlling personnel access until the ozone concentration is at an acceptable level in the irradiation room is to provide a time delay interlock mechanism which prevents personnel access doors from being opened before a pre-set time has elapsed after termination of irradiation.

[3] Earthquakes with accelerations of 0.3 g or greater are generally classified as severe.

3.2.7.2. Nitrogen oxides

Nitrogen oxides such as NO and NO_2 are also generated by the radiolysis of air, but measurements in irradiation rooms associated with sealed source irradiators indicate that the levels are well below the threshold limit values prescribed by health authorities.

3.2.8. Warning signs and symbols

3.2.8.1. Irradiation device warning sign

There shall be a clearly visible warning sign at the personnel access door to the irradiation room bearing the radiation symbol and warnings as prescribed by the regulatory authority.

Any warning signs positioned inside the irradiation room shall be made from materials that will withstand high doses of radiation with the general environmental conditions that may exist.

3.2.8.2. Irradiation (source) status indicators

Clearly visible irradiation status indicators shall be provided at the control console to indicate when the irradiation:

– is terminated (source down or de-energized);
– is in progress (source up or energized); and
– is in preparation (source in transit position or about to be energized).

An irradiation status indicator shall be visible at each personnel or product entry/exit port.

3.2.8.3. Audible signals

Each audible signal designed into the irradiator control system shall be distinct and loud enough to gain immediate attention of persons in the area and should not be capable of being confused with any other signals in use in the area.

3.2.8.4. Status indicator colours

The following colours shall be used for illuminated or colour coded controls:

Condition	**Colour**
Emergency (stop buttons or lights)	Red
Warning — hazard	International trefoil or red
Critical information (irradiator malfunction)	Red
Caution (not an emergency, but some function taking place to be aware of)	Yellow or orange
Normal (irradiator not in use, or function safe)	Green
Information	Blue

3.2.8.5. Labelling

Category I gamma irradiators shall have clearly visible labels identifying the contained radionuclides, their activities and the dates to which the source activities relate. The irradiator shall bear the radiation symbol and warnings according to national regulations.

The irradiator shall also bear a label or labels with the following information:

– Name and address of manufacturer;
– Model and serial number of irradiator;
– Approval number, if appropriate; and
– Maximum source activity of irradiator.

If a separate control panel or console is utilized, it shall be easily identifiable as being part of the irradiator.

When labels are being secured on fully shielded irradiators, care shall be taken not to drill through the metal container shell into the lead shield.

3.3. Design safety for electron accelerator facilities

The following features shall be considered in industrial accelerator design:

– Positive means of disabling the main acceleration system;
– Built-in machine parameter monitoring; and
– Built-in remote machine diagnostics.

3.3.1. Main acceleration system disabling mechanism

The main acceleration system disabling mechanism must deactivate the acceleration capability without harm to machine components. It shall disable the acceleration system in such a manner as to allow as many other subsystems as possible to function for diagnostic purposes. The disabling feature must be clearly identified and explained by the manufacturer in the documentation accompanying the machine

3.3.2. Built-in machine parameter monitoring

Operating parameters shall be continuously monitored.

This offers the opportunity of event logging of failure sequence information for maintenance engineers and for planning repairs.

3.3.3. Built-in remote machine diagnostics

Strategic electronic test points shall be located in the control room in order to permit operators and maintenance crews to carry out accelerator diagnostics on the total system without resorting to disabling the main acceleration system or bypassing access interlocks.

3.3.4. Shielding

Low atomic number materials should be used as far as possible for structures that are exposed to electron beams, to minimize the generation of X radiation, so long as X ray conversion is not the purpose of the operation of the electron accelerator. Shielding

calculations shall be performed under the assumption that all electrons are absorbed by the heaviest element that may be exposed to the beam. Account shall be taken of the composition of the structural materials and products that might be irradiated in the facility. The shielding calculations shall be performed for the maximum energy and the maximum current that the electron accelerator can deliver.

Attention shall also be paid to 'spurious' X radiation, particularly in accelerators operating at high voltage levels with accelerator tubes located outside the irradiation room.

There are several causes of spurious X radiation:

Backscattered electrons can possess sufficient energy to stream back through the accelerator tube. This effect is particularly pronounced when high energy electrons impinge on a high atomic number target for X ray conversion.

During conditioning of the electron accelerator and during operation under relatively poor vacuum conditions, dark currents in the accelerator tube occur which generate X rays.

Access ducts shall be shielded with lead or steel shot in order to reduce radiation to acceptable levels.

Electrons have a finite range in matter which is a function of their initial energy and the density of the absorbing material. The maximum range of the electrons is small compared with that of the X rays; therefore, in calculations of the shielding requirements of electron accelerator facilities, only the generated X rays need be taken into account.
Characteristic X radiation is an important factor to consider only with electron accelerators up to 300 keV that are self-shielded with a heavy element such as lead or depleted uranium. In most cases, bremsstrahlung is more important for radiation shielding.

3.3.5. Operating parameters

The operating parameters of accelerators (voltage and current) shall be interlocked with the product transport mechanisms.

3.3.6. Commissioning and testing

Commissioning and testing shall be carried out at maximum operating parameters (voltage and current) and with product handling equipment under the beam as close as possible to actual operating conditions.

3.4. Operational safety

3.4.1. Testing and maintenance of equipment

To ensure the continued safe operation of the facility, the licensee shall ensure that all safety functions are regularly tested by setting up a formal programme of maintenance and testing.

Formal testing and maintenance programmes shall follow the recommendations provided by the irradiator manufacturer and source supplier in the operating and maintenance manuals that they provide. Such manuals must be obtained by the licensee and should be translated into the local language.

The tests shall include the following:

– Safety interlock components shall be regularly tested for correct operation according to the instructions of the equipment manufacturers. These tests shall be carried out by appropriately qualified and trained persons and shall be undertaken in the presence of a radiation protection officer.
– Portable radiation meters shall be calibrated before they are first used, after repair and at intervals specified by the regulatory authority. The pre-use test should include a test of the instrument's overload performance, i.e. it should operate correctly up to the maximum credible dose rate it may encounter.
– Periodic examination of the hoist cable and guide cables shall be made and the cables shall be replaced as required by existing national regulations or at intervals recommended by the manufacturers.
– Periodic leak tests of the radiation sources shall be carried out in a manner and at a frequency determined in discussion with the source supplier and plant manufacturer or as required by the regulatory authority.

3.4.1.1. Weekly tests

The following tests should be carried out weekly:

– A check that the continuous radiation monitoring device on the pool water circulation system is functioning correctly (in the case of Category IV gamma irradiation facilities).
– Analysis by a well regulated national laboratory of samples of pool water taken from the water circulation system (a less frequent analysis may be appropriate if water is continuously monitored for radiation or if experience shows this to be acceptable).
– A check of the water deionizer for correct operation and of air filter, water filter and resins for contamination.
– A check for correct function of the emergency stop button on the control console, the emergency stop device inside the irradiation room, the door interlock and, in the case of wet storage irradiators, the water level control, the low pool water interlock and the water treatment system.

Attempts shall also be made to operate the irradiator after deliberately violating the approved startup procedure, to ensure that the interlocks and sequential controls are functioning correctly.

3.4.1.2. Monthly tests

The following additional tests shall be carried out on a monthly basis:

– A test that the irradiation room monitor is functioning properly; this is done by exposing the monitor probe to a check source until the alarm sounds.
– A check, in accordance with the manufacturer’s instructions, of the safety control systems that prevent access to the irradiation room when any radiation is present.
– A test that the product exit monitor is functioning properly; with the irradiator operating, the test is carried out by exposing the monitor probe to a check source until the alarm sounds. The product exit conveyor shall stop and the source shall automatically become fully shielded. In the case of electron accelerator facilities, the radiation shall be switched off.

– A test of the source exposure mechanism, the ventilation system and similar hardware, which contribute to the safe operation of the irradiator and its related product positioning mechanism.
– A check that other main items of equipment associated with source movement and control function properly and show no signs of potential failure.
– A check that all product containers are undamaged and in good condition.

If any of the checks indicate a fault or if interlocks do not function properly, the irradiator shall not be used until repairs have been carried out.

3.4.1.3. Six-month test

Semi-annually (or at other intervals approved by the regulatory authority), an inspection of the source movement and suspension system shall be carried out. This shall include the entire length of the cable. Any necessary replacement of the cable shall be carried out.

3.4.1.4. Tests for leakage of radioactive material

Tests for leakage of radioactive material shall be carried out at a frequency specified by the regulatory authority, usually between six and twelve months.

The testing method shall be as recommended by the source supplier and a record of each test shall be maintained, including information comprising:
– identification of the irradiator by manufacturer, model, serial number and type of radioactive material;
– location of the irradiator;
– date of test;
– test sample collection method;
– identification of the measuring instrument by manufacturer, model and serial number;
– date of the most recent measuring instrument calibration;
– the correction factors, if any, used to compensate for measuring instrument variables and environmental conditions;
– the conversion factor used to convert to the activity for the type of radioactive material under test;
– measuring instrument reading of test sample;
– measuring instrument background reading;
– calculation of activity detected;
– evaluation of test results i.e. whether the source(s) are considered to be leaking or not (see note below);
– action taken; and
– identity of the individual responsible for the test.

Tests which reveal the presence of contamination on the test sample shall be considered as evidence that the sealed source is leaking. In this event, the irradiator shall be immediately withdrawn from service and appropriate action taken to prevent exposure of

personnel and further dispersal of radioactive material. The licensee shall immediately notify the regulatory authority and should notify the manufacturer of the equipment and the supplier of the source that an incident has occurred which might have caused or threatens to cause a radiation hazard. Under no circumstances shall unauthorized or untrained persons attempt to examine or decontaminate the irradiator.

If the test results are considered negative, no action other than record keeping is required.

Note: Levels of contamination are specified in international publications [7], but where national standards exist the latter should be observed. For example, the Atomic Energy Control Board (Canada) specifies that levels of less than 2 kBq may he considered negative; British Standard 5288 recommends 185 Bq as the limit below which the contamination test may be considered negative.

3.5. Security of sources

The objective of source security is to ensure continuity in the control and accountability of each source at all times. Special provisions should be made for typical situations in which loss of control has led to accidents:

– storage of sources before installation;
– temporary or permanent cessation of use; and
– storage after decommissioning pending decision on source return or disposal.

The licensee shall develop procedures to ensure the safe receipt and despatch of radioactive sources within the institution, and establish controls to prevent theft, loss, unauthorized withdrawal, or damage of sources, or the entrance of unauthorized personnel to the controlled areas.

The licensee should check the number of sources on site both when receiving or when despatching sources and make a physical inventory of all sealed sources in order to confirm that they are in their assigned locations and secure.

4. OCCUPATIONAL RADIATION PROTECTION

4.1. Designation of areas, workplace and individual monitoring

4.1.1. Designation of controlled and supervised areas

4.1.1.1. Controlled area

Any area where specific protective measures or safety provisions are, or could be, required for controlling normal exposure or preventing or limiting the extent of potential exposure, shall be designated as a controlled area.

This will consist of the following areas for irradiation facilities:

– Self-contained gamma irradiators (Categories I and III); the room in which the irradiator is housed;
– Panoramic gamma irradiators (categories II and IV); the exposure room and control room;

– Electron beam irradiator (Category I); the room in which the irradiator is housed; and
– Electron beam irradiator (Category II); the exposure room and control room.

The designation of these areas shall be kept regularly under review and may be changed or extended during initial installation, maintenance and source loading and unloading operations.

All controlled areas shall be identified by physical barriers, such as doors, where practicable, or by other means such as markings on the floor. Access points to controlled areas shall be clearly labelled with signs including the radiation warning symbol, the statement radiation controlled area and any necessary instructions in the local language.

Access to controlled areas shall be effectively restricted to qualified operators and other staff authorized, in writing, by the radiation protection officer. This access control shall be ensured by physical barriers and interlocking systems, where practicable, and by written administrative controls such as entry permits issued by the radiation protection officer. Such permits shall specify the persons concerned, the areas to be entered, the reason for entry, the duration of the permit and any special restrictions, e.g. monitoring arrangements and the level of supervision required.

It is recommended that permits are valid only when authorized by both the radiation protection officer and the facility manager.

For normal operations, a dose-rate criterion for a controlled area may be useful and convenient. Therefore, for example, any area where dose rates exceed 2.5 μSv/h may be designated as a controlled area. The licensee should also comply with any requirements of the regulatory authority in this respect.

4.1.1.2. Supervised areas

The following areas shall be designated as supervised areas unless circumstances warrant their designation as controlled areas:

– Panoramic gamma irradiators (Categories II and IV): product entry and exit areas and service areas such as source hoist and water treatment plant rooms.
– Electron beam irradiator (Category II): product entry and exit areas, and service areas.

4.1.2. Workplace monitoring

The licensee shall develop programmes for monitoring the workplace. [BSS I.37–40]

Appropriate portable X and gamma radiation monitors shall be provided. Surveys shall be undertaken at positions around the facility and at intervals as advised by the radiation protection officer, and records of these surveys shall be kept for a period prescribed by the regulatory authority.

Electron beam facilities operating above 10 MeV shall also be monitored for neutrons.

Portable monitoring instruments shall be tested for proper function prior to each entry into the irradiation room by means of a check source. This shall be located at the entry door.

The monitoring instruments used shall:

- have a response appropriate for the type of radiation being measured;
- be in good working condition;
- be capable of measuring dose rates to be encountered under normal conditions and also under accident conditions with no saturation; and
- have readily obtainable batteries and a built-in battery check feature.
- be robust and reliable.

All survey meters used for workplace monitoring shall be calibrated at intervals specified by the regulatory authority and the calibration shall be traceable to a standards dosimetry laboratory approved by the regulatory authority.

Monitoring is required to confirm the definition of controlled and supervised areas to identify changes to normal levels which may indicate a failure in the control of the radiation source.

Initial access to the irradiation room after termination of irradiation shall be made by a qualified operator, who shall use a portable monitor to determine whether the ambient radiation levels are normal for that facility.

A second portable monitor shall be available for use to enable one monitor to be sent for periodic calibration or maintenance.

4.1.3. Individual monitoring

The BSS (I.33 & I.34) state that:

"For any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure, individual monitoring shall be undertaken where appropriate, adequate and feasible.

For any worker who is regularly employed in a supervised area or who enters a controlled area only occasionally, individual monitoring shall not be required but the occupational exposure of the worker shall be assessed. This assessment shall be on the basis of the results of monitoring of the workplace or individual monitoring."

In irradiation facilities, workers-including radiation protection officers (RPOs), operators, qualified experts and some maintenance staff who are routinely exposed to radiation in controlled areas- shall have individual dose monitoring.

This individual dose monitoring, e.g. using film, thermoluminescent dosimeters (TLDs), shall be provided and processed by a laboratory or company that has been authorized by the regulatory authority and is traceable to a standards dosimetry laboratory approved by the regulatory authority.

The tools and procedures for monitoring workers, including the type of dosimeter required and the frequency of replacement, shall be chosen in consultation with the RPO or qualified expert, and as required by the regulatory authority. The results of personal monitoring measurements shall be recorded and reported as required by the regulatory authority.

Because evaluation of dose is an important part of the radiation protection programme, it is important that workers return dosimeters on time for processing.

Licensees should be vigilant in efforts to recover any missing dosimeters. Delays in the evaluation of a dosimeter can result in the loss of the stored information.

If a worker's dosimeter is lost, the licensee should perform and document an evaluation of the dose the individual received and add it to his/her dose record. Often, the most reliable method for estimating the dose is to use his/her recent dose history. In those cases where the individual performs non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate.

4.2. Investigation and follow-up

The licensee shall conduct formal investigations, as required by the regulatory authority, whenever:

- the individual annual effective dose exceeds investigation levels;
- any of the operational parameters subject to periodic quality control are out of the normal range established for operational conditions;
- any equipment failure, severe accident or error takes place, which causes, or has the potential to cause, a dose in excess of regulatory limits (e.g. radiation source fails to return to the shielded position); and
- any other event or unusual circumstance that causes, or has the potential to cause, a dose in excess of the regulatory limits or the operational restrictions imposed on the installation (e.g. the significant change in workload of personnel or operating conditions of irradiation equipment).

If overexposure occurs or is suspected, the dosimeters shall be immediately processed. These and all reported dosimeter overexposures and abnormal exposures shall be investigated by the licensee.

The investigation shall be initiated as soon as possible following the event, and a written report shall be prepared concerning its cause, and shall include determination or verification of any doses received, corrective or mitigating actions, and instructions or recommendations to avoid recurrence.

The report shall be submitted to all concerned parties and within the time frame required by the regulatory authority.

In addition, a direct reading dosimeter and an audible or alarming rate meter shall be carried by each qualified operator. Such devices are not a substitute for radiation survey meters.

4.3. Local rules and supervision

4.3.1. Local rules

The operational instructions shall be fully understood by the qualified operators and other relevant staff who may be occupationally exposed, and should, at least, include:

- a reminder of the nature of the hazards posed by the facility and the safety features used to minimize the risks;
- a reference to the existence and location of the written emergency procedures;

– a description of the safety organization, including the functions, duties and responsibilities of the qualified expert and radiation protection officers;
– the method of implementing the operating instructions and ensuring that the facility is being operated safely. This should include:
– a description and schedule of the inspections and test procedures for ensuring that all safety interlock devices and components associated with the irradiator are functioning properly. Each safety item and the appropriate test, check and inspection for it should be specified;
– the requirement that the operating procedures be available at the control station and that the emergency procedures be conspicuously posted in the area;
– the method of ensuring that all persons entering the controlled radiation area wear proper radiation monitoring devices and that the results are recorded;
– the method of ensuring that only qualified operators can use the irradiator or have access to the area. This can involve the use of controlling keys to the door of the room containing the irradiator control console, controlling operating console keys, or other positive methods for preventing access.

Written instructions shall also he provided covering action to be taken in the event of machine malfunction. These shall include a general outline of the action to be taken by people who are notified of a machine malfunction the correction of which may involve the source. Remedial action in situations involving work around the irradiator shall be attempted only by persons specifically trained in radiological safety who are authorized to perform such work, or under the direct or indirect supervision of such persons.

Entry into the irradiation room following remedial action should never be made by one person alone.

The safe operation of a facility will depend on the qualified operators following clearly defined procedures laid down by the manufacturer or supplier and approved by the regulatory authority. In addition to qualified operators, suitably trained and qualified persons will need to be employed by the licensee to undertake a range of duties, such as maintenance. The competence of these persons should be verified and work authorized by the radiation protection officer on behalf of the licensee.

4.3.2. Staff training

The licensee shall ensure that its employees engaged in work with ionizing radiation receive such information, instruction and training as will enable them to conduct the work in accordance with the requirements of the written safe operational procedures.

All persons who work with ionizing radiation shall be provided with sufficient information, instruction and training to enable them to understand the importance of restricting exposure and the specific work practices that should be followed. Examples of topics in which such personnel are trained include:

– the nature of ionizing radiation;
– the health hazards from exposure to such radiation;
– the basic principles and methods of protection (e.g. time, distance and shielding);
– measurement of radiation fields and the units of measurement;
– the warning signs and signals and any action to be taken; and
– action to be taken in emergencies.

Training shall be reinforced regularly and updated when necessary. Annual review of staff training needs shall be undertaken. Arrangements shall be made to ensure that all new staff receive the required training and that the training needs of staff affected by any internal reorganization are reviewed and effected.

The radiation protection officer and qualified expert shall provide advice on staff training needs and on how those needs may best be satisfied. In many cases, the radiation protection officer can provide much of the required training.

The training discussed above is in addition to what is required to operate the facility safely, which the licensee shall ensure is provided with the co-operation of the manufacturer or supplier.

The RPO requires a thorough knowledge of radiation protection with respect to practical and operational matters and regulatory and licensing conditions applicable to the facility.
Outlines for training programmes for RPOs and qualified operators are provided in Appendix III and IV. Further guidance is available in the Agency's documents listed as Refs. [5-6]
One important outcome of the training should be to make such persons alert to the simple actions they can take to minimize radiation exposure received by themselves and others.
Employees of outside contractors will also require information (and possibly on-site training). This information should include copies of relevant procedures for the facility.

4.3.3. Health surveillance

The BSS require the licensee to make arrangements as approved by the regulatory authority for appropriate health surveillance to be provided to assess the initial and continuing fitness of staff for their work with ionizing radiation, based on the general principles of occupational health.

No specific routine health surveillance related to exposure to ionizing radiation is necessary for staff involved in the operation of irradiation facilities.

4.3.3.1. Records

The licensee shall maintain exposure records for each worker and preserve them according to the requirements of the regulatory authority.

5. PUBLIC EXPOSURE

5.1. Responsibilities

The licensee is responsible for controlling public exposure resulting from sources used in practices.

Public exposure is controlled, in large part, by ensuring that radiation sources are properly shielded and secured, (e.g. located in a locked area, interlocks functional, keys to the control panel secured) to prevent unauthorized access or use.

5.2. Control of access to visitors

The licensee shall:

– make arrangements to control access of visitors to the radiation facility, and provide adequate information and instruction to these persons before they enter a controlled area so as to ensure appropriate protection (e.g. members of public shall be accompanied);

– ensure that adequate control over entry of visitors to a supervised area is maintained and that appropriate signs are posted in such areas.

5.3. Sources not in active use

The licensee shall :

(a) Notify the regulatory authority and submit a plan for transfer or disposal of the sources, if they are no longer in use.

5.4. Decommissioning and source disposal

At the end of the useful life of the irradiation facility, the licensee shall ensure that:

– buildings and equipment are free from contamination before disposal or resale;
– all radioactive sources are properly accounted for before returning them to the supplier or disposing of them in accordance with national regulations;
– any radioactive waste resulting from decontamination is disposed of in accordance with national regulations.

6. SAFE TRANSPORT OF RADIOACTIVE MATERIAL

The licensee shall comply with the requirements of the IAEA Regulations for the Safe Transport of Radioactive Material [8], any applicable international modal regulations (e.g. the Technical Instruction of the International Civil Aviation Organization or the International Maritime Dangerous Goods Code of the International Maritime Organization), and any existing national legislation and applicable national regulations for all activities involving transport of radioactive sources.

6.1. General requirements

The licensee shall ensure that local rules are available for all aspects of the transport of radioactive materials covered in this section.

> As there may be significant differences between shipments (different packages, routes and modes of transport), it must not be assumed that the same local rules are applicable in all cases. They should, therefore, be prepared and reviewed for each shipment.

Local rules for transport operations should include arrangements for ensuring the security of the consignment during breaks in the journey, such as rest and overnight stops, and contingency plans for dealing with all reasonably foreseeable incidents, such as traffic accidents.

6.2. Receipt of radioactive material

Prior to each shipment of radioactive material to be dispatched to the licensee, there shall be a detailed exchange of information with the source supplier. For each package or container this information shall include:

– the nuclide, activity and form of the radioactive material (special form or other than special form) of each source;
– a description of the source construction and performance tests, including leakage tests;
– special form approval certificate, where appropriate;

– a description of the transport packaging;
– a valid competent authority approval certificate for Type B package authorized for the specific contents, or statement of compliance with IAEA TS-R-1 (ST–1, Revised) if the source does not require a certified package;
– details of any special arrangements required, including multilateral approvals, where necessary; and
– a copy of the transport documents, to be sent to the licensee by fax or e-mail before dispatch if possible.

The licensee shall not agree to the dispatch of the consignment by the supplier unless satisfied that all the above items are satisfactory.

The supplier and licensee should agree on the transport route and responsibility for each stage of the journey. The supplier may choose to be responsible from the time of dispatch until the consignment reaches the point of entry to the country of the licensee, who shall then take responsibility for transport from that point until it reaches the irradiation facility. Other arrangements are satisfactory provided they are agreed on in advance by both parties and are also acceptable to the appropriate regulatory authority(ies).

Arrangements shall also be made, where necessary, for:
– special handling equipment (e.g. cranes, forklift trucks) during transfer from one mode of transport to another, or between conveyances;
– checking radiation dose rates from the package;
– checking that the packages are correctly marked and that correct transport labels are attached to the package, and replacing any that are damaged or illegible;
– ensuring that the package is securely attached to the conveyance and that, if transported by road or rail, the vehicle is correctly placarded;
– dealing with border controls and customs authorities; and
– security of the consignment during transport, particularly during delays or overnight stops.

6.3. Dispatch of radioactive material

The licensee shall be required to return the packagings used for the transport of the radioactive sources to the source supplier after receipt of a consignment of radioactive material. These packagings may be returned either as empty packagings if they free from contamination, as unloaded packages properly labelled and consigned, or as loaded packages containing spent radioactive sources.

6.3.1. Empty packagings

With regard to returning empty packages, the licensee shall:
– carry out dose-rate and contamination monitoring of both the inside and outside of the packaging to ensure that there is no residual radioactive material present and that it can therefore be treated as an empty package consistent with the dose rate and contamination requirements of the Regulations for empty packages;
– remove or cover all transport labels relating to the sources contained in the package when received;

– examine the package to ensure that it is in good condition, and that it is securely closed, referring to any procedures provided by the source supplier;
– attach a label to the outside of the package stating "UN 2908 RADIOACTIVE MATERIAL EXCEPTED PACKAGE — EMPTY PACKAGING";
– complete a transport document and;
– contact the source supplier, agree on the transport route and responsibility for each stage of the journey and inform the supplier of the proposed date of dispatch.

6.3.2. Unloaded packagings transported as radioactive material packages

With regard to returning unloaded packages other than as empty packages, the licensee shall:

– carry out dose-rate and contamination monitoring of both the inside and outside of the packaging to establish the activity contents of the residual radioactive material present and that the dose rate and contamination requirements of the Regulations are satisfied and the package category is properly established;
– replace previous transport labels with labels appropriate to any residual radioactive contamination contained in the package, with the appropriate UN number;
– the transport labels relating to the sources previously contained in the package should not be reused
– examine the package to ensure that it is in good condition, and that it is securely closed, referring to any procedures provided by the source supplier;
– complete a transport document and
– contact the source supplier, agree on the transport route and responsibility for each stage of the journey and inform the supplier of the proposed date of dispatch.

6.3.3. Return of spent or disused sources

With regard to returning spent or disused sources, the roles of licensee and source supplier are effectively reversed compared to the earlier section "Receipt of radioactive materials", but the requirements are essentially the same. The licensee shall provide information to the consignee for each package, including:

– the nuclide, activity and form of the radioactive material (special form or other than special form) of each source;
– a description of the source construction and performance tests, including leakage tests;
– special form approval certificate, where appropriate;
– a description of the transport packaging;
– a valid competent authority approval certificate for Type B package authorized for the specific contents, or statement of compliance with IAEA TS-R-1 (ST–1, Revised) if the source does not require a certified package;
– details of any special arrangements required, including multilateral approvals, where necessary; and
– a copy of the transport documents, to be sent to the licensee by fax or e-mail before dispatch if possible.

The licensee shall not dispatch the consignment unless confirmation has been received from the consignee of willingness to accept it.

The licensee and consignee should agree on the transport route and responsibility for each stage of the journey. The licensee may choose to be responsible from the time of dispatch until the consignment reaches the point of entry to the country of the consignee, who shall then take responsibility for transport from that point until it reaches the consignee's premises. Other arrangements are satisfactory provided they are agreed on in advance by both parties and are also acceptable to the appropriate regulatory authority(ies).

In order to prepare the consignment for dispatch, the licensee shall:

- load the sources into the packaging, verifying the details to be provided to the consignee (e.g. serial numbers) and to be entered on the transport document;
- close the packaging securely and then examine and test it to ensure that it is in good condition, referring to any procedures provided by the source supplier;
- carry out contamination monitoring of the outside of the package to ensure that there is no residual radioactive material present, the external contamination levels are in compliance with the limits established in the Regulations and that it is therefore suitable for transport;
- carry out dose-rate monitoring of the package, determine the category and attach appropriate transport labels. The transport labels relating to the sources contained in the package when received should not be reused; and
- complete a transport document.

Arrangements shall also be made, for:

- special handling equipment (e.g. cranes, forklift trucks) during transfer from one mode of transport to another, or between conveyance;
- ensuring that the package is securely attached to the conveyance and that the vehicle is correctly labelled;
- dealing with border controls and customs authorities; and security of the consignment during transport, particularly during delays or overnight stops.

6.3.3.1. General requirements

The licensee shall ensure that local rules are available for all aspects of the transport of radioactive materials covered in this section.

As there may be significant differences between shipments (different containers, routes and modes of transport), it must not be assumed that the same local rules are applicable in all cases. They should, therefore, be prepared and reviewed for each shipment.
Local rules for transport operations should include arrangements for ensuring the security of the consignment during breaks in the journey, such as rest and overnight stops, and contingency plans for dealing with all reasonably foreseeable incidents, such as traffic accidents.
It may be appropriate for the RPO to travel with the consignment whilst it remains the responsibility of the licensee.

6.4. Loading and unloading of sources

Operations involving handling, stowage and interim storage during transport may expose persons to dose rates in excess of those experienced in normal operation of the facility. A radiation protection programme consistent with the requirements of the IAEA Transport Regulations shall be established for the transport of these sources; and the programme documents shall be available, on request, for inspection by the relevant competent authority(ies). As part of the programme, the licensee shall make an evaluation of source

loading and unloading procedures to ensure that the exposure of persons is kept as low as reasonably achievable (ALARA).

The licensee shall make an assessment of any safety hazards associated with the handling, stowage and interim storage operations. Any necessary contingency plans should be incorporated into the written instructions for operation of the facility and, as appropriate, the operations of the carrier. It is imperative that the integrity of the safety control systems not be compromised by the source loading and unloading procedures and the handling, stowage and interim storage of the package. The unloading and handling of the radioactive sources on arrival at the facility or the loading, handling and stowage on dispatch from it are potentially hazardous operations and shall be undertaken under close radiation protection supervision. Safety in these operations depends on co-operation between those responsible for radiation protection and the team appointed to load or unload the radioactive source. In many cases this will be the supplier of the source. Ultimately, however, responsibility for safety while the radioactive source is on the site resides with the operating organization.

7. EMERGENCY PLANNING, PREPAREDNESS AND RESPONSE

Requirements for the safety of sources and facilities are set out in Section 3. This section focuses on identifying possible situations of emergency or accident, and preventing, preparing for and mitigating the consequences

7.1. Potential exposure

7.1.1. Safety assessment

In order to comply with BSS requirement IV.3, the licensee shall prepare a safety assessment applied to the stages of design, construction, operation, maintenance and decommissioning of the irradiation facility, and present it to the regulatory authority.

The assessment should be systematic and include information on the identification of reasonable foreseeable events that can lead to accidental exposure.

The safety assessment shall be documented and revised by an independent expert when:

- modification of a radiation source or its facility is made;
- operational experience or information on accidents or errors indicates that the safety assessment should be reviewed; and
- techniques are modified in such a way that safety may be compromised.

In order to ensure that the safety assessment is comprehensive, consideration should be given to using probabilistic safety assessment (PSA) techniques (e.g. ref. ICRP Publication No. 76, [16]).

7.1.1.1. Accident prevention and mitigation

The licensee shall incorporate:

- defence-in-depth measures to cope with identified events, and evaluate the reliability of the safety systems (including administrative and operational procedures, and equipment and facility design);

– the operational experience and lessons learned from accidents and errors in the training, maintenance and quality assurance programmes.

7.1.1.2. Emergency plans

On the basis of the events identified by the safety assessment, the licensee should elaborate mitigation measures to be incorporated into a set of emergency procedures.

The procedures should be succinct, unambiguous and posted visibly in the places where their need is anticipated. The procedures should identify the responsibilities of individuals and be practised with sufficient frequency to ensure efficiency.

7.1.2. Emergency planning

The licensee shall make an assessment of the consequences of any reasonably foreseeable accident, occurrence or incident and shall draw up a contingency plan to restrict, so far as is reasonably achievable, any resulting exposures.

The contingency plan shall be specific to each situation and should include, as appropriate:

– identification of the reasonably foreseeable accidents, incidents or occurrences and their predicted consequences;
– communication procedures, including an emergency call-out list;
– recommended actions for specified situations; including the identification of persons able to implement and take responsibility for stated parts of the plan, and positive identification of situations requiring evacuation together with the procedures for implementation;
– a statement regarding immediate life-saving actions;
– statutory responsibilities and the names of persons able to take actions to satisfy them;
– availability of emergency equipment, including a list of the equipment that should be available, and its location;
– availability of first aid equipment, including a list of the equipment that should be available its location, and the names of persons trained to use it (where applicable); and
– where appropriate, an outline of the post-emergency procedures designed to restore normal operating conditions.

Emergency procedures shall be described in concise, easily followed instructions. They shall identify situations requiring emergency action, specify the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator, and foresee the development of a written contingency plan for effecting entry to the irradiation room.

The licensee shall inform staff of any contingency plan that might affect their area of work, and their role if the plan has to be implemented, and shall arrange for staff training and emergency drills appropriate to each situation. Training shall include the review of lessons learned from previous accidents most relevant to the practice.

The licensee shall review the contingency plan at appropriate intervals, normally not exceeding 12 months. The frequency and depth of such reviews shall be related to the

potential consequences of the identified emergency situations. Plans shall always be reviewed following relevant operational changes and after an accident in similar facilities and with similar sources.

Emergency and first aid equipment shall be provided by the licensee. They shall be inventoried regularly and tested for good working order at appropriate intervals. Inoperative or outdated items should be removed, and repaired or replaced without delay.

Liaison shall be maintained with relevant off-site services or agencies, as appropriate to each accident situation. These will include ambulance, fire, police, hospital services, local and national authorities. In the event of an accident, it is the duty of the licensee to initiate the emergency procedures, and co-ordinate the initial response of the emergency services and other bodies, and inform the regulatory authority and all relevant parties.

The emergency response plan shall cover the most likely events leading to significant radiation exposure and/or contamination. These include:

– a jammed source with the source assembly failing to return to its shielded position;
– part of the source assembly detached and left in an unshielded position;
– malfunction or deliberate defeat of the safety control system;
– leakage of the source; and
– fire inside the shielded room.

The plan shall contain names and telephone numbers of the next responsible officers to be contacted. Notices shall be posted inside the facility, showing:

– how to contact the RPO or an alternative person, who should be notified immediately of any emergency;
– how to call the fire brigade and medical services; and
– where to find emergency equipment.

Emergency equipment shall be kept in a clearly labelled cabinet in a readily accessible place. A list of the emergency equipment shall be affixed to the cabinet so that checks can be made periodically and immediately after use to ensure that all items are present or replaced as necessary.

Practical exercises shall be used to test the effectiveness of emergency response plans and to ensure that all persons concerned know what action to take in an emergency. Mock or low-activity sources should be used during training exercises

7.2. Accident response

In responding to an accident, the licensee shall:

– limit radiation exposure, both individual and collective;
– regain control of the situation in order to restore the site to its normal condition; and
– treat the injured and overexposed.

For accidents involving gamma sources, the licensee shall consider the possibility of contamination. Urgent actions would include:

– evacuating the area containing the hazard;

– warning persons in the immediate vicinity of the accident;
– rendering first aid to any injured persons;
– notifying the RPO;
– evaluating the cause and extent of the hazard; and
– setting up appropriate barriers and notices to secure the area against unauthorized re-entry.

For accidents caused by loss of shielding or through failure of the source transport mechanism, the licensee shall take action to protect workers and public. This will include:
– constructing temporary shielding;
– evacuating the immediate area;
– erecting barriers to restrict access; and
– recovering the source, undertaken in accordance with pre planned procedures which take into consideration the doses likely to be incurred.

7.3. Accidents in transportation

In the event that a consignment of radioactive sources is involved in a transport accident, it is likely that the consignor and the consignee will be among the first to be informed, because the documentation accompanying the vehicle will contain their names and addresses. Both organizations should be fully aware of the arrangements for dealing with such accidents and, where appropriate, should provide or call their regulatory authority for advice and assistance. It should be recognized that information about the accident may be required by the press and the public in general, and arrangements should be made for handling such inquiries.

Reference [14] gives guidance and recommendations for dealing with transport accidents and should be used as a guide in the preparation of the relevant parts of the contingency plan. The most relevant sections for the purposes of the present publication are as follows: Section II summarizes the transport regulations; Section III outlines the requirements for emergency plans; Section V describes the actions required in response to a transport accident and allocates the responsibility for such actions; Section VIII draws attention to the need to provide accurate and authoritative information to the public.

7.4. Accident reports

Any accident must be reported to the regulatory authority according to a time schedule to be specified in the licensee, depending on the severity of the incident.

Accident reports shall be evaluated by the competent authority so that lessons can be learned and, if necessary, improvements made to safety at all existing facilities. Special attention shall be given to precursor events that have the potential to lead to more severe incidents.

Guidance on emergency planning and preparedness is given in Refs. [14,15]. Appendix IX gives some general advice regarding remedial actions for accidents involving leaking sources, high radiation levels and exposure to personnel. The role of IAEA assistance with accidents is also discussed.

Appendix I

SCHEMATIC DIAGRAMS OF CATEGORY I , II, III AND IV GAMMA IRRADIATORS AND CATEGORY I AND II ELECTRON BEAM IRRADIATORS

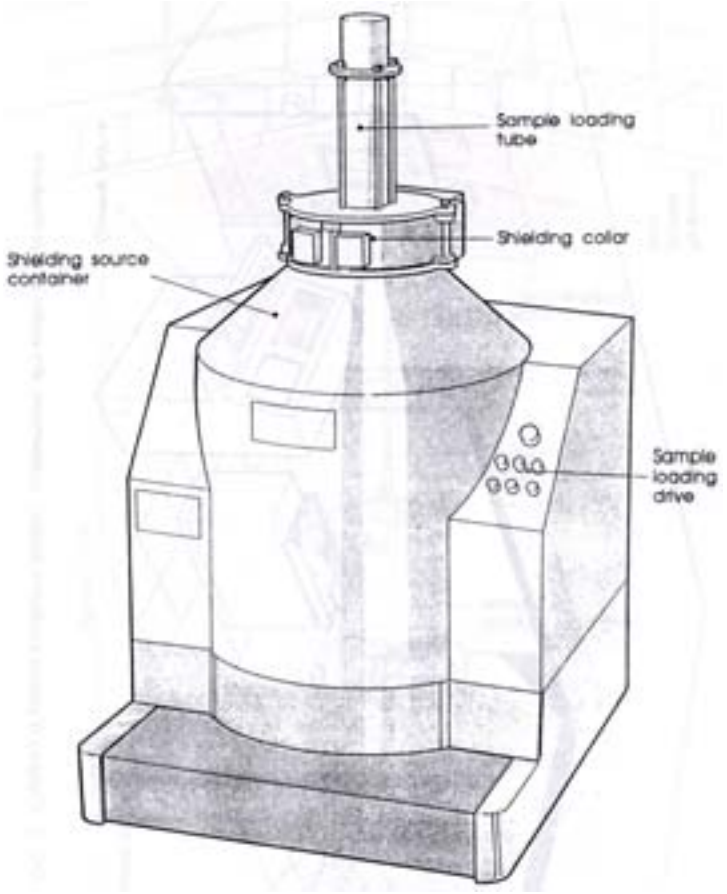

FIG. 1. Category I gamma irradiation facility: a self-contained, dry source storage irradiator.

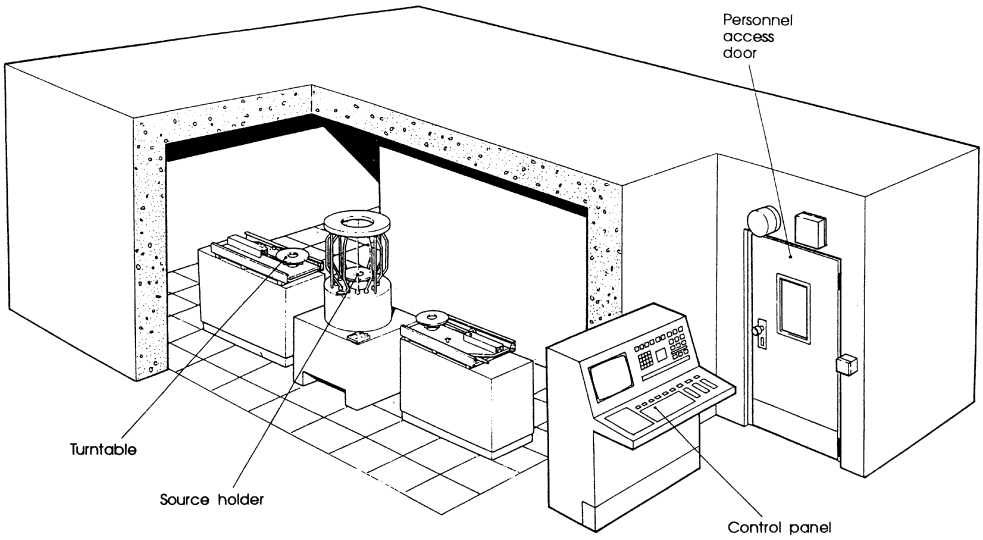

FIG. 2. Category II gamma irradiation facility: a panoramic, dry source storage irradiator.

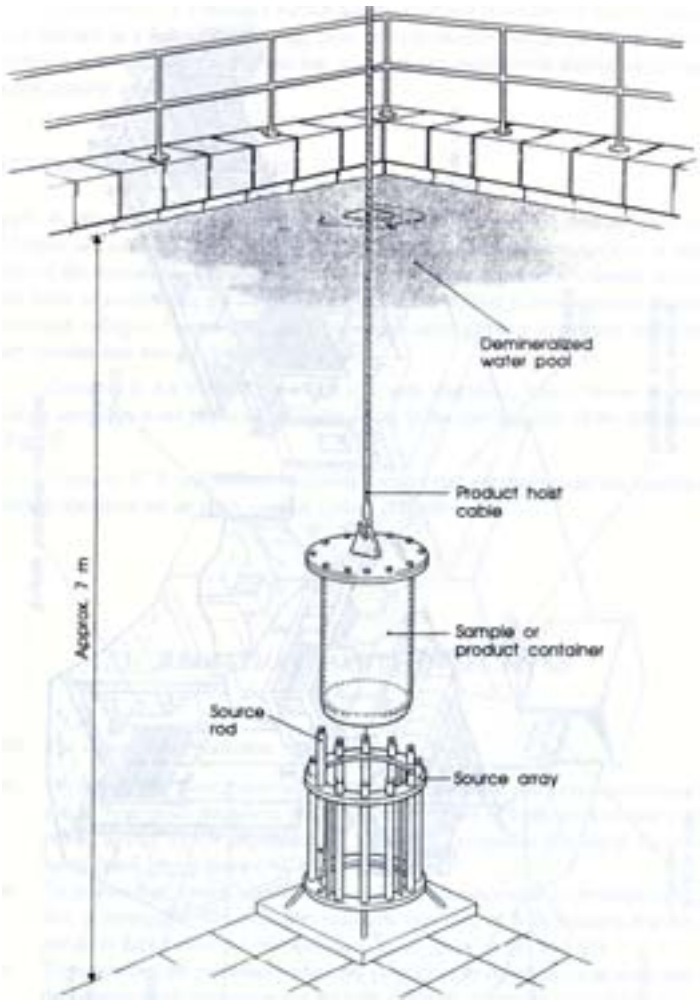

FIG. 3. Category III gamma irradiation facility: a self-contained, wet source storage irradiator.

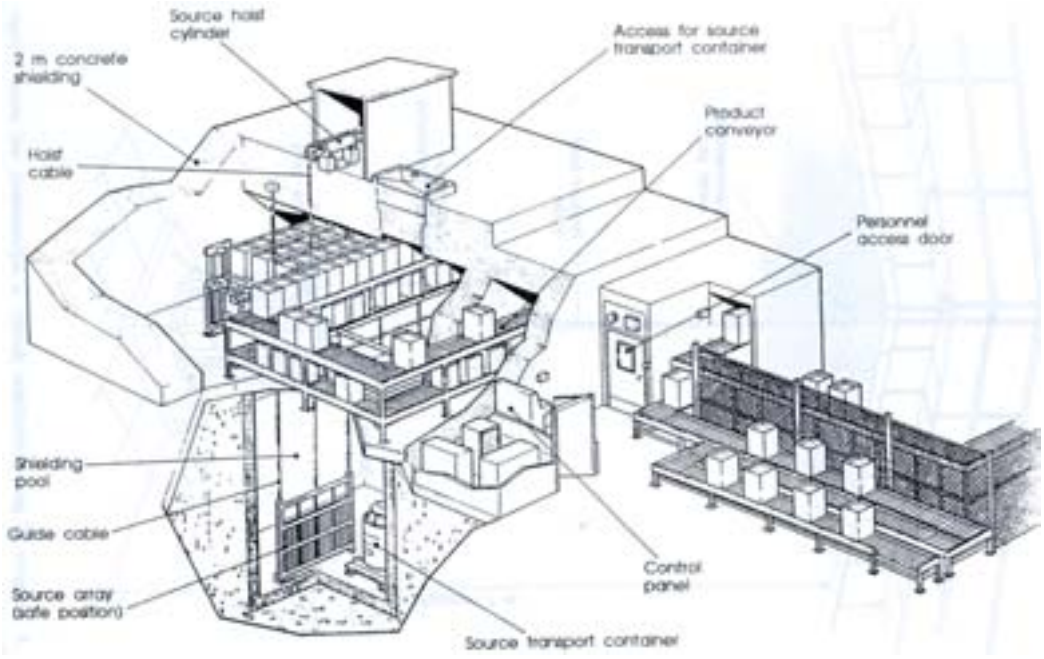

FIG. 4. Category IV gamma irradiation facility: a panoramic, wet source storage irradiator.

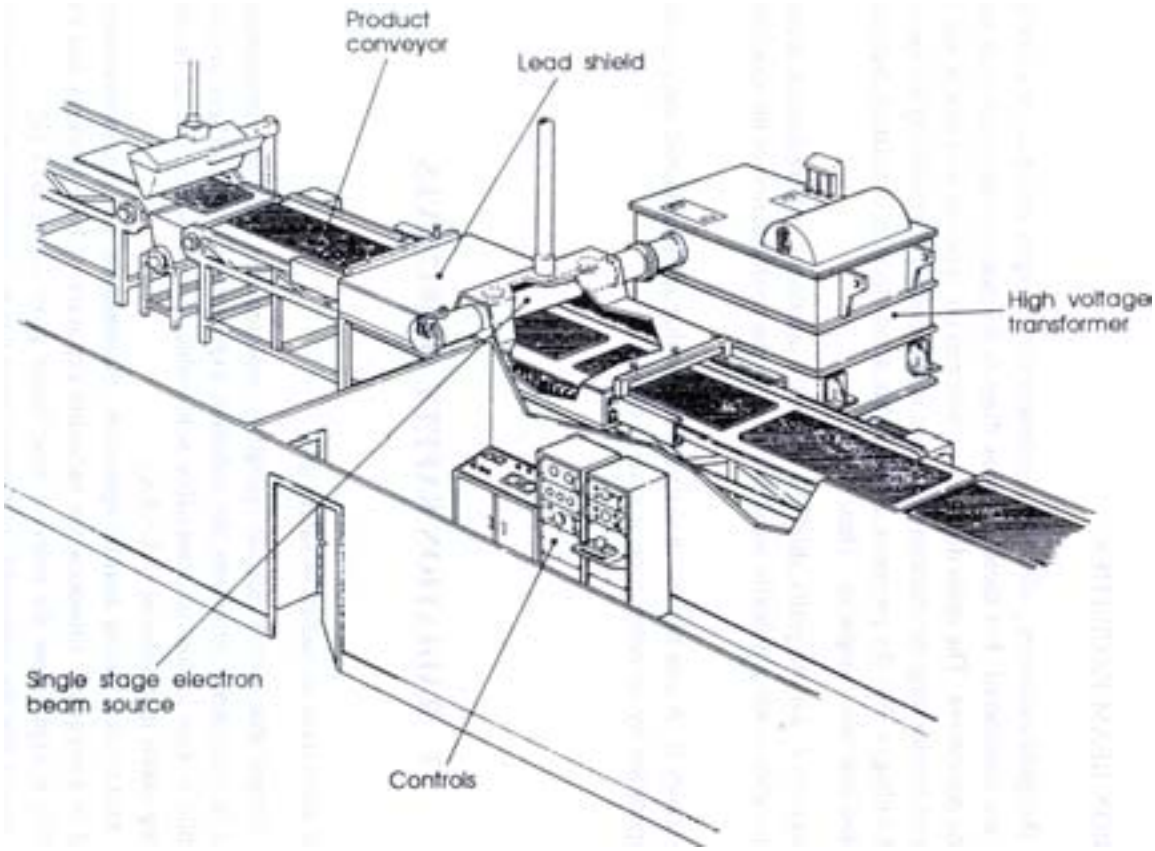

FIG. 5. Category I electron beam facility: an integrally shielded unit with interlocks.

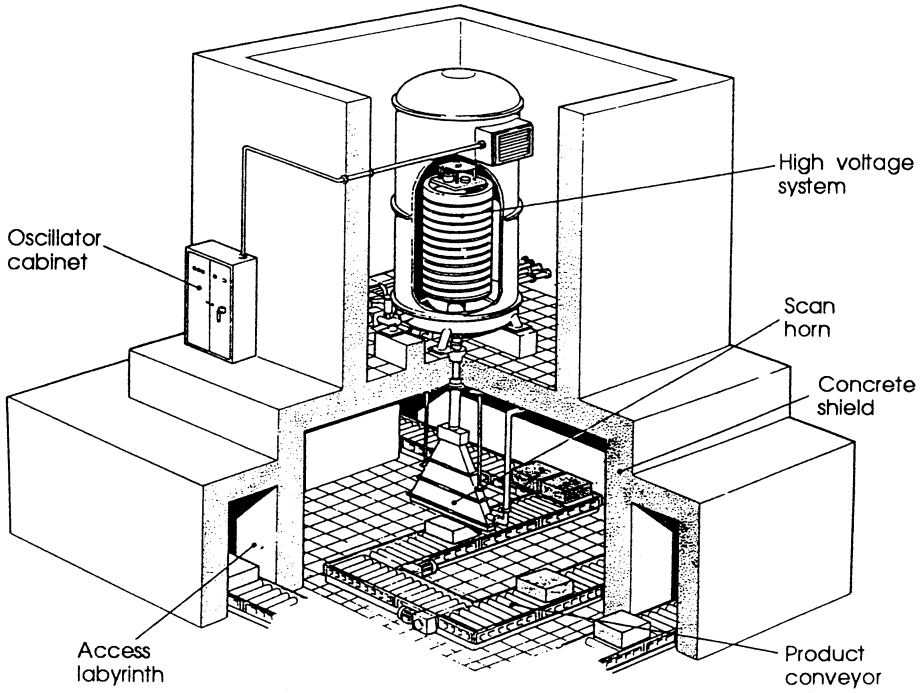

FIG. 6. Category II electron beam facility: a unit housed in shielded rooms maintained inaccessible during the irradiation process.

Appendix II

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR A GAMMA IRRADIATOR FACILITY

TYPE OF AUTHORIZATION

New application
Amendment to existing authorization number: _____
Renewal of authorization number: _____

PURPOSE OF APPLICATION

Construction (Complete Sections I through III)
Import/Purchase (Complete Sections I and II)
Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s).

The legal person who will be responsible for using any sealed source or radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I–GENERAL INFORMATION

I–1. Name and address of organization:

Main address	Mailing address (if different)	Address of use (if different)
Tel., Fax, e-mail	Tel., Fax, e-mail	Tel., Fax, e-mail

I–2. Qualified experts:

Expertise: Radiation protection officer (RPO) Name:	Expertise: Name:
Degree:	Degree:
Certification:	Certification:
Experience:	Experience:
Address, Telephone, Fax, e-mail:	Address, Telephone, Fax, e-mail:
Expertise: Name:	Expertise: Name:
Degree:	Degree:
Certification:	Certification:
Expérience:	Experience:
Address, Telephone, Fax, e-mail:	Address, Telephone, Fax, e-mail:

I–3. The responsible representative of the legal person:

Name:	Telephone number:
Title:	Fax number:
	e-mail address:

I–4. Proposed date of installation and/or commissioning of facilities and equipment:

Date of installation/commissioning	Facilities/equipment

SIGNATURE AND CERTIFICATION

Signature of the authorized representative of the legal person
Title:
Date:

Notes:

1. The regulatory authority may require additional information in order to fully consider this application prior to issuing an authorization.

2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization allowing the applicant only to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorizing use of the radiation sources.

II–SOURCES AND IRRADIATOR

II–1. Model/Type and identification number of irradiator

Model	Type	Identification number of irradiator

II–2. Name and address of:

a) manufacturer of the irradiator	Address
b) supplier of the irradiator (if different from a))	

II–3. Name and address of:

a) manufacturer of the sources	Address
b) supplier of the sources (if different from a))	

Details of radioactive sources:

Radionuclides	Number of sources				Total activity (Bq)		Source details		Storage (wet/dry)
	per pencil	per module	per rack	Total	Initial	At installation	Model no(s).	Designation	

II–4. Standards

Are the sources manufactured, prototype tested, and subject to quality control provisions of standards recognized by national or international standard setting organizations (e.g. ISO 2919)? If so, identify the standards and any applicable classification numbers.

III–FACILITIES AND EQUIPMENT

In an attachment to this application, describe the irradiator facilities, including:

III–1. Location of the facility

Provide full address of location of the facility.

III–2. Layout of the facility

Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, engineering controls such as interlock and warning safety devices, and remote handling tools See Ref. (5). Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials, such as conduits or ventilation ducts. Include evaluation of the ground surface and adverse environmental conditions that may cause harm to the facility (e.g. seismic history, strong winds, air crashes). Controlled and supervised areas should be clearly identified on the drawings.

III–3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions, e.g. number of sources, activity). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

III–4. Safety system

a) Describe the overall safety system which will be used to ensure the safe operation of the irradiator (e.g. design features, defence in depth, layout). Further describe, in detail, the safety systems for preventing access to the irradiation room whilst the source is exposed and for warning of unsafe conditions (e.g. interlocks, installed monitors).

b) Attach the manufacturer's specifications of those systems [5].

III–5. Personal protective equipment

Describe any personal protective equipment that will be provided:

IV–RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the radiation protection programme, including:

IV–1. Organizational structure

a) Describe your organizational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular, include staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and means of identifying and correcting problems affecting safety.

b) Identify the authorized users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorized user and/or radiation protection officer may be the same individual).

c) Confirm that training will include explanations of radiation hazards and effects, of written procedures, of use of equipment (e.g. instrumentation), and of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV–2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37–I.40), including the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.

b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21–I.25).

c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32–I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken if doses are exceeded.

Name and address of dosimetry service:

_____

_____

_____

Denote type:

i) film _____

ii) thermoluminescent dosimeter (TLD) _____

iii) direct reading dosimeter (DRD) _____

iv) other: _____

IV–3. Local rules and supervision

a) Describe your local rules and procedures regarding investigation or authorized levels, protective measures and safety provisions, providing adequate supervision, providing workers with information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26–I.27).

b) Provide copies of your operating and safety procedures, including area access control, entry procedures, product entry and exit, source inventory and leak testing.

c) Describe your training programme to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety (BSS, I.27).

d) Describe your policies regarding workers who become pregnant (notification, adaptation of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16–I.17 and I.27).

e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41–I.43).

IV–4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.

b) Describe your programme for periodically reviewing procedures, keeping them current and available, and modifying them.

c) Describe your programme for optimizing occupational and public exposures to levels as low as reasonably achievable.

d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, hoist cable and guide cable, etc.). Attach the manufacturer's instructions.

e) Describe service arrangements with other organizations and qualified experts.

IV–5. Transportation of radioactive material

If you will be transporting or shipping new or used sources, describe your arrangements for preparation and transport of packages containing radioactive sources (Ref.[8]). These procedures should address documentation of package certification, package surveys, transfer/receipt documents, and details of shipments preparation.

IV–6. Emergency procedures

Provide your procedures for emergencies such as potential damage to the source, loss of source shielding, stuck sources or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases, the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV–7. Transfer or disposal of radioactive sources

Describe arrangements for transfer or disposal of spent radioactive sources.

IV–8. System of records (BSS; 2.40, I.44–I.49)**, including:**

I. Disposal of spent sources.
II. Personnel exposure:
    (a) current records;
    (b) prior work history.
III. Area surveys:
    (a) dose or dose rate;
    (b) contamination.
IV. Instrument tests and calibrations.
V. Tests for radioactive sealed source leakage.
VI. Inventory of sources and accountability.
VII. Audits and reviews of radiation safety programme.
VIII. Incident and accident investigation reports.
IX. Maintenance and repair work.
X. Facility modifications.
XI. Training provided.
XII. Evidence of health surveillance of workers.
XIII. Transportation.

APPLICATION FOR AUTHORIZATION AND REVIEW PLAN FOR AN ELECTRON IRRADIATOR FACILITY

TYPE OF AUTHORIZATION

- ✪ New application
- ✪ Amendment to existing authorization number: _____
- ✪ Renewal of authorization number: _____

PURPOSE OF APPLICATION

- ✪ Construction (Complete Sections I through III)
- ✪ Import/Purchase (Complete Sections I and II)
- ✪ Use/Begin operation (Complete Sections I through IV)

You may refer to previous submissions by date and application or authorization number(s).

The legal person who will be responsible for using any radiation generator must, unless the source is exempted, submit the following information to the regulatory authority.

I–GENERAL INFORMATION

I–1. Name and address of organization:

Main address Tel., Fax, e-mail	Mailing address (if different) Tel., Fax, e-mail	Address of use (if different) Tel., Fax, e-mail

I–2. Name and information about qualified experts:

Qualified experts:

Expertise: Radiation protection officer (RPO) Name:	Expertise: Name:
Degree:	Degree:
Certification:	Certification:
Experience:	Experience:
Address, Telephone, Fax, e-mail:	Address, Telephone, Fax, e-mail:

Expertise: Name:	Expertise: Name:
Degree:	Degree:
Certification:	Certification:
Experience:	Experience:
Address, Telephone, Fax, e-mail:	Address, Telephone, Fax, e-mail:

I–3. The responsible representative of the legal person:

Name:	Telephone number:
Title:	Facsimile number:
	e-mail address:

I–4. Proposed date of installation and/or commissioning of facilities and equipment:

Date of installation/commissioning	Facilities/equipment

SIGNATURE AND CERTIFICATION

Signature of the authorized representative of the legal person

Title:

Date:

Notes:

1. The regulatory authority may require additional information in order to fully consider this application prior to issuing an authorization.
2. In the event that all the above information is not available at the time of application, the regulatory authority may issue an authorization allowing the applicant only to import, acquire, or store radiation sources, or construct facilities. Complete information will be required from the applicant prior to authorizing use of the radiation sources.

II–ACCELERATOR

II–1. Model/Type and identification number of accelerator

Model	Type	Identification number of irradiator

II–2. Name and address of:

a) manufacturer of the accelerator	Address
b) supplier of the accelerator (if different from a))	

II–3. Details of the accelerator:

a) Maximum energy and type of radiation to be generated: _____

b) Voltage: _____

c) Current: _____

II–4. Standards

Is the accelerator manufactured, prototype tested, and subject to quality control provisions of standards recognized by national or international standard setting organizations (e.g. IEC 976, IEC 977)? If, so please identify the standards and any applicable classification numbers.

_____

_____

III–FACILITIES AND EQUIPMENT

In an attachment to this application, describe the accelerator facilities, including:

III–1. Location of the facility

Provide full address of location of the facility.

III–2. Layout of the facility

Describe factors such as the layout of the facility and its immediate surroundings, building materials, alarms, shielding, and engineering controls such as interlock and warning safety devices (Safety Series No. 107, Ref. [5]). Attach a detailed sketch or drawing of the facility showing the above details. Include on the drawings any penetrations or openings in the shielding materials such as conduits or ventilation ducts, and clearly identify controlled and supervised areas.

III–3. Safety assessments

Taking account of shielding, provide calculations of maximum dose rates in all areas outside the facility (specify all assumptions, e.g. energy, electron flux). Provide estimates of the magnitude of expected doses to persons during normal operations. Identify the probability and magnitude of potential exposures arising from accidents or incidents.

III–4. Safety system

a) Describe the overall safety system which will be used to ensure the safe operation of the irradiator (e.g. design features, defence in depth, layout). Further describe, in detail, the safety systems for preventing access to the irradiation room whilst radiation is being generated and for warning of unsafe conditions (e.g. interlocks, installed monitors).

b) Attach the manufacturer's specifications of those systems (Safety Series No. 107 Ref. [5]).

III–5. Personal protective equipment

Describe any personal protective equipment that will be provided.

IV–RADIATION PROTECTION AND SAFETY PROGRAMME

In an attachment to this application, describe the irradiator facilities, including:

IV–1. Organizational structure

a) Describe your organizational and management control systems, including assignment of responsibilities and clear lines of authority related to radiation safety. In particular, include staffing levels, equipment selection, other assignments of the radiation protection officer, authority of the radiation protection officer to stop unsafe operations, personnel training, maintenance of records, and means of identifying and correcting problems affecting safety.

b) Identify the authorized users, qualified experts, and radiation protection officer by name and include their training, education, experience and qualifications. (Note: the authorized user and/or radiation protection officer may be the same individual).

c) Confirm that training will include explanations of radiation hazards and effects, of written procedures, of use of equipment (e.g. instrumentation), and of warning signals, and a method to confirm adequacy of training (testing or demonstrations).

IV–2. Workplace monitoring, area classification and individual monitoring

a) Describe your programme for monitoring the workplace (BSS, I.37–I.40), including the quantities to be measured, where and when the measurements are to be made, the measurement methods and procedures, and reference levels and the actions to be taken if they are exceeded.

b) Describe your policies and procedures for classification of controlled and supervised areas. (BSS, I.21–I.25).

c) Describe personal dosimeters provided to workers and your policies for assigning dosimetry to individual workers (BSS, I.32–I.36). Describe your policy for reviewing individual doses, including reference levels and actions to be taken if doses are exceeded.

Name and address of dosimetry service:

_____

_____

_____

Denote type:

i) film _____

ii) thermoluminescent dosimeter (TLD) _____

iii) direct reading dosimeter (DRD) _____

iv) other: _____

IV–3. Local rules and supervision

a) Describe your local rules and procedures regarding investigation or authorized levels, protective measures and safety provisions, providing adequate supervision, providing workers with information regarding health risks due to occupational exposure, and emergency planning instruction (BSS, I.26–I.27).

b) Provide copies of your operating and safety procedures including area access control, entry procedures, and product entry and exit.

c) Describe your training programme to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety (BSS, I.27).

d) Describe your policies regarding workers who become pregnant (notification, adaptation of working conditions to protect foetus/embryo) and the instructions you will provide to them (BSS, I.16–I.17 and I.27).

e) Describe your programme of health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks (BSS, I.41–I.43).

IV–4. Quality assurance

a) Describe your programme for ensuring that regulatory radiation safety requirements are addressed and satisfied.

b) Describe your programme for periodically reviewing procedures, keeping them current and available, and modifying them.

c) Describe your programme for optimizing occupational and public exposures to levels as low as reasonably achievable.

d) Describe your programme of periodic maintenance and testing (safety interlocks, radiation meters, hoist cable and guide cable, etc.). Attach the manufacturer's instructions.

e) Describe service arrangements with other organizations and qualified experts.

IV–5. Emergency procedures

Provide your procedures for emergencies such as potential damage to the safety control systems, loss of shielding, or substantial accidental exposure of an individual. If other emergencies are envisaged, please provide additional appropriate emergency procedures. In all cases, the magnitude of the hazard should be evaluated. Any off-site consequences should also be evaluated. Local emergency services (e.g. fire, police) may need to be provided with copies of the emergency procedures.

IV–6. System of records (BSS; 2.40, I.44–I.49)**, including:**

I. Personnel exposure:
   (a) current records;
   (b) prior work history.
II. Area surveys (dose or dose rate).
III. Instrument tests and calibrations.
IV. Audits and reviews of radiation safety programme.
V. Incident and accident investigation reports.
VI. Maintenance and repair work.
VII. Facility modifications.
VIII. Training provided.
IX. Evidence of health surveillance of workers.

Appendix III

EXAMPLE OF A TRAINING PROGRAMME: THE RPO

Module 1 — Basic radiation physics

1. Atomic and nuclear structure.
2. Types and properties of radiation (including interaction with matter).
3. Activity half-life and decay.
4. Shielding:
   - Attenuation in shielding materials;
   - Half, tenth, value layers.
5. Production of X rays.

Module 2 — Biological effects of radiation

1. Genetic effects.
2. Somatic effects.
3. Deterministic and stochastic effects.
4. Mutations and radiocarcinogenesis.
5. Linear dose theory.
6. Threshold dose effect theory.
7. ALARA.

Module 3 — Design considerations

1. Activation of Co–59 to Co–60.
2. Source decay and the need for source replenishment:
   - Design of source rack to allow space for decay.
3. Considerations for design of shield:
   - Maze design to account for scattered radiation;
   - Gamma heating in capsule/ product/ shield;
   - Access requirements for source replenishment.

Module 4 — Radiation quantities and units

1. Absorbed dose.
2. Equivalent dose.
3. Committed equivalent dose.
4. Committed effective dose.
5. Collective equivalent dose and collective effective dose.
6. Dose commitment.
7. Background radiation levels.

Module 5 — Design of industrial irradiators

Field visit (1/2 day to 1 day)

1. Principle of defence-in-depth.
2. Description and illustrations of equipment, design safety systems, including:
   - Safe operating procedures, e.g. search and lock-up, testing of monitors, and other equipment prior to start-up;
   - Normal control indicators;
   - Fault indicators resulting from automatic shut down of equipment when faults are detected;
   - Requirements for periodic testing of safety interlocks;
   - Maintenance requirements.
3. Categories of non medical irradiation facilities:
   - Gamma I to IV;
   - Electron beam I and II.

Module 6 — Principles of radiation protection

1. The system of radiation protection.
2. Radiation protection requirements:
    - Justification of practices;
    - Dose limitation;
    - Optimization of protection and safety;
    - ICRP recommended dose limits.
3. Potential exposure and risk limits (Just a paragraph).
4. Control of radiation hazards:
    - Time/ distance/ shielding
5. Control of contamination hazards
6. Individual and workplace monitoring.
7. Designation of control areas.

Module 7 — Detection, measurement and control of radiation

1. Basic types of radiation measuring instruments.
2. Portable dose rate meters used to:
    - carry out surveys;
    - carry during entry to irradiation room;
    - monitor around transport packages
3. Installed dose rate meters for:
    - monitoring if it is safe to enter the irradiation room;
    - detecting that no source activity is being moved out by product conveyer;
    - detecting that no leakage from sealed sources is in the pool water or ventilation system.
4. Personal dosimeters.
5. Testing of radiation measuring equipment.
6. Use of dose-rate measuring equipment.
7. Use of personal dosimeters.
8. Accident dosimetry.
9. Calibration of equipment

Module 8 — Radiation safety standards and regulatory requirements

1. Overview of BSS and legislative structure.
2. Overview of practice specific regulations (Code of Practice).
3. Responsibilities:
    - Regulatory authority;
    - Operating organization;
        - Radiation protection advisers;
        - Radiation protection officer;
        - Qualified operator;
        - Staff training.
4. Designers and manufacturers.
5. Importers and suppliers.
6. Constructors and installers.
7. Co-operation.
8. Typical failures and non-compliances.
9. Potential consequences of failures and non-compliances.
10. Approval process:
    - Stages of the approval process;
    - Requirements of the applicant;
    - Existing facilities.
11. Regulatory inspections:
    - Inspection functions.

12. Enforcement:
    - Written warning or directive;
    - Order to curtail activities;
    - Revocation of approval.
13. Feedback of information that may have implications for protection or safety.
14. Regulatory requirements for investigation and follow-up.
15. Requirements for accountability for sources.
16. Decommissioning.
17. Public protection.

Module 9 — Management Requirements

1. Requirements for notification and authorization for sources.
2. Quality assurance programme for actions, procedures and records required by the BSS.
3. Policies and procedures to ensure a good safety culture is established and maintained.
4. Written procedures for all important aspects of operation and maintenance of the equipment.
5. Qualified experts.
6. Staff training regarding their responsibilities and work practices, requirements and responsibilities for security of sources.

Module 10 — Safety assessment plans for authorization and inspection of radiation sources

1. Discussion of IAEA-TECDOC-1113.
2. Exercises on completion and assessment of application for authorization of an irradiation facility.

Module 11 — Potential exposures (including hazard analysis)

1. Brief discussion of ICRP No. 76 [16] as it applies to irradiators i.e. probability of death = 1.
2. Example of irradiator from ICRP No. 76.
3. Methods of hazard analysis:
    - Fault Mode Event Analysis (FMEA);
    - Event tree;
    - Fault tree.
4. Some examples.

Module 12 — Transport of radioactive materials

1. Introduction and overview of IAEA ST–1 [8] Regulations for the Safe Transport of Radioactive Materials.
2. Package types:
    - Excepted;
    - Type A;
    - Type B.
3. Documentation:
    - Special form sources;
    - Transport documents.
4. Package labelling:
    - Transport index;
    - Category I, II and III labels.

Module 13 — Emergency planning for irradiators

1. Emergency plans:
    - Requirements for plans;
    - Requirements for written procedures;
    - Example of a typical emergency plan;
    - Review and updating;
    - Rehearsal.

2. Equipment required.
3. Supplier assistance and equipment available for detection and removal of leaking sources, etc.
4. Requirements to notify regulatory authorities.
5. Periodic training of staff on review of accidents with similar equipment and lessons learned.

Module 14 — Accident case histories and lessons learned

1. The radiological accident in San Salvador, IAEA 1990.
2. The radiological accident in Soreq, IAEA 1993.
3. The radiological accident at the irradiation facility in Nesvizh, IAEA 1996.
4. An electron accelerator accident in Hanoi, Vietnam, IAEA 1996.
5. The Radiological Accident in Goiânia**,** IAEA 1988

Appendix IV

DOSE LIMITS FOR OCCUPATIONAL AND PUBLIC EXPOSURE

The following is reproduced from the BSS.

OCCUPATION AL EXPOSURE

Dose limits

II-5. The occupational exposure of any worker shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 20 mSv per year averaged over five consecutive years[4];
(b) an effective dose of 50 mSv in any single year;
(c) an equivalent dose to the lens of the eye of 150 mSv in a year; and
(d) an equivalent dose to the extremities (hands and feet) or the skin[5] of 500 mSv in a year.

II-6. For apprentices of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of age 16 to 18 who are required to use sources in the course of their studies, the occupational exposure shall be so controlled that the following limits be not exceeded:

(a) an effective dose of 6 mSv in a year;
(b) an equivalent dose to the lens of the eye of 50 mSv in a year; and
(c) an equivalent dose to the extremities or the skin[39?] of 150 mSv in a year.

Special circumstances

II-7. When, in special circumstances[6], a temporary change in the dose limitation requirements is approved pursuant to Appendix I:

(a) the dose averaging period mentioned in para. (II.5)(a) may exceptionally be up to 10 consecutive years as specified by the regulatory authority, and the effective dose for any worker shall not exceed 20 mSv per year averaged over this period and shall not exceed 50 mSv in any single year, and the circumstances shall be reviewed when the dose accumulated by any worker since the start of the extended averaging period reaches 100 mSv; or
(b) the temporary change in the dose limitation shall be as specified by the regulatory authority but shall not exceed 50 mSv in any year and the period of the temporary change shall not exceed 5 years.

PUBLIC EXPOSURE

Dose limits

II-8. The estimated average doses to the relevant critical groups of members of the public that are attributable to practices shall not exceed the following limits:

(a) an effective dose of 1 mSv in a year;
(b) in special circumstances, an effective dose of up to 5 mSv in a single year provided that the average dose over five consecutive years does not exceed 1 mSv per year;
(c) an equivalent dose to the lens of the eye of 15 mSv in a year; and
(d) an equivalent dose to the skin of 50 mSv in a year.

---

4 The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of the Standards, with no retroactive averaging.

5 The equivalent dose limits for the skin apply to the average dose over 1 cm^2 of the most highly irradiated area of the skin. Skin dose also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.

6 See Appendix I: the provisions for `alternative employment' set out in para. 418 may be relevant.

Dose limitation for comforters and visitors of patients

II-9. The dose limits set out in this part shall not apply to comforters of patients, i.e. to individuals knowingly exposed while voluntarily helping (other than in their employment or occupation) in the care, support and comfort of patients undergoing medical diagnosis or treatment, or to visitors of such patients. However, the dose of any such comforter or visitor of patients shall be constrained so that it is unlikely that his or her dose will exceed 5 mSv during the period of a patient's diagnostic examination or treatment. The dose to children visiting patients who have ingested radioactive materials should be similarly constrained to less than 1 mSv."

Appendix V

ROUTINE CHECKS TO BE CARRIED OUT BY THE RPO

The frequency with which these checks should be undertaken will depend upon the nature of the facility, its age and previous operating experience. Some, such as the checking of certain records, are linked to the frequency of the tests to which the records relate e.g. leakage test records. Routine checking of the correct operation of warning and safety systems should take place at regular intervals, usually weekly or monthly.

Checks that the operators are wearing dosimeters and correctly following local rules and procedures should be at irregular intervals and not announced in advance to the operators.

1. **Documentation**

Training record of new staff
Irradiator log book Note and follow up items with radiological protection implications
Individual monitoring records
Workplace monitoring records
Radiation monitoring instrument test records
Leakage test records
Check availability of local rules and procedures

2. **Monitors**

Hand held monitor available, battery Ok.?
Check source present and giving correct reading.
Installed monitors: position 1
position 2, etc.

3. **Safety systems (as fitted)**

Interlocks: access door
product entry/exit
shield plugs
etc.
Safety delay timer
Emergency stop
Water: level
conditioning
Collision detector
Ozone
Smoke/fire

4. **Warning signs and signals**

Check against list of known locations. All present? Legible? (signs)
Operating correctly? (lights)
Control console. Check against list of installed signals. Operating correctly?

5. **General observations**

Tidiness and general conditions:	Control room
	Irradiation room
	Maintenance areas
	Product carriers
Operators and other staff:	Personal dosimeters being worn?
	Check correct start-up/shutdown procedure is followed
	Hand held monitor used on entry?

6. **Radiation survey record**

Carry out a radiation survey of the facility to a predetermined plan, record the results and compare with previous and standard results.

Appendix VI

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF PANORAMIC GAMMA IRRADIATION FACILITIES

Prepare a visit agenda to review the operating programme with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI). Check the following for compliance with the authorization and with the regulatory authority requirements.

I–IDENTIFYING INFORMATION

I–1. Name of institution: _____

_____

I–2. Address of facility: _____

_____

I–3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail:

I–4. Authorization number: _____

I–5. Name and qualification of the radiation protection officer:

Name:
_____
Degree:
_____
Certification:
_____
Experience:
_____
_____

I–6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name:
_____
Degree:
_____
Certification:
_____
Experience:
_____
_____

Name:
_____
Degree:
_____
Certification:
_____
Experience:
_____
_____

Name:
_____
Degree:
_____
Certification:
_____
Experience:_____

I–7. Name and title of the responsible representative of the legal person: _____

_____

II–VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV of the Standards, "Potential Exposure: Safety of Sources".

II–1. Irradiator design

Compare the irradiator and sources with application descriptions and design specifications.

a)	Are the irradiator and radiation sources as described in the application approved by the regulatory authority?	Yes	No
b)	Irradiator model/type:		
c)	Irradiator identification number:		
d)	Radionuclide:		
	i) Model no(s). of the source(s):		
	ii) Initial activity of sources:		
	iii) Number of sources installed:		
	iv) Per pencil:		
	v) Per module:		
	vi) Per rack:		
e)	Maximum design activity:		
f)	Total activity installed:		
g)	Date installed:		
Describe any irradiator differences or modifications:			

Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls):

_____

_____

_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the irradiation and source storage areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the irradiation and source (dry) storage areas:	provided? working?	Yes Yes	No No
e)	For wet storage:			
	i) Is the leak proof liner in good condition?		Yes	No
	ii) Is there good water clarity?		Yes	No
	iii) Is the pool clear of debris?		Yes	No
	iv) Is a water treatment system:	provided? working?	Yes Yes	No No
	v) Are water level controls and re supply:	provided? working?	Yes Yes	No No
	vi) Are a pool guard and cover:	provided? working?	Yes Yes	No No
	vii) Are these harness anchor points?		Yes	No
	viii) Is there a long emergency hook?		Yes	No
	ix) Are there long handling tools (must not be hollow or filled with air)?		Yes	No

II–2. Safety controls system

a)	Are the safety controls for irradiator operation and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are electrical or mechanical interlocks (e.g. plug, protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d)	Is automatic source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
e)	Is manual source return to shielded position (e.g. power failure):	provided? working?	Yes Yes	No No
f)	Are emergency stop buttons:	provided? working?	Yes Yes	No No
g)	Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
h)	Is a radiation monitor at the material product exit port:	provided? working?	Yes Yes	No No
	i) Is an interlock with the radiation monitor to shut down product movement:	provided? working?	Yes Yes	No No
	ii) Are alarms to alert operators of jams of the product conveyor system:	provided? working?	Yes Yes	No No
i)	Is a radiation monitor for the water circulation system:	provided? working?	Yes Yes	No No
j)	Is a shroud or other barrier to protect the source rack and sources from interference by product on the conveyor system:	provided? working?	Yes Yes	No No
k)	Are position indicators for source rack:	provided? working?	Yes Yes	No No
l)	Is key control for electrical/mechanical connections:	provided? working?	Yes Yes	No No
m)	Is interlocked access control (entry by an intruder causes the sources to return to the shielded position):	provided? working?	Yes Yes	No No
n)	Is interlocked access control (safety delay timer with alarm before sources can move from the shielded position):	provided? working?	Yes Yes	No No
o)	Is a means of escape or communications (e.g. bell telephone) from within the irradiation room:	provided? working?	Yes Yes	No No

II–3. Warning systems

a)	Are distinctive signals (visible and/or audible) and posted explanations inside and outside the irradiation room for:			
	i) source exposed	provided? working? in local language?	Yes Yes Yes	No No No
	ii) source in transit	provided? working? in local language?	Yes Yes Yes	No No No
	iii) source safe	provided? working? in local language?	Yes Yes Yes	No No No
b)	Are warning notices (e.g. illuminated signs, written signs, posters)	provided? working? in local language?	Yes Yes Yes	No No No

II–4. Safety operations -management

a) Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b) Does management provide adequate staffing levels?		Yes	No
c) Has management invested the radiation protection officer with authority to stop unsafe operations?		Yes	No
d) Does management provide adequate resources for personnel training (time and money)?		Yes	No
e) Does management provide adequate equipment?		Yes	No
f) Does management provide for periodic programme reviews and recommendations to be:	scheduled? performed?	Yes Yes	No No
i) Date of the last programme review:			
ii) Status of recommendations: _____ _____ _____			

II–5. Safety operations — technical

a) Does the radiation protection officer (RPO) have adequate knowledge and expertise? (Note: In a small organization, the manager and the RPO may be the same individual.)		Yes	No
b) Does the RPO have qualified experts available?		Yes	No
c) Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?		Yes	No
d) Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e) Does RPO maintain knowledge of activities of workers using radiation sources?		Yes	No
f) Does the RPO conduct initial and periodic training of workers?		Yes	No
g) Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h) Are there provisions for inventory of sources and accountability:	procedures? to be performed?	Yes Yes	No No
i) Are there provisions for audits and reviews of radiation safety programme:	procedures? to be Performed?	Yes Yes	No No

II–6. Investigations and quality assurance

a) Have there been any incidents or accidents?		Yes	No
b) If so, were incident and accident investigation reports prepared?		Yes	No
c) Were safety assessments reviewed or made based on lessons learned from any incidents or accidents at similar facilities?		Yes	No
d) Are there written quality assurance programme Procedures? Are they performed?		Yes Yes	No No
e) Is maintenance and repair work in accordance with manufacturer's recommendations:	scheduled? performed?	Yes Yes	No No
f) Are repair/maintenance procedures:	developed? followed?	Yes Yes	No No

III–VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I of the Standards, "Occupational Exposure".

III–1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points:	provided?	Yes	No
		legible?	Yes	No
		in local language?	Yes	No
c)	Is radiation source storage at a physically defined location (e.g. pool, pit, hot cell, room)?		Yes	No
	i) Is the location locked/secured with key control?		Yes	No
	ii) Are radiation warning notices:	provided?	Yes	No
		legible?	Yes	No
		in local language?	Yes	No
	iii) Is there proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) Is it reserved only for radiation sources?		Yes	No
d)	Are supervised areas demarcated?		Yes	No
e)	Are approved signs at access points:	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		in local language?	Yes	No

III–2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorized levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
e)	Specifically, are operating and working procedures for:			
	I) entry into the irradiation room	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	ii) product loading	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iii) source loading and manipulation	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iv) responding to alarms	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	v) performing repairs to and maintenance of safety systems	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	vi) making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III–3. Monitoring

a) Does the authorized organization provide personal dosimeters?	Yes	No
b) Are the dosimeters:		
i) worn properly?	Yes	No
ii) calibrated?	Yes	No
iii) exchanged at required frequency?	Yes	No
c) Are personnel exposures within limits?	Yes	No
d) Are area and portable survey instruments		
i) appropriate?	Yes	No
ii) calibrated?	Yes	No
iii) operational?	Yes	No
iv) operational check performed before use?	Yes	No
v) are spare batteries available?	Yes	No
e) Do the authorized organization's surveys indicate that the irradiation room shielding is adequate and the dose rates around the room meet authorized radiation levels?	Yes	No
f) Does the authorized organization make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g) Is the instrumentation:		
i) appropriate?	Yes	No
ii) calibrated?	Yes	No
iii) operational?	Yes	No
Record independent measurements made during the inspection:		
Type/model no. of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorized organization?	Yes	No
Document any significant differences and any plan agreed upon to resolve the discrepancies:		

IV–VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III of the Standards, “Public Exposure”.

IV–1. Control of visitors

Are visitors accompanied in controlled area?	Yes	No
Is adequate information provided to visitors entering controlled areas?	Yes	No
Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV–2. Sources of exposure

Are the shielding and other protective measures optimized for restricting public exposure to external sources of radiation?	Yes	No
Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
Have provisions been made to detect and control contamination on irradiated product in the event of a leaking source?	Yes	No

IV–3. Radioactive waste and discharges

Have provisions been made to transfer the source to an appropriate registrant or licensee or to an authorized waste disposal facility at the end of use?	Yes	No
If sources are no longer in use and being stored, does the authorized organization have a plan for timely transfer or disposal of the sources?	Yes	No

Are there provisions for control of discharges into the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV–4. Monitoring of public exposure

Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
Do surveys show that the irradiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorized radiation levels?	Yes	No
Record independent measurements made during the inspection:		
_____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organizations routine measurements?	Yes	No
Document any significant differences and any plan agreed upon to resolve the discrepancies::		

V–EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V of the Standards, "Emergency Exposure Situations"

V–1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Is appropriate emergency equipment available?	Yes	No

V–2. Training and exercises

a)	Have workers involved in implementing the plan received training?		Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?		Yes	No
c)	Date of the last rehearsal:			
d)	If appropriate, has prior information been provided to members of the public who are reasonably expected to be affected by an accident?	appropriate? provided?	Yes Yes	No No

VI–RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be completed. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

I. Copy of authorization certificate.
II. System of records management.
III. Dosimetry:
    (a) current;
    (b) prior work history.
IV. Area surveys.
V. Instrument tests and calibrations.
VI. Tests for leakage of radioactive material from sources.
VII. Inventory of sources and accountability.
VIII. Audits and reviews of radiation safety programme.
IX. Incident and accident investigation reports.
X. Maintenance and repair work.
XI. Facility modifications.
XII. Training provided:
    (a) initial;
    (b) refresher.
XIII. Evidence of health surveillance.
XIV. Waste disposal.
XV. Transportation.
    (a) package documentation;
    (b) package surveys;
    (c) transfer/receipt documents;
    (d) details of shipments dispatched.
XVI. Source exchange/replacement procedures.

Appendix VII

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF SELF-CONTAINED GAMMA IRRADIATION FACILITIES

Prepare a visit agenda to review the operating programme with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI of this TECDOC.)

Check the following for compliance with the authorization and with the regulatory authority requirements.

I–IDENTIFYING INFORMATION

I–1. Name of the institution: _____

_____

I–2. Address of facility: _____

_____

I–3. Telephone/facsimile/e-mail: Tel.: _____ Fax: _____

e-mail: _____

I–4. Authorization number: _____

I–5. Name and qualification of the radiation protection officer: Name: _____

Degree: _____

Certification: _____

Experience: _____

_____

_____

_____

I–6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

I–7. Name and title of the responsible representative of the legal person: _____

_____

II–VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV of the Stnadards, “Potential Exposure: Safety of Sources

II–1. Irradiator design

a)	Compare the irradiator and sources with application descriptions and design specifications.		
b)	Are the irradiator and radiation sources as described in the application approved by the regulatory authority?	Yes	No
c)	Irradiator model/type:		
d)	Irradiator identification number		
e)	Radionuclide:		
f)	Model no. of the source:		
	i) Initial activity of sources:		
	ii) Number of sources installed:		
g)	Maximum design activity:		
h)	Total activity installed:		
i)	Date installed:		
j)	Describe any irradiator differences or modifications: _____		

Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, and controls):

_____

_____

_____

_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the sources from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the irradiation and source storage areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the irradiation and source (dry) storage areas:	provided? working?	Yes Yes	No No

II–3. Safety controls system

a)	Are the safety controls for irradiator operation and storage of radiation sources as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are electrical or mechanical interlocks (e.g. plug, protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d)	Is automatic source return to shielded position (e.g. on power failure):	provided? working?	Yes Yes	No No
e)	Is manual source return to shielded position (e.g. on power failure):	provided? working?	Yes Yes	No No
f)	Are emergency stop buttons:	provided? working?	Yes Yes	No No

g)	Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
h)	Is a radiation monitor at the material product exit port:	provided? working?	Yes Yes	No No
i)	Are position indicators for source rack:	provided? working?	Yes Yes	No No
j)	Is key control for electrical/mechanical connections:	provided? working?	Yes Yes	No No
k)	Are there position indicators for source, shutter, and/or sample holder	provided? working?	Yes Yes	No No

II–4. Warning systems

a)	Are distinctive signals (visible and/or audible) and posted explanations inside and outside the irradiation room for:			
	i) source exposed	provided? working? in local language?	Yes Yes Yes	No No No
	ii) source in transit	provided? working? in local language?	Yes Yes Yes	No No No
	iii) source safe	provided? working? in local language?	Yes Yes Yes	No No No
b)	Are warning notices (e.g. illuminated signs, written signs, posters):	provided? working? in local language?	Yes Yes Yes	No No No

II–5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management invested the radiation protection officer with authority to stop unsafe operations?		Yes	No
d)	Does management invested adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic programme reviews and recommendations?	scheduled? performed?	Yes Yes	No No
	i) Date of the last programme review: _____ ii) Status of recommendations: _____ _____			

II–6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No

d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?		Yes	No
e)	Does the RPO maintain knowledge of activities of workers using radiation sources?		Yes	No
f)	Does the RPO conduct initial and periodic training of workers?		Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?		Yes	No
h)	Are there provisions for inventory of sources and accountability:	procedures? performed?	Yes Yes	No No
i)	Are there provisions for audits and reviews of radiation safety programme:	procedures? performed?	Yes Yes	No No

II–7. Investigations and quality assurance

a)	Havethere been any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any incidents or accidents at similar facilities?		Yes	No
d)	Are there written quality assurance programme procedures?		Yes	No
e)	Are they performed		Yes	No
f)	Is maintenance and repair work in accordance with manufacturer's recommendations:	scheduled? performed?	Yes Yes	No No
g)	Are repair/maintenance procedures:	developed? followed?	Yes Yes	No No

III–VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I "Occupational Exposure".

III–1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points:	provided? legible? in local language?	Yes Yes Yes	No No No
c)	Is radiation source storage at a physically defined location (e.g. pit, hot cell, room)?		Yes	No
	i) Is the location locked/secured with key control?		Yes	No
	ii) Are radiation warning notices:	provided? legible? in local language?	Yes Yes Yes	No No No
	iii) Is there proper shielding (e.g. individual containers, enclosure)?		Yes	No
	iv) Is it reserved only for radiation sources?		Yes	No
e)	Are supervised areas demarcated?		Yes	No
f)	Are approved signs at access points?:	needed? provided? legible? in local language?	Yes Yes Yes Yes	No No No No

III–2. Local rules and supervision

a)	Are rules established in writing, in a local language?	Yes	No
b)	Do rules include investigation levels and authorized levels and the procedure to be followed when a level is exceeded?	Yes	No
c)	Are workers instructed in the implementing procedures?	Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

e) Specifically, are operating and working procedures for:			
i) operating the irradiator	provided? adequate? followed?	Yes Yes Yes	No No No
ii) responding to alarms	provided? adequate? followed?	Yes Yes Yes	No No No
iii) performing repairs to and maintenance of safety systems	provided? adequate? followed?	Yes Yes Yes	No No No
iv) making surveys	provided? adequate? followed?	Yes Yes Yes	No No No

III–3. Monitoring

a) Does the authorized organization provide personal dosimeters?	Yes	No
b) Are the dosimeters:		
i) worn properly?	Yes	No
ii) calibrated?	Yes	No
iii) exchanged at required frequency?	Yes	No
c) Are personnel exposures within limits?	Yes	No
d) Area and portable survey instruments:		
i) appropriate?	Yes	No
ii) calibrated?	Yes	No
iii) operational?	Yes	No
iv) operational check performed before use?	Yes	No
v) spare batteries available?	Yes	No
e) Do the authorized organization's surveys indicate that the irradiation room shielding is adequate and the dose rates around the room meet authorized radiation levels?	Yes	No
f) Does the authorized organization make periodic tests for leakage of radioactive materials from sealed sources?	Yes	No
g) Is the instrumentation:		
i) appropriate?	Yes	No
ii) calibrated?	Yes	No
iii) operational?	Yes	No
Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorized organization?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____ _____		

IV–VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III of the Standards, "Public Exposure".

IV–1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV–2. Sources of exposure

a)	Are the shielding and other protective measures optimized for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No
c)	Have provisions been made to detect and control contamination in the event of a leaking source?	Yes	No

IV–3. Radioactive waste and discharges

a)	Have provisions been made to transfer the source to an appropriate registrant or licensee or to an authorized waste disposal facility at the end of use?	Yes	No
b)	If sources are no longer in use and being stored, does the authorized organization have a plan for timely transfer or disposal of the sources?	Yes	No
c)	Are there provisions for control of discharges into the environment in the event of contamination or leakage from a sealed source?	Yes	No

IV–4. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b)	Do surveys show that the irradiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorized radiation levels?	Yes	No
c)	Record independent measurements made during the inspection: _____		
Type/model no. of survey meter:			
Date last calibrated:			
Are the inspector's independent measurements in agreement with the organization's routine measurements?		Yes	No
Document any significant differences and any plan agreed upon to resolve discrepancies: _____ _____ _____			

V–EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V of the Standards, "Emergency Exposure Situations".

V–1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Is appropriate emergency equipment available?	Yes	No

V–2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI–RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

I. Copy of authorization certificate.
II. System of records management.
III. Dosimetry:
    (a) current;
    (b) prior work history.
IV. Area surveys.
V. Instrument tests and calibrations.
VI. Tests for leakage of radioactive material from sources.
VII. Inventory of sources and accountability.
VIII. Audits and reviews of radiation safety programme.
IX. Incident and accident investigation reports.
X. Maintenance and repair work.
XI. Facility modifications.
XII. Training provided:
    (a) initial;
    (b) refresher.
XIII. Evidence of health surveillance.
XIV. Waste disposals/source transfers.
XV. Transportation:
    (a) package documentation;
    (b) package surveys;
    (c) transfer/receipt documents;
    (d) details of shipments dispatched.
XVI. Source exchange/replacement procedures.

Appendix VIII

CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF ELECTRON IRRADIATION FACILITIES

Prepare a visit agenda to review the operating programme with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports. (References to appropriate sections and appendices of Safety Series No. 115, "International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources" (BSS), are provided at the beginning of Sections II–VI this appendix).

Check the following for compliance with the authorization and with the regulatory authority requirements.

I–IDENTIFYING INFORMATION

I–1. Name of the institution: _____

_____

I–2. Address of facility: _____

_____

I–3. Telephone/facsimile/e-mail: Tel.: _____ Fax: _____

e-mail: _____

I–4. Authorization number: _____

I–5. Name and qualification of the radiation protection officer: Name: _____

Degree: _____

Certification: _____

Experience: _____

_____

_____

_____

I–6. Name and qualifications of any qualified experts (engineers, physicists, etc.) retained:

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience: _____
_____
_____

Name: _____
Degree: _____
Certification: _____
Experience:_____
_____
_____

I–7. Name and title of the responsible representative of the legal person: _____

_____

II–VERIFICATION OF SAFETY

BSS requirements related to this section may be found in Appendix IV of the Standards, "Potential Exposure: Safety of Sources

II–1. Accelerator design

Is the accelerator as described in the application approved by the regulatory authority?	Yes	No
Model:		
Identification number:		
Type (electron, X ray, other):		
Energy of radiation:		
Describe any differences or modifications: _____ _____ _____		

II–2. Facility design

Describe any facility differences or modifications from those approved by the regulatory authority and considered in the safety assessment (e.g. shielding design, building materials, installed fire protection and controls): _____				
a)	Was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
b)	Is protection of the accelerator from adverse environmental conditions (heat, moisture, etc.):	provided? working?	Yes Yes	No No
c)	Is fire detection and protection in the irradiation areas:	provided? working?	Yes Yes	No No
d)	Is adequate ventilation in the irradiation areas:	provided? working?	Yes Yes	No No

II–3. Safety controls system

a)	Are the safety controls for irradiation operations as described in the application approved by the regulatory authority?		Yes	No
b)	If not, was a safety assessment by a qualified expert performed prior to any modifications?		Yes	No
c)	Are electrical or mechanical interlocks (e.g. protective barriers, material entry/exit):	provided? working?	Yes Yes	No No
d)	Are emergency stop buttons:	provided? working?	Yes Yes	No No
e)	Is a radiation monitor inside the entrance to the irradiation room with measurements displayed outside the room and interlocked to the entrance door:	provided? working?	Yes Yes	No No
f)	Is key control for electrical/mechanical connections (note that the control should cover both the accelerating voltage and the emission source since "dark current" from cold filaments has been sufficient to cause serious personnel exposures):	provided? working?	Yes Yes	No No
g)	Is interlocked access control (entry by an intruder causes the electrical power to the accelerator to be shut off)	provided? working?	Yes Yes	No No
h)	Is interlocked access control (search and lock-up system before voltage can be supplied to the accelerator)	provided? working?	Yes Yes	No No
i)	Is a means of escape or communications (e.g. bell telephone) from within the irradiation room	provided? working?	Yes Yes	No No

II–4. Warning systems

a)	Are separate and distinctive signals (visible and/or audible) and posted explanations inside and outside the irradiation room for:			
	i) accelerator ready to be energized	provided? working? in local language?	Yes Yes Yes	No No No
	ii) accelerator 'ON' (radiation being produced)	provided? working? in local language?	Yes Yes Yes	No No No
	iii) accelerator 'OFF'	provided? working? in local language?	Yes Yes Yes	No No No
b)	Are warning notices (e.g. illuminated signs, written signs, posters):	provided? working? in local language?	Yes Yes Yes	No No No

II–5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?		Yes	No
b)	Does management provide adequate staffing levels?		Yes	No
c)	Has management invested the radiation protection officer with authority to stop unsafe operations?		Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?		Yes	No
e)	Does management provide adequate equipment?		Yes	No
f)	Does management provide for periodic programme reviews and recommendations to be:	scheduled? performed?	Yes Yes	No No
	i) Date of the last programme review: _____ ii) Status of recommendations: _____ _____			

II–6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?	Yes	No
e)	Does the RPO maintain knowledge of activities of workers?	Yes	No
f)	Does the RPO conduct initial and periodic training of workers?	Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?	Yes	No

II–7. Investigations and quality assurance

a)	Have there been any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Are there written quality assurance programme procedures?		Yes	No
e)	Are they performed		Yes	No
f)	Is maintenance and repair work in accordance with manufacturer's recommendations:	scheduled? performed?	Yes Yes	No No
g)	Are repair/maintenance procedures:	developed? followed?-	Yes Yes	No No

III–VERIFICATION OF WORKER PROTECTION

BSS requirements related to this section may be found in Appendix I of the Standards, "Occupational Exposure".

III–1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points:	provided?	Yes	No
		legible?	Yes	No
		in local language?	Yes	No
c)	Are supervised areas demarcated?		Yes	No
d)	Are approved signs at access points:	needed?	Yes	No
		provided?	Yes	No
		legible?	Yes	No
		in local language?	Yes	No

III–2. Local rules and supervision

a)	Are rules established in writing, in a local language?		Yes	No
b)	Do rules include investigation levels and authorized levels and the procedure to be followed when a level is exceeded?		Yes	No
c)	Are workers instructed in the implementing procedures?		Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?		Yes	No
e)	Specifically, are operating and working procedures for:			
	i) operating the accelerator	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	ii) product loading	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iii) responding to alarms	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	iv) performing repairs to and maintenance of safety systems	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No
	v) making surveys	provided?	Yes	No
		adequate?	Yes	No
		followed?	Yes	No

III–3. Monitoring

a)	Does the authorized organization provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
	i) worn properly?	Yes	No
	ii) calibrated?	Yes	No
	iii) exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments:		
	i) appropriate?	Yes	No
	ii) calibrated?	Yes	No
	iii) operational?	Yes	No
	iv) Is an operational check performed before use?	Yes	No
	v) Are spare batteries available?	Yes	No
e)	Do the authorized organization's surveys indicate that the irradiation room shielding is adequate and the dose rates around the room meet authorized radiation levels?	Yes	No

Record independent measurements made during the inspection: _____ _____ _____ _____		
Type/model no. of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys agree with the survey results of the authorized organization?	Yes	No
Document any significant differences and any plan agreed upon to resolve the discrepencies: _____ _____ _____ _____		

IV–VERIFICATION OF PUBLIC PROTECTION

BSS requirements related to this section may be found in Appendix III of the Standards "Public Exposure".

IV–1. Control of visitors

a)	Are visitors accompanied in controlled area?	Yes	No
b)	Is adequate information provided to visitors entering controlled areas?	Yes	No
c)	Are there adequate controls over entries into supervised areas and appropriate postings?	Yes	No

IV–2. Sources of exposure

a)	Are the shielding and other protective measures optimized for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment as described in the application and appropriate considering any public areas adjacent to the installation?	Yes	No

IV–3. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in public areas adjacent to controlled and supervised areas made by the staff or qualified expert?	Yes	No
b)	Do surveys show that the irradiation room shielding is adequate and the dose rates outside the controlled and supervised areas meet authorized radiation levels?	Yes	No
c)	Record independent measurements made during the inspection: _____ _____ _____		
Type/model no. of survey meter:			
Date last calibrated:			
Are the inspector's independent measurements in agreement with the organizations routine measurements?		Yes	No
Document any significant differences and any plan agreed upon to resolve the discrepancies:			

V–EMERGENCY PREPAREDNESS

BSS requirements related to this section may be found in Appendix V of the Standard "Emergency Exposure Situations".

V–1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

V–2. Training and exercises

a)	Have workers involved in implementing the plan received training?	Yes	No
b)	Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c)	Date of the last rehearsal:		

VI–RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

I. Copy of authorization certificate.
II. System of records management.
III. Dosimetry:
    (a) current;
    (b) prior work history.
IV. Area surveys.
V. Instrument tests and calibrations.
VI. Audits and reviews of radiation safety programme.
VII. Incident and accident investigation reports.
VIII. Maintenance and repair work.
IX. Facility modifications.
X. Training provided:
    (a) initial;
    (b) refresher.
XI. Evidence of health surveillance.

Appendix IX

SPECIAL EMERGENCY PROCEDURES FOR GAMMA IRRADIATORS

IAEA Safety Series No. 91, "Emergency Planning and Preparedness for Accidents Involving Radioactive Materials Used in Medicine, Industry, Research and Teaching", provides detailed information on the subject. Nevertheless, in many of the circumstances, such emergency plans may be very simple.

Special problems with gamma radiation facilities

Removal of a damaged or leaking source

The appropriate method of removal, transfer, or disposal of a damaged or leaking source will be dictated by circumstance, but the following procedure is generally applicable:

If an actual source leak has occurred, the use of the irradiator must be terminated and a decision taken as to the desirability of closing down the water circulation and air ventilation systems to prevent the spread of contamination and exposure of workers.

The affected area must be isolated and contact should be made for assistance, as appropriate to the regulatory authority, the manufacturer of the device, the supplier and the installer of the source (if different from the manufacturer of the device), and a person authorized to remove the defective source. Special permission to remove and transport the source should be obtained from the regulatory authority.

Removal of the defective source should be prompt once the decision has been made and should be performed by, or under the supervision and in the physical presence of, someone authorized by the regulatory authority.

Contaminated material generally results from a leaking source. Under no circumstances should any contaminated material such as water-filler medium, resin, or components be removed, transferred, or disposed of without the express permission of the regulatory authority. Disposal of contaminated material must be performed by, or under the supervision and in the physical presence of, someone authorized by the regulatory authority.

Remedial actions under increased radiation levels

During the operation of gamma facilities, situations may arise when the source rack remains fully or partially unshielded due to malfunction of the source movement system. Causes of such events may be technical failures in the source movement mechanism itself or damage of the source rack by product boxes. The remedial actions in such situations should principally proceed in the following way:

(a) Ensure that access to the irradiation room remains impossible for any person.
(b) Prevent combustion of products due to excessive heating of the product boxes (e.g. by increasing the ventilation).
(c) Inform the radiation protection adviser and officers, plant management, regulatory authority and manufacturer, if necessary, according to the established reporting procedure.
(d) Assess the position of the source by examining external indicators and by measuring dose rates.

(e) Develop a remedial action plan taking into account the specific source movement system, its components, the design of the facility, the information gathered so far concerning the possible cause of the incident, the possibilities of introducing additional portable shielding components, the possibilities of using special tools to provide for a certain working distance from the source, or remotely controlled devices and the doses that would be received by radiation workers.
(f) Ensure that all remedial actions that can lead to a radiation exposure have been approved by the regulatory authority.

These measures are intended as guidance. Each incident will need to be dealt with cautiously and on a case–by–case basis.

Emergencies involving high accidental personnel exposures

Planning for emergencies involving high accidental exposures should be made in accordance with the IAEA Safety Series Publications — Emergency Planning and Preparedness for Transport Accidents Involving Radioactive Material (Safety Series No.87, 1988) [14] and Emergency Planning and Preparedness for Accidents Involving Radioactive Materials Used in Medicine, Industry, Research and Teaching (Safety Series No.91, 1989) [15].

Lessons learned from accidents in irradiation facilities

The IAEA performed a review of information available on fatal accidents that occurred in industrial irradiation facilities and published the results in "Lessons Learned from Accidents in Industrial Irradiation Facilities" [16]. This section provides some of the conclusions from that review which may be useful to organizations preparing contingency plans for their own equipment or processes.

Major causes of accidents

Three contributory elements were apparent in each accident. First, there was a flaw in the initial design, or the facility or equipment was not maintained to meet the initial design, or new procedures and modifications created situations not anticipated in the design. Second, a complete safety system was not available because of component failure, or because of actions taken by the operating organization, management or personnel to disable or bypass the system. Third, someone acted inappropriately because of misinformation or lack of knowledge, or a decision was made to ignore conflicting information.

In the majority of the accidents involving gamma irradiation, the initiating event entailed a secondary support mechanism and not malfunctioning of the source transfer mechanism itself. Mechanical devices that transfer the products to be irradiated to and from the irradiation chamber were frequently designed for the specific circumstances of the operating facility. The source supplier may or may not have contributed to the design and evaluation of the product transfer devices. Failure of the product transfer system may or may not have interfered with the source transport mechanism. In several of these accidents, product jams appeared to have been frequent, and tolerated by personnel and management. Thus, challenges to the safety systems were also frequent, and operating personnel had adopted a policy of dealing with the consequences of a problem (clearing jammed transport systems) rather than correcting its cause (product container or transport system design and maintenance). Some of the accidents occurred after the source supplier and designer of the irradiation equipment had recommended installation of a protective shroud to ensure that

product containers would not come into contact with the source/source rack and the hoist structures.

Control systems at the entry point to the irradiation chamber were of particular importance. The design of these facilities was such that control of access relied heavily on the use of interlocked systems. Serious consequences resulted from personnel access through openings that were not interlocked because entry through small openings or over pits was considered unlikely. Additionally, in some instances the interlock controls were not designed to be sequential, so that any attempt to override or apply them out of sequence would abort the intended operation and require that the sequence be restarted. Use of a radiation monitor to alert personnel, or of an interlock to prevent access when high radiation doses were possible, was crucial. However, in all these accidents such a system had not been installed or was not working, or was easily bypassed by methods known to the operating personnel.

Workers and operating personnel in every accident performed inappropriate actions based on the information that was available to them and on the instructions that had been provided. In a few accidents, the personnel involved were simply not adequately trained to understand the hazards. In other accidents, operators who were knowledgeable about radiation and its risks made bad judgements on the actual condition of the sources. Operators were so focused on routine operations and correcting minor problems that even the potentially severe consequences of radiation exposure from high activity sources did not induce them to exercise the appropriate caution. Some of these inappropriate actions were relatively long standing practices and should have been detected and corrected by the management of the operating facility.

LESSONS LEARNED

Lessons have been learned from the findings of investigations into severe accidents at gamma and electron beam irradiation facilities. Redundant and diverse safety systems could have prevented most accidents. For example:

(1) In all the overexposures, the operator placed ultimate reliance on access barriers and/or interlocks governed by the source rack position, or on condition signals alone;
(2) In all the overexposures, an access barrier based on radiation–activated interlocks had not been installed, had been removed, or was defeated easily;
(3) In several overexposures, the radiation source position indicator was wrong because of failure of a single component, or because it could be manipulated to give a false signal at the control panel;
(4) In several accidents, access barriers were able to be defeated with the control panel in the operating or ready mode.

Safety is compromised if the facility design is not carefully reviewed to identify conditions critical to safety. This requires consideration of redundancy, of avoiding single mode failures and of human factors. Where these points were not adequately taken into account, unsafe conditions resulted. For example:

(a) Disconnecting a critical safety system from the control console resulted in unsafe conditions when power could still be supplied to operate an accelerator or cause a gamma source to remain in the ‘unshielded’ position.

(b) Disconnecting a critical safety system from the control panel resulted in unsafe conditions when this disconnection did not automatically result in shutting off power to an accelerator or cause a gamma source to move to the 'shielded' position.

(c) When trying to resolve problems, personnel were tempted to circumvent barriers if they could be easily bypassed, e.g. with ladders, by stooping or crawling, or by manipulating switches, using tape.

The management of the operating organization can quickly lose control of the employee's level of knowledge and performance unless systematic audits are conducted and frequent training is provided. For example:

(i) In several facilities, the personnel involved in accidents had employed tricks to circumvent the safety systems.

(i) Operators involved in accidents had usually not used a portable radiation monitor when entering the irradiation chamber, indicating that such failures to follow procedures were common. It should also be noted that most of these operators had also not worn the assigned personnel monitoring devices.

Management practices or attitudes resulted in degradation of the safety systems and operating procedures. It appears that product and production costs sometimes took precedence over safety. This was particularly evident when control by the regulatory authority was absent or weak. For example:

(a) Toleration by management of the removal or defeat of radiation activated interlocks played a major role in some accidents;

(b) Several accidents occurred after management had received the source supplier's recommendation to install a protective shroud that could have prevented the accident, but had not done so.

In at least one accident, management apparently approved the installation of a switch to bypass an interlock and the removal of the only passive detection system that could not be circumvented easily by stooping or crawling.

Many of the accidents occurred during shifts with only one trained worker on duty or on call; employee behaviour appeared to reflect a management policy of having one person take on as many tasks and responsibilities as possible.

Personnel adequately trained to handle routine operations were not knowledgeable enough to deal with situations where an electron beam was not shut off or where gamma sources were not returned to a safe condition. For example:

(a) Personnel involved in accidents routinely failed to appreciate the necessity of making a radiation survey with a demonstrably operational radiation monitor;

(b) Personnel involved in accidents routinely failed to follow instructions to alert radiation safety supervisors when alarms indicated that the source was not in the safe, 'shielded' position;

(c) Personnel exposed to large doses of radiation sometimes lacked an understanding of the fundamental principles of the devices with which they were working, e.g. the cold discharge currents for electron sources or the connection between a strong odour of ozone and the interaction of ionizing radiation with air.

The role of the IAEA in emergency response

In 1987, a serious radiological emergency involving a radioactive source (caesium-137) occurred in Brazil. The emergency, in aspects related to its causes, was remarkably similar to one involving a cobalt–6O source which took place in Mexico (and via transport of contaminated materials to the USA) about four years earlier. Other serious radiological emergencies, some less well-documented and some with fatalities or serious injuries, have occurred in other countries. The IAEA has provided assistance in several of them (San Salvador and Vietnam are discussed in Ref. [6]. In the Brazilian case, the IAEA was requested to provide various types of assistance. Brazil also requested and accepted assistance on a bilateral basis from several Member States. The Mexican case was largely handled through bilateral activities between Mexico and the USA.

Most emergencies involving irradiators can be effectively resolved by the national regulatory authorities, and regulations would normally require operators to inform the authorities immediately of serious accidents. However, the IAEA is willing and able to provide assistance to States in the event of serious radiological accident.

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