LEM/TEK/57
02 DISEMBER 2008

CODE OF PRACTICE ON RADIATION PROTECTION OF NON MEDICAL GAMMA & ELECTRON IRRADIATION FACILITIES

Lembaga Perlesenan Tenaga Atom
Kementerian Sains, Teknologi dan Inovasi
Batu 24, Jalan Dengkil, 43800 Dengkil
Selangor Darul Ehsan

Tel: 03-89284130 / 89267699
Faks: 03-89254578
Laman web: http://www.aelb.gov.my

CONTENTS

PART IX
GLOSSARY

ANNEXES

GENERAL INTRODUCTION

The radioactive material and electron beam used as irradiators are controlled by the Atomic Energy Licensing Act 1984 (Act 304). The responsible regulatory authority is the Atomic Energy Licensing Board (AELB).

The radioactive material used in irradiators are generally of a level of activity that would, if not adequately shielded, constitute a significant health hazard and security concern.

Under no circumstances should untrained or inappropriately qualified personnel or unauthorized persons operate, attempt to remove, or in any way interfere with, the radioactive materials or carry out any maintenance, adjustments or modifications to the irradiator.

This code has been prepared to supplement the Atomic Energy Licensing Act 1984 and its subsidiary legislations. This code is further extended to serve as a basis for detailed working procedures appropriate to the use of irradiators.

PART I
INTRODUCTION

1.1 Irradiators

Two types of sources are used in industrial irradiators:

1. Sealed sources where the radioactive material, usually cobalt-60 or caesium-137, is enclosed within two stainless steel metal capsules, one inside of the other, to give two layers of protection against leakage.

2. Machine sources where electrons are produced by high voltage accelerators.

Classification of Gamma Irradiation Facilities

For the purpose of the code, four general categories of irradiators are defined[1] according to the design of the facility and particularly the accessibility and shielding of the radioactive material. The categories are:

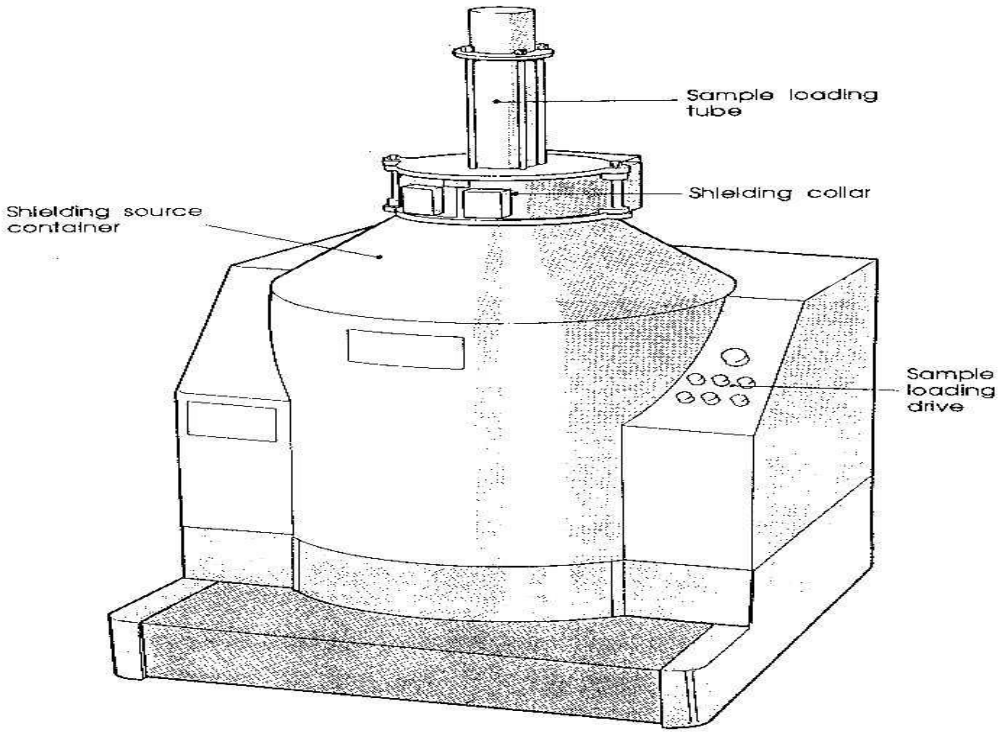
Category I: An irradiator in which the sealed source is completely enclosed in a dry container constructed of solid materials and is shielded at all times, and where human access to the sealed source and the volume undergoing irradiation is not physically possible in the designed configuration.

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 is maintained inaccessible during use by an entry control system.

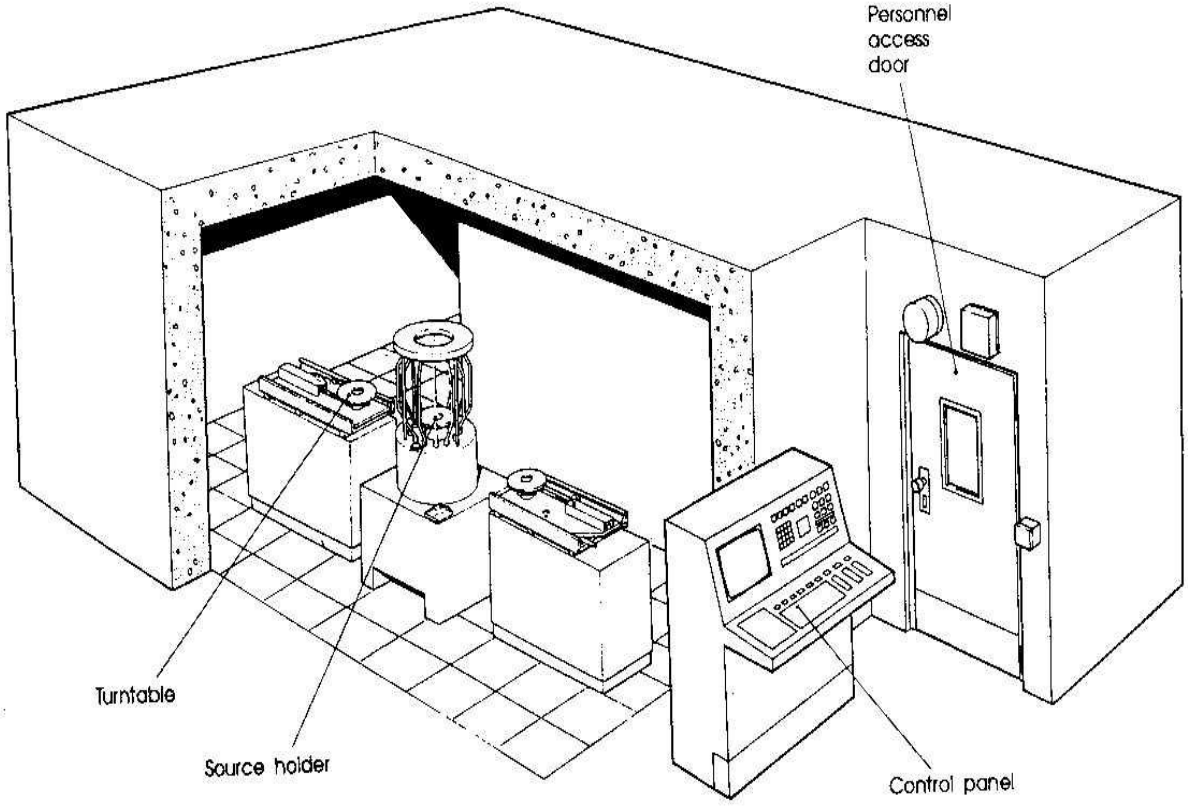
Category III: An irradiator in which the sealed source is contained in a water filled storage pool and is shielded at all times and where human access to the sealed source and the volume undergoing irradiation is physically restricted in the designed configuration and proper mode of use.

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 is maintained inaccessible during use by an entry control system.

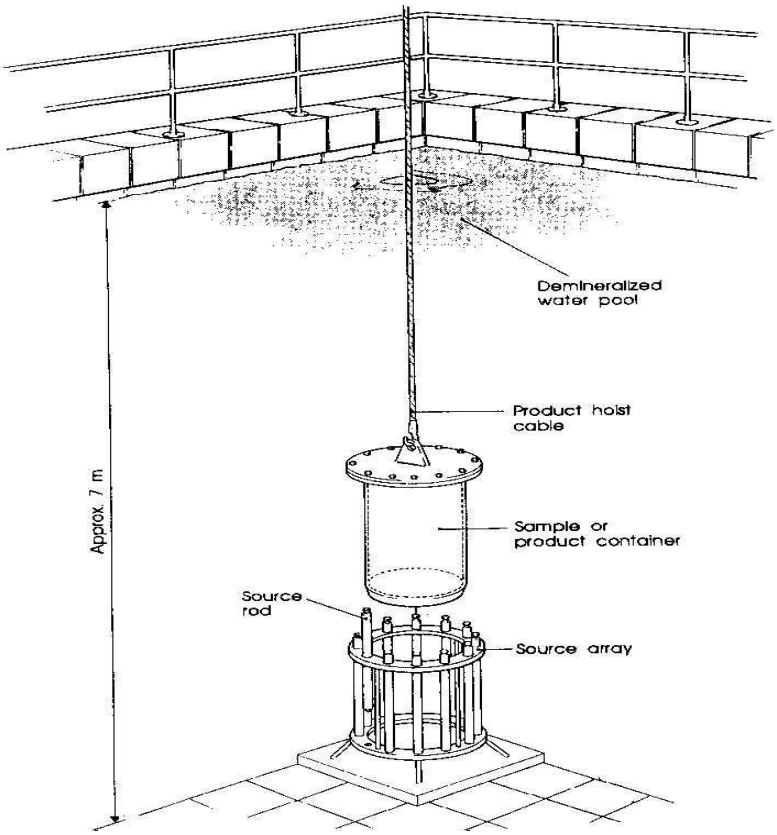
[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Safety of Gamma and Electron Irradiation Facilities, Safety Series No. 107, IAEA, Vienna (1992).



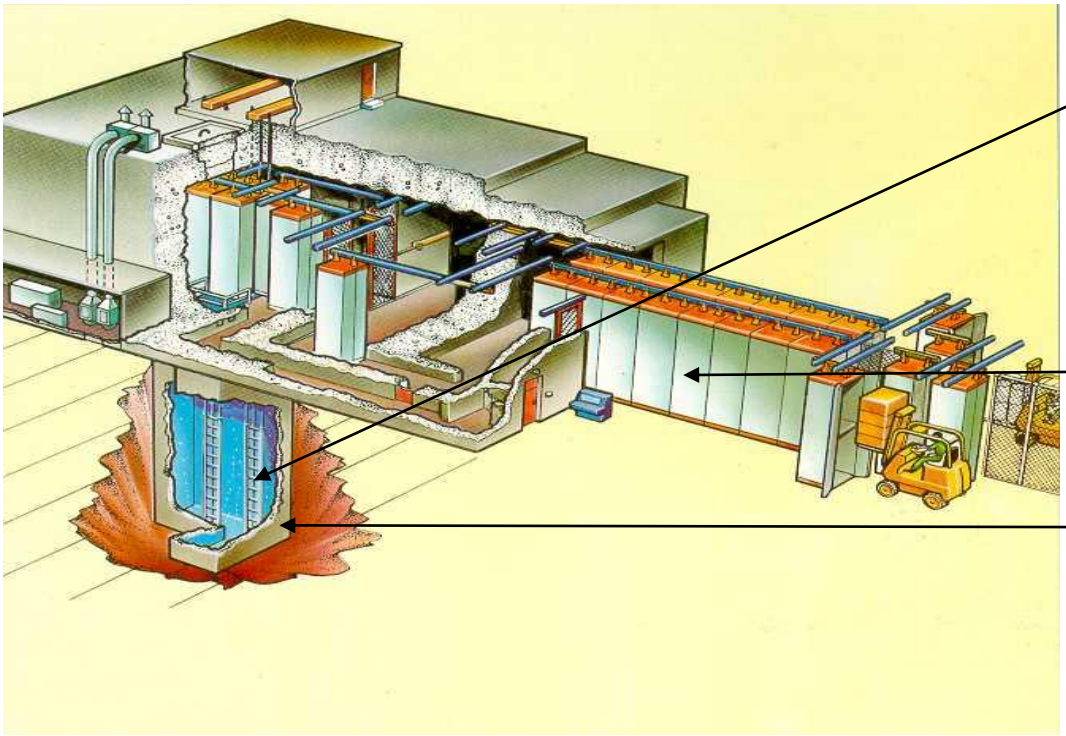
CATEGORY I: SELF CONTAINED, DRY SOURCE STORAGE IRRADIATOR



CATEGORY II: PANORAMIC, DRY SOURCE STORAGE IRRADIATOR



CATEGORY III:
SELF CONTAINED, WET SOURCE STORAGE IRRADIATOR



CATEGORY IV: PANORAMIC, WET SOURCE STORAGE IRRADIATOR

Classification of Electron Beam Facilities

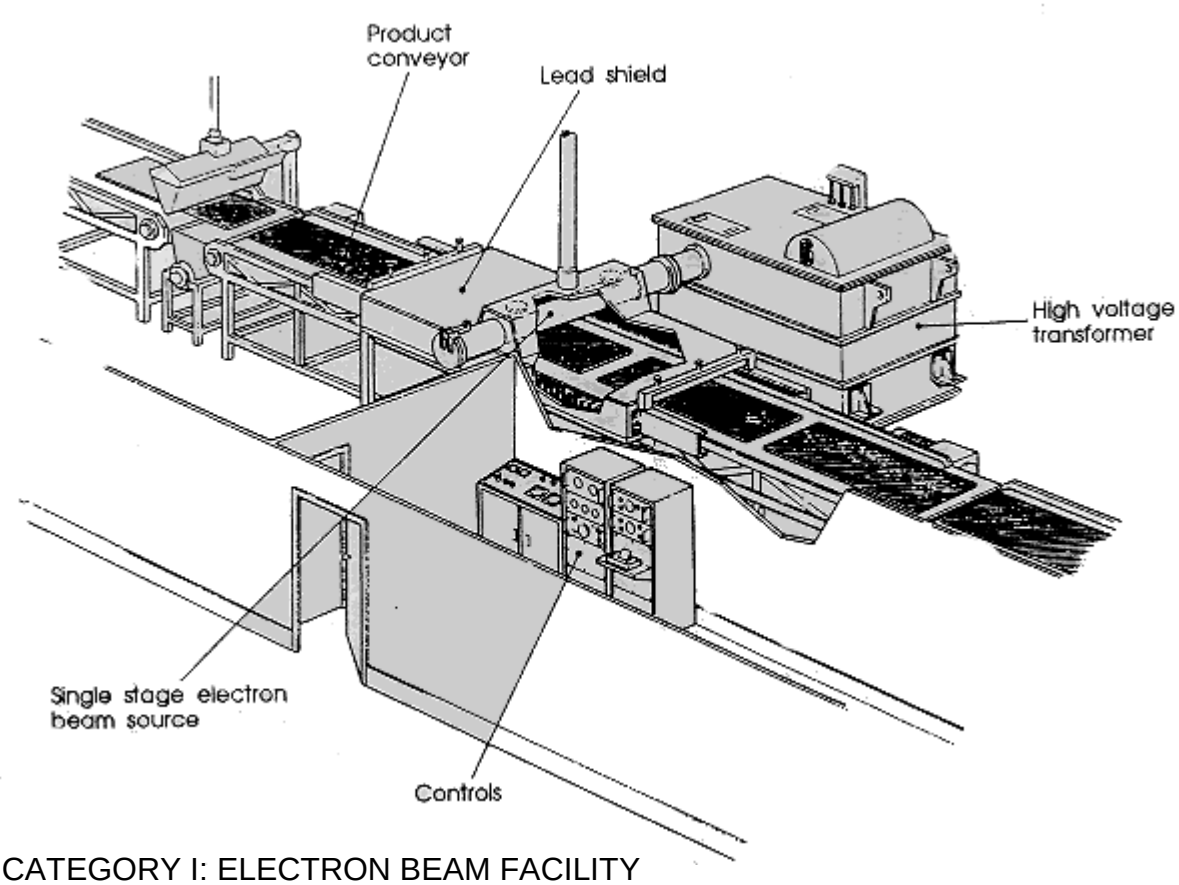
In this code, only electron accelerators of energies less than or equal to 10 MeV are considered. For these energies there is no induced radioactivity in any part of the equipment. For electron accelerators of energies above 10 MeV, the effects of induced radioactivity shall be considered for materials used in construction and for materials in the product being processed.

Electron irradiation facilities are divided into two categories[2]. These 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.

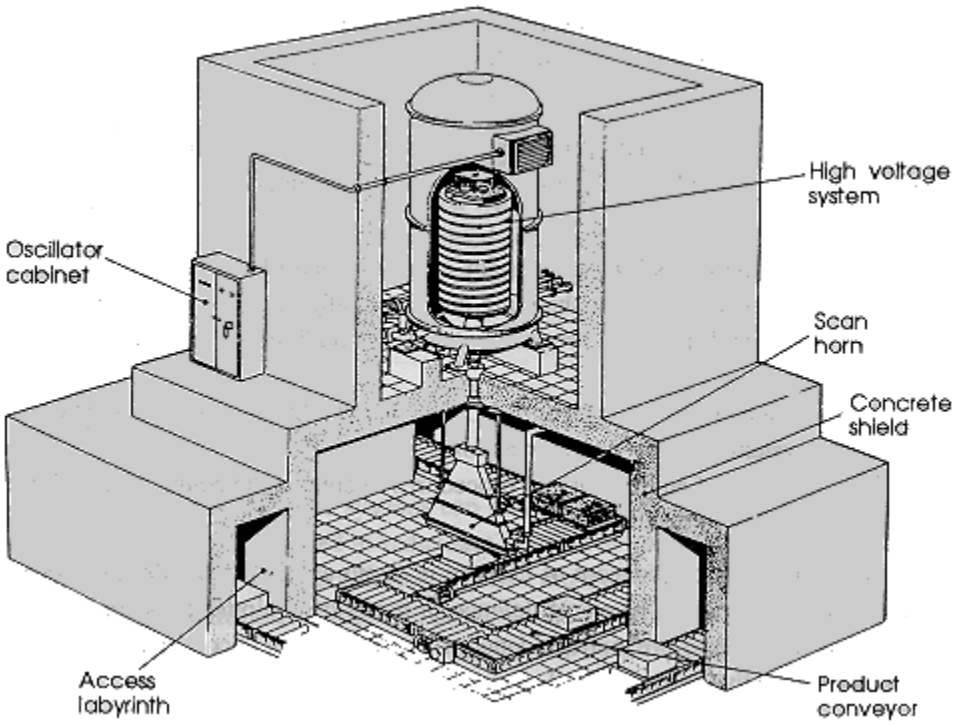
Category II: A unit housed in shielded rooms that are maintained inaccessible during operation by an entry interlock system.

The main differences between the types of accelerator are in the mode of accelerating the electron beam and in the method of producing the necessary high voltages.



CATEGORY I: ELECTRON BEAM FACILITY

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Safety of Gamma and Electron Irradiation Facilities, Safety Series No. 107, IAEA, Vienna (1992).



CATEGORY II ELECTRON BEAM FACILITY

1.2 Purpose of This Code

The purpose of this code is to specify the protective measures that will ensure that the dose limits specified in the Radiation Protection Standards (see section 1.6 and Annex I) are not exceeded as a result of the use of irradiators. It is further intended to ensure that radiation exposures are kept as low as reasonably achievable (ALARA).

This code lays down physical requirements for irradiators, working procedures in their use, and radiation surveillance requirements. Informed and consistent use of this code will ensure the safe operation of the irradiator.

1.3 Scope of This Code

This code applies to all types of irradiation facilities (for non-medical activities), whether operated on a commercial basis or for research and development purpose. It does not, however, deal with radiography units or irradiators used to provide medical treatment. It is solely concerned with radiation safety and does not deal with the use of irradiation facilities and their requirements, nor does it cover the topics of irradiation of products and their quality assurance.

1.4 Specialized Meanings for ‘shall’ and ‘should’

The words ‘shall’ and ‘should’ where used in this code have specialized meanings.

‘Shall’ indicates that the particular requirement is to be complied with

‘Should’ indicates that the particular requirement is to be complied, wherever practicable to further improve the situation or performance.

1.5 Protective Measures Required in This Code

This code lays down detailed requirements for the following protective measures:

i. Allocation of responsibility for all safety procedures and for the provision and maintenance of all safety equipment.

ii. Design, construction and testing of radioactive materials used in irradiators.

iii. Design, construction, testing and maintenance of source containers for irradiators’ radiation sources.

iv. Siting and installation of irradiation facility and provision of protective barriers and other safety features.

v. Consistent and informed use of personal monitors to measure and assess personal doses and of suitable radiation measuring instruments to measure radiation exposure from irradiators and to assess potential hazards.

vi. Formulation of comprehensive safety procedures, including working rules, emergency procedures and accounting procedures for radioactive materials.

vii. The initial and continued instruction of all persons involved in use and maintenance of irradiator.

viii. Provision and display of warning label, notice and marking.

ix. Recording and keeping of all relevant data.

PART II
ADMINISTRATIVE REQUIREMENTS

2.1 Authorization of Practice

Any person intending to build or operate a non-medical irradiation facility AELB and shall apply for an authorization by 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 form of a license.

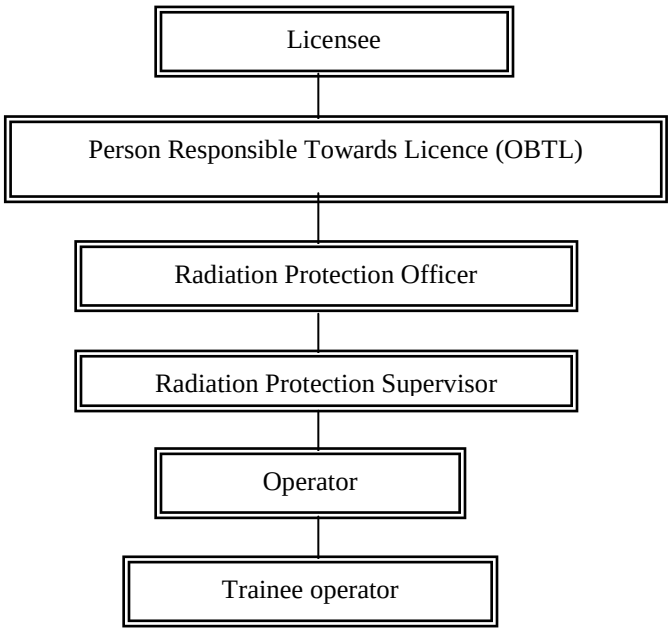
2.2 Personnel Accreditation

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 respect to a non-medical irradiation facility, these individuals are:

- Radiation Protection Officer;
- Radiation Protection Supervisor; and
- Radiation Worker (Qualified Operator);

Chart 1: Example of Organization Chart



Radiation Protection Officer

Radiation protection officer is a technically competent person appointed by licensee and accredited by the AELB[3].

For a person to be appointed as a radiation protection officer, he or she shall have the relevant theoretical training, both technical and non-technical, as approved by the AELB, covering practical radiation protection and regulatory requirements with respect to the irradiation facility for which they are appointed.

Radiation protection officer shall have the relevant practical experience and commands sufficient respect from the people doing the work to be able to exercise the necessary supervision of radiation protection activities and to stop unsafe practices.

Qualified Operator

A qualified operator shall be at least 18 years old and holds a certificate of competence having passed an examination following approved training which is recognized by AELB (see Annex II). The examination shall test knowledge and show understanding and should cover at least the following:

i. a knowledge of the basic design, operation and preventive maintenance of the irradiator;
ii. an understanding of area security safeguards such as locks, posting of signs, warning lights, audible and visible signals, and interlock systems;
iii. the principles and practices of radiation protection; the biological effects of radiation; the written procedures for routine and emergency irradiator operation;
iv. a knowledge of the principal requirements of legislation, regulations and codes of practice as laid down by AELB and relevant to the operation of the irradiation facility;
v. a knowledge of exposure rates at all areas around the irradiator and the radiation detection instrumentation which is used and the requirements for personal dose monitoring as specified by AELB.

Each operator shall demonstrate competence to use the radiation source 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.

[3] Radiation Protection Regulations (Basic Safety Standards) 1988.

2.3 Authorization of Other Practices Related to Irradiation Facility

The AELB requires the licensee to obtain prior approval to any of the following:

i. Import, export, transfer, disposal of radioactive sources and/or electron beam machines.
ii. Appointment/transfer/resignation/of accredited changes personnel

The AELB requires the licensee to engage licensed companies and/or agencies recognized by the AELB for any of the services below:

i. Construction.
ii. Installation.
iii. Maintenance.
iv. Source change.
v. Leak test.
vi. Decommissioning.

2.4 Authorization of Facility Modification

The licensee shall notify the AELB (and supplier where appropriate) and obtain approval from the AELB to any modifications that may have radiological protection implications. This includes:

i. Modifying operating procedures;
ii. Modifying the safety control system;
iii. Major modification of the irradiator;
iv. Source loading, replenishment, removal or redistribution, or electron beam orientation, in any way at variance with the agreed approval; and
v. Changes in supervisory personnel or advisers.

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

2.5 Radiation Protection Requirements

The radiation protection requirements on justification of the practice, dose limitation and optimization of protection, and dose constraints (BSS 2.20 to 2.26) shall be applied to irradiator. The dose limits for occupational and public exposure is reproduced in Annex I.

The licensee shall establish a comprehensive quality assurance program 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 Program. For guidance on the preparation of Radiation Protection Program, please refer to LEM/TEK/45 (Section E)

PART III
RESPONSIBILITIES AND DUTIES

3.1 Requirements for Supplier of Irradiation Facility

Designers and Manufacturers

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

(a) Complying with the requirements of Radiation Protection (Basic Safety Standards) Regulations 1988 to ensure the safe design of these facilities.

(b) 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 as 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 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 8 of this document.

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 regarding defects in materials 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 periodically seek this information from the manufacturer or supplier rather than to rely upon them to supply it.

Constructors and Installers

The licensee shall ensure that constructors and installers work does not compromise the safety aspects of the facility by fully complying with the requirements of the designer, the manufacturer and the AELB. On completion of the installation, or at appropriate stages in the construction, the constructor or installer and the licensee shall thoroughly and critically review the facility or any component part before it is commissioned to ensure that:

(a) The safety features and warning devices have been properly installed and correctly operated; and
(b) There is sufficient radiation protection for all persons and the environment.

The licensee shall also ensure that the constructor or installer provides adequate information about proper operation maintenance and decommissioning of the facility.

The licensee shall ensure that designers, manufacturers, constructors and installers provide cooperation in order to provide employees the necessary theoretical and practical training to enable them to do their work in a safe manner.

3.2 Responsibilities of Users

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 directly contribute 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:

(a) identify the individual (Member of the Board of Directors or key senior manager) with overall responsibility for safety and as the person responsible to the license;
(b) clearly state that safety is one of the principal objectives of the organization of equal status to all other principal objectives e.g. commercial or research;
(c) clearly state that the organization's approach to safety is directed towards prevention;
(d) identify, below director or key senior manager level, those staff with safety responsibility;
(e) indicate the primary communication links and organizational structure between those in (d) above;
(f) indicate the roles, responsibilities and authorities of those individuals with specialist safety functions e.g. for radiation safety, and their reporting lines and communication links with other management functions;
(g) provide the framework within which the necessary resources of both time and money will be made available for the implementation of safety policy;
(h) describe how standards for safety will be established, how prevention strategies will be chosen, and the procedures and criteria that will be used to monitor compliance with standards;
(i) explain how the workforce and their representatives will be involved in the promotion of safety in the organization;
(j) provide the framework for the provision of training in safety throughout the whole range of employees and others, e.g. contractors, including both managers and workers; and
(k) 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 or performance achieved in order to maximize learning and to ensure that appropriate action is taken to improve the control of hazards, which in turn assist with the development of safety policy.

The safety policy should provide the basis for a positive approach in 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" demonstrate their commitment to safety and provide clear direction.

All individuals with specific safety duties should be aware of those duties and responsibilities, and they 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 be held accountable for their actions.

There should be regular and meaningful consultation with staff and their representatives. Information about the hazards, risks and preventive 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. It can therefore be seen that an effective safety policy is not a fixed and unchanging document but an evolving and developing attitude towards a safety culture.

Organization and Responsibilities

The licensee shall be responsible for the possession and use of irradiator and shall obtain from the appropriate authority a license for the design, construction, acquisition, storage and use of the irradiator. The licensee shall be responsible for the operation of the irradiator in accordance with the conditions of the license.

The licensee shall notify the appropriate authority of any proposed modifications to the irradiator. Notification and approval for changes to the key personnel shall be made in particular the person responsible to the license, the radiation protection officer, supervisor and qualified operators.

3.3 The Person Responsible towards License - "Orang yang Bertanggungjawab Terhadap Lesen" (OBTL)

The OBTL is responsible for all matters related to the appropriate authority, provides the infrastructure (including financial and training) required by the RPO. Other responsibilities of the OBTL shall include:

a) submit to the appropriate authority an employee who fulfills all conditions prescribed by AELB to be certified as RPO.
b) Explains to the RPO his or her responsibilities.
c) Ensures that the adopted Radiation Protection Program is in line with AELB's directive and requirement and ensuring that the Radiation Protection Program is completed and implemented.
d) Ensures that all medical examinations are carried by the approved Medical Practitioner's only.
e) Establish, maintain and keep all records required by the appropriate authority.
f) Ensures all activities related to ionizing radiation complies with the Atomic Energy Licensing Act 1984 and its subsidiary regulations.

3.4 Responsibilities of Radiation Protection Officer (RPO)

Licensee shall get approval from the appropriate authority for the appointment of the RPO. The RPO should report directly to senior management. The RPO shall have sufficient authority to allow them to exercise close supervision to ensure that the work is done in accordance with the written administrative procedures. The RPO should not however have other responsibilities, which could compromise radiation safety interests.

The Licensee shall carry out the general responsibility of compliance with the regulations and the conditions of license issued by the appropriate authority.

The duties of the RPO should include the following;

(a) 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;
(b) identification of controlled and supervised areas;
(c) control of access to controlled areas;
(d) restriction of exposure and maintenance of engineering controls and other equipment provided for such restriction;
(e) deciding whether any special restriction are required with respect to the exposure of pregnant female employees;
(f) arranging the testing of radiation monitoring instruments;
(g) maintaining source and other relevant records;
(h) routine radiation surveys and environmental monitoring;
(i) supervision of issuance and return of personal dosimeters;
(j) arranging statutory tests for leakage of radioactive material;
(k) undertaking a program of periodic safety checks on safety and warning systems, general conditions of the facility etc. An example check list for such checks is in Annex III;
(l) liaison with contractors, designers, maintenance staff, designers and suppliers with respect to radiation protection matters and significant changes to physical or operational aspects of the facility;
(m) arranging suitable radiation protection training for operators, maintenance staff, contractors and others as appropriate;
(n) ensuring the adequacy of safety assessments and contingency plans for any reasonably foreseeable incident with radiation protection consequences;
(o) arranging periodic exercise to test the effective implementation of these contingency plans; and
(p) to initiate investigation of any incident or a near miss involving the facility

RPO 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. meeting production targets and radiation safety, the radiation safety requirements must always take priority. At least one officer (either the RPO or the Supervisor) has to be available, though not necessarily present at all time.

3.5 Responsibilities of Supervisor

In order to ensure there will be at least one person on duty or otherwise readily available for supervision of radiation protection, the licensee shall also appoint a sufficient number of supervisors whose duties shall be assisting the RPO. The appointment of supervisors by the licensee shall be approved by the appropriate authority.

3.6 Responsibilities of Qualified Operators

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 day to day responsibility for safe operation is generally theirs. The operators training, experience, attitude and competence will establish the degree of safety associated with operation of the irradiator.

PART IV
SAFETY OF SOURCES AND FACILITIES

4.1 Design Safety for Gamma Irradiation Facilities

4.1.1 Design of Sealed Sources

Sealed sources used in gamma irradiation facilities shall meet the general requirements of sealed sources given in ISO Standard 2919[4].

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

[4] International Organization for Standardization, ISO 2919, Radiation Protection – Sealed Radioactive Sources – General Requirements and Classification (1999).

If the activity of the source exceeds those stated in Annex I, a specific evaluation of the use of the sealed source and its design shall be made by the licensee and be approved by the appropriate authority.

The licensee shall also take into account of the possible effects of fire, explosion, corrosion and any aspects related to the continuous use of the sealed source[5]. Factors to be considered are:

The consequences of failure of source integrity can be influenced by:
(a) The quantity of radioactive material contained in the sealed source;
(b) The radiotoxicity, leachability and solubility of the radioactive material;
(c) The chemical and physical form of the radioactive material; and
(d) The environment, in which the source is stored, moved and used.

Specific Requirements for Wet Storage Conditions

When selecting a source, 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. Consideration 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, cesium chloride is highly soluble in water and shall not be used.

Certification and Documentation

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

(a) Model number and identification number of the source, the contained radionuclide, the source activity and the date to which the source activity relates (LPTA/BM/3 form);
(b) ISO classification certificate;
(c) Leak test certificate;
(d) Contamination test certificate; and
(e) Special form test certificate for transportation purposes[6].

[5] International Atomic Energy Agency, Safety Assessment Plans for Authorization and Inspection of Radiation Sources, TECDOC-1113, IAEA, Vienna, 1999.
[6] Radiation Protection Regulations (Transport) 1989

4.1.2 Internal Design

Source Holder and Rack

The sealed source shall be firmly 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 the outside of 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 might cause radiation hazard.

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. This may take the form of protective shroud, guide bars or floor guides on the product positioning system.

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 be interlocked with the irradiator controls such that if radiation at the exit port exceeds a predetermined level, the conveyor which carries products from the radiation room to the exit port will stop and the source will be automatically fully shielded.

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 so that servicing can 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.

4.1.3 Wet Storage Irradiators

Pool Accessories

An automatic water level control shall be 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 material that will not float, i.e. density greater than 1000 kgm^{-3}. If hollow tubing is used, it shall be fully vented to allow water to flood the tubing to eliminate the risk of high radiation beam up the tube.

Pool Integrity

The containment of the pool shall be watertight and designed to retain 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.

Pool Component Material

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

Water Level Control – Normal

Means shall be provided to automatically replenish water loss from the pool. The system shall be capable of maintaining 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 loss is principally due to evaporation.

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 that 30 cm below the normal make-up water level.

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[7]. Care shall be exercised to avoid the introduction of contaminants into the water system (e.g. deionizer regenerates, cleaning materials, corrosive fire extinguishing materials and spilled product).

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 levels. Reducing evaporation loss from the pool will also facilitate maintaining the conductance of the water below 1000 µS/m for a longer period before regeneration or replacement of deionizer resins is required.

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.

Pool Guard and Cover

A physical barrier such as railing and/or 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 operation.

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.

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

4.1.4 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 radiation room. The triggering of the devices shall cause the source to automatically be 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 radiation 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.

4.1.5 Power Failure

Electrical

Safety control systems shall not be compromised in the event of a power failure. 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.

Non-Electrical

In the event of failure of non-electrical power (e.g. pneumatic or hydraulic power) which is used to control or operate any irradiator safety feature or device means shall be provided to ensure that the source is automatically in the fully shielded position and the irradiator shut down.

4.2 Design Safety for Both Gamma and Electron Accelerators Facilities

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

4.2.1 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 and shall comply to the requirements specified by Act 304 and its subsidiary legislations.*

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 appropriate authority.

Penetrations 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 qualified radiation protection personnel[8] and approved by the appropriate authority.

Penetration pose 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 will need to be restricted.

The shielding properties of particular materials are well established, but experience from existing irradiation facilities should be taken into account.

4.2.2 Access to the Radiation Source and Interlocked System

Facilities requiring access shall be designed such that persons cannot access the radiation 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 of the radiation 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.

Personnel Access Door Interlocks

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

[8] Radiation Protection Officer or Supervisor or accredited personnel.

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 radiation 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 entry has occurred. That individual shall have been trained on how to respond to the alarm and be prepared to promptly render or summon assistance.

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 inter-locked such that a visible or audible alarm indicates when the entry/exit port control mechanism has malfunctioned or has been overridden or tampered with. The irradiation shall be automatically terminated when this occurs and shall prevent the irradiation from being restarted unless the cause has been remedied.

Removable Radiation Room Shield Plugs

Removable radiation 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 interlocked control shall not be accessible outside the radiation shields.

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 the monitor 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 only be undertaken under the direct control of a radiation protection officer.

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

Fully Shielded Facilities[9]

The irradiator shall not be operable until all shielding is in place and all other safety device are actuated. Movable shielding shall be interlocked so that it cannot be displace 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.

4.2.3 Control Console

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

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 is used to operate the irradiator during normal use. This key may be used to operate the control console, gain access to the radiation room and to 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.

[9] Category I and III gamma irradiation facilities and category I electron beam machine.

Emergency Stop Device

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

4.2.4 Radiation Room

Safety Delay Timer with Alarms

The radiation room shall be equipped with a safety delay timer that will automatically generate visible and audible signals to alert persons in the area that 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 leave the area. The timer shall be integrated with the master control system such that irradiation cannot begin unless the start-up sequence has been properly completed within a pre-set time.

Emergency Exit or Shielding

For the protection of anyone inadvertently shut inside the radiation room one or more of the following systems shall be provided:

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

Emergency Stop Device

Means shall be provided within the radiation room to prevent, quickly interrupt or abort irradiator operation and terminate irradiation at any time. The device shall be clearly labeled and readily accessible to workers in the radiation room, and shall cause visible or audible signal to be given outside the room.

4.2.5 Geological Site Considerations

Geological features that could adversely affect the integrity of the radiation shields shall be evaluated by taking into account the physical properties of materials underlying the irradiator site or in its environments. 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.

Seismic Detector

In areas with a significant potential for severe seismic disturbance(10), each of category II or IV gamma irradiator shall be equipped with a seismic detector that causes the radiation source to be automatically 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 actuate at acceleration above 0.05 g.

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 on an evaluation of the maximum earthquake potential in which the regional and local geology and seismology and the specific characteristics of local subsurface materials are taken into consideration.

4.2.7 Ventilation

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

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

4.2.7 Warning Signs and Symbols

Irradiation Device Warning Sign

[10] Earthquakes with acceleration of 0.3 g pr greater is generally classified as severe.

There shall be clearly visible warning sign at the personnel access door to the radiation room bearing the radiation symbol and warnings as prescribed by the Regulatory Authority.

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

Irradiation (Source) Status Indicators

Clearly visible irradiation status indicators shall be provided at the control console to indicate:
(a) when irradiation is terminated (source down or de-energized);
(b) when irradiation is in progress (source up or energized); and
(c) when irradiation 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.

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.

Status indicator Colours

The following colours shall be use when illuminated or colour coded controls are used:

Condition	Colour
Emergency (stop buttons or lights)	Red
Warning – hazard	International trefoil
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

Labeling

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 with the following information:

(a) Name and address of manufacturer;
(b) Model and serial number of irradiator;
(c) Approval number if appropriate; and
(d) Maximum source activity of irradiator.

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

4.3 Design Safety for Electron Accelerators Facilities

The following features shall be considered in industrial accelerator design:

(a) Positive means of disabling the main acceleration system;
(b) Built-in machine parameter monitoring; and
(c) Built-in remote machine diagnostics.

Main Acceleration System Disabling Mechanism

The main acceleration system disabling mechanism must inactive 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.

Built-in Machine Parameter Monitoring

Continuous monitoring of operating parameters shall be used. It offers the opportunity of event logging of failure sequence information for maintenance engineers and for planning repairs.

Built-in Remote Machine Diagnostics

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

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 with 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 maximum current that the electron accelerator can deliver.

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

There are several causes for spurious X-radiation:

(a) 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.
(b) 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 the calculations of the shielding requirements of electron accelerator facilities, only the generated X-rays need be taken into account.

Characteristics X-radiation is an important factor to consider only with electron accelerators up to 300 keV that are self-shielded with heavy element such as lead or depleted uranium. In most cases Bremsstrahlung is more important for radiation shielding.

Operating Parameters

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

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 condition.

4.4 Operational Safety

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 programme 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 local language.

The tests shall include:

(a) Regular testing of safety interlock components for correct operation, according to the instructions of the equipment manufacturers. These tests shall be carried out by the RPO, Supervisor or the Operator and shall be undertaken in the presence of a radiation protection officer, if not done by him.

(b) Only calibrated and good condition radiation meters shall be used. The pre-use test should include a test of the instrument's overload performance, i.e. it should operate correctly up to maximum credible dose rate it may encounter.

(c) 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.

Weekly Tests.

The following tests should be carried out weekly:

(a) A check to ensure that the continuous radiation-monitoring device on the pool water circulation system is functioning correctly (in the case or category IV gamma irradiation facilities).
(b) 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).
(c) A check of the water deionizer for correct operation and air filter, water filters and resins for contamination.
(d) A check to ensure the correct function of the emergency stop button on the control console, the emergency stop device inside the radiation 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.

Monthly Tests

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

(a) A test to ensure that the radiation room monitor is functioning properly; this is done by exposing the monitor probe to a check source until the alarm sounds.
(b) A check, in accordance with the manufactures instructions, of the safety control systems that prevent access in the radiation room when there is any radiation present.
(c) A test to ensure that the product exit monitor is functioning properly; the test is carried out, with the irradiator operating 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.
(d) 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.
(e) A check to ensure that other main items of equipment associated with source movement and control function properly and show no signs of potential failure.
(f) A check to ensure that all product containers are not damaged and in good condition.

If any of the checks indicates a fault or if interlocks do not function properly, the irradiators shall not be used until repairs have been made.

6-monthly Test

Semi-annually, 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.

4.5 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 led to accidents:

(a) storage of sources before installation;
(b) temporary or cease in the use; and
(c) Storage after decommissioning waiting for decision on source return or disposal.

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

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

PART V
OCCUPATIONAL RADIATION PROTECTION

5.1 Designation of Controlled and Supervised Areas

Controlled Area

Any area where specified 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 these areas for irradiation facilities:

(a) Self-contained gamma irradiators (categories I and lll); the room in which the irradiator is housed;
(b) Panoramic gamma irradiators (categories ll and lV); the exposure room and the control room;

(c) Electron beam irradiator (category l); the room in which the irradiators is housed; and
(d) Electron beam irradiator (category ll); 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 marking on the floor. Access points to controlled areas shall be clearly labeled with signs including the radiation warning symbol, the statement “Radiation Controlled Area” and “Kawasan Kawalan Sinaran”.

Access to controlled areas shall be effectively restricted to qualified operators and other staff authorized, in writing, by the RPO. This access control shall be ensured by physical barriers and interlocking systems, where practicable, and by administrative controls such as entry permits issued by the RPO. Such permits shall specify the persons concerned, the areas to be entered, the reason for entry, the duration of 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 RPO and facility manager.

For normal operations a dose rate criterion for a controlled area may be useful and convenient. Therefore, for example, any area where the dose rates exceed 2.5 μSv/h may be designated as a controlled area.

Supervised Areas

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

(a) Panoramic gamma irradiators (categories ll and lV); product entry and exit areas and service areas such as source hoist and water treatment plant rooms.
(b) Electron beam irradiator (category ll); product entry and exit areas, and service areas.

5.2 Workplace Monitoring

Appropriate radiation monitors shall be provided. Surveys shall be undertaken at positions around the facility and at intervals as advised by the RPO, and records of these surveys shall be kept for at least 20 years.

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 radiation room by means of a check source. This shall be located at the entry door.

The monitoring instrument used shall have the following features:

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

All survey meters used for workplace monitoring shall be calibrated at least once a year and only at agencies approved by the AELB.

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 radiation room after the termination of irradiation shall be made by a qualified operator who shall use portable monitor to determine 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.

5.3 Individual Monitoring

For radiation worker who is regularly employed in a supervised area, individual monitoring shall not be required but the occupational exposure of the worker shall be assessed. This assessment shall be done on the basis of the results of monitoring of the workplace or individual monitoring.

Radiation workers in irradiation facilities, including RPO, who are routinely exposed to radiation in controlled areas, operators, qualified experts and some maintenance staff, shall have individual dose monitoring.

This individual dose monitoring (e.g., film, thermoluminescent dosimeters [TLDs]), shall be provided and processed by an agency that has been authorized by the AELB and is traceable to a Standard Dosimetry Laboratory.

The results of personal monitoring measurements shall be recorded and reported as required by the AELB.

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 its effort to recover any missing dosimeters. Delays in the evaluation of a dosimeter can result in the loss of the stored information.

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

5.4 Investigation and Follow-up

The Licensee shall first inform the AELB within 24 hours when it is first known and then shall conduct formal investigations, whenever:

(a) The individual annual effective dose exceeds investigations levels;
(b) Any of the operational parameters subject to periodic quality control are out of the normal range established for operational conditions;
(c) 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
(d) Any other event or unusual circumstances that causes, or as 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 or irradiation equipment).

If overexposure occured 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, including the determination or verification of any doses received, corrective or mitigating actions, and instructions or recommendations to avoid recurrence.

The report shall be submitted to the AELB within 30 days after the incident. 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 or the personal dosimeter.

5.5 Local Rules and Supervision

Local Rules

The operational instructions shall be fully understood by qualified operators and other relevant staff, who maybe occupationally exposed, and should include, as a minimum, the following:

(a) A reminder of the nature of the hazards posed by the facility and the safety features used to minimize the risks.
(b) A reference to the existence and location of the written emergency procedures.
(c) A description of the safety organization, including the functions, duties and responsibilities of the RPO and Supervisor.
(d) The method of implementing the operating instructions and ensuring that the facility is being operated safely. This should include:
    (i) 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, cheek and inspection for it should be specified.
    (ii) The requirement that the operating procedures be available at the control station and that the emergency procedures be conspicuously posted in the area.
(e) The method of ensuring that all persons entering the controlled radiation area wear proper radiation monitoring devices and that the results are recorded.
(f) The method of ensuring that only qualified operator can use the irradiator or have access to the area. This can include controlling keys to the door of the room containing the irradiator control console, controlling operating console keys, or other positive methods to excluding access.

Written instructions shall also be 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 attempt only by approved radiation workers.

Entry into the radiation room following remedial actions should never be made by one person alone.

The safe operation of a facility will depend on the qualified operators following the clearly defined procedures laid down by the manufacturer or supplier and approved by the AELB. In addition to qualified operators, suitably trained and qualified radiation workers 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 RPO on behalf of the Licensee.

Staff Training

The Licensee shall ensure that those of its employees who are engaged in work with ionizing radiation receive such information, instruction and training as will enable them to conduct that 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 specific work practices that should be followed. Examples of the topics in which these personnel are trained include:

(a) The nature of ionising radiation;

(b) The health hazards from exposure to such radiation;

(c) The basic principles and methods of protection (e.g. time, distance and shielding);

(d) Measurement of radiation fields and the units of measurement;

(e) The warning signs and signals and any actions to be taken; and

(f) Actions 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 needs to staff affected by any internal reorganization are reviewed and effected.

The RPO, assisted by the Supervisor shall provide advice on staff training needs and on how those needs may best satisfied. In many cases the RPO can provide much of the training that is required.

The training discussed above is in addition to that which is required to operate the facility safely and which the Licensee shall ensure is provided with the cooperation of the manufacturer or supplier. One important outcome of the training should be to make such persons alert to the simple actions they can take to minimize the 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.

Medical Surveillance

The Licensee shall ensure that medical surveillance for the employees are carried out as follows:

i. Pre-employment medical examination – to be carried out prior to employment.

ii. Periodic review of health – to be carried out once in two years or more frequently if the employee's exposure conditions and state of health so requires.

iii. Medical examination at termination of employment or retirement – to be carried out at termination of employment or retirement.

iv. Special medical examination – to be carried out whenever the employee receives dose exceeding the Annual Dose Limits or in case of suspected overexposure.

PART VI
PUBLIC EXPOSURE

6.1 Responsibilities

The Licensee is responsible for controlling public exposure resulting from sources used in practice.

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 are functional, keys to the control panel are secured to prevent unauthorized access or use.

6.2 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 to ensure appropriate protection (e.g. members of public, shall be accompanied).

- Ensure that adequate control over entry of visitors to a supervised area be maintained and that appropriate signs be posted in such areas.

6.3 Sources that are Not in Active Use

The Licensee shall:

Notify the AELB and submit a plan for transfer or disposal of the sources, if the sources are no longer in use.

6.4 Decommissioning and Source Disposal

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

(a) Buildings and equipment are free from contamination before disposal or re-sale;
(b) All radioactive sources are properly accounted for before returning them to the supplier or disposal;
(c) Any radioactive waste resulting from decontamination is disposed of with the approval by the AELB;

PART VII
SAFETY IN THE TRANSPORT OF RADIOACTIVE MATERIALS

The Licensee shall comply with the requirements of the Radiation Protection (Transport) Regulations 1989 for all activities involving the transport of radioactive sources.

It may be appropriate for the Radiation Protection Officer to travel with the consignment whilst it remains the responsibility of the Licensee.

7.1 Receipt of Radioactive Materials

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. This information shall include the following for each package container:

(a) The nuclide, number and activity of sources.

(b) A description of the source construction and performance tests, including leakage tests.
(c) Special form approval certificate (where appropriate).
(d) A description of the container.
(e) Approval certificate for Type B container.
(f) Details of any special arrangements required, including multilateral approvals, where necessary.
(g) 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 they are satisfied that all the above items are satisfactory.

The supplier and Licensee shall agree on the transport route and responsibility for each stage of the journey. The supplier will normally be responsible from dispatch up until the consignment reaches the point of entry to Malaysia. The Licensee shall then take responsibility for the transport from point of entry to the irradiation facility. Other arrangements are satisfactory provided they are agreed in advanced by both parties and are also acceptable to the AELB.

Arrangements shall also be made for the following where necessary:

(a) The need for special handling equipment, e.g. cranes, forklift trucks etc., during transfer from one mode of transport to another, or between vehicles.
(b) Checking of radiation dose rates from the package or container.
(c) Checking the correct transport labels are attached to the package or container, and replacing any that are damaged or illegible.
(d) Ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labeled.
(e) Security of the consignment during transport, particularly during delays or overnight stops.

7.2 Dispatch of Radioactive Materials

The Licensee shall be required to return packages or containers with radioactive sources to the source supplier after receipt of a consignment of radioactive material. These packages or containers may be either returned empty or containing spent radioactive sources.

Empty Packages

With regard returning empty packages the Licensee shall:
(a) Carry out dose rate and contamination monitoring of both the inside and outside of the package or container to ensure that there is no residual radioactive material present and it can therefore be treated as an empty package or container.

(b) Remove or cover all transport labels relating to the sources contained in the package or container when received.
(c) Examine the package or container to ensure that it is in good condition, and then close it securely, referring to any procedures provided by the source supplier.
(d) Attach a label on the outside of the package or container stating “UN 2908 RADIOACTIVE MATERIAL EXCEPTED PACKAGE – EMPTY PACKAGING”.
(e) Complete a transport document.
(f) Contact the source supplier and agree the transport route and responsibility for each stage of the journey. Inform the source supplier of the proposed date of dispatch.

Return of Spent Sources

With regards to returning spent sources the Licensee shall provide the following information to the consignee for each package or container:

(a) The nuclide, number and activity of sources.
(b) A description of the source construction including leakage tests.
(c) Special form approval certificate (where appropriate).
(d) A description of the container.
(e) Approval certificate for Type B container.
(f) Details of any special arrangements required, including multilateral approvals, where necessary.
(g) A copy of the transport documents (To be sent to the consignee by fax or e-mail before dispatch if possible).

The licensee shall not dispatch the consignment unless they have received confirmation from the consignee that they are prepared to accept it.

The Licensee and consignee shall agree the transport route and responsibility for each stage of the journey. The Licensee will normally be responsible from dispatch up until the consignment reaches the point of entry to the country of the consignee, who shall then take responsibility for transport from point of entry to the consignee’s premises. Other arrangements are satisfactory provided they are agreed in advance by both parties and are also acceptable to the regulatory authorities.

In order to prepare the consignment for dispatch the licensee shall:
(a) Load the sources into the container, verifying the details to be provided to the consignee, e.g. serial numbers and to be entered on the transport document.
(b) Close it securely and then examine and test the package or container to ensure that it is in good condition, referring to any procedures provided by the source supplier.

(c) Carry out contamination monitoring of the outside of the package or container to ensure that there is no residual radioactive material present and it is therefore suitable for transport.
(d) Carry out dose rate monitoring of the package or container and attach appropriate transport labels. The transport labels relating to the sources contained in the package or container when received should not be reused.
(e) Complete a transport document.

Arrangements shall also be made for the following where necessary:

(a) The need for special handling equipment e.g. cranes, forklift trucks etc. during transfer from one mode of transport to another, or between vehicles.
(b) Ensuring that the package or container is securely attached to the vehicle and that the vehicle is correctly labeled.
(c) Dealing with border controls.
(d) Security of the consignment during transport, particularly during delays or overnight stops.

In this situation 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.

7.3 Loading and Unloading of Sources

Loading and unloading operations may expose persons to dose rates in excess of those experienced in normal operations of the facility. 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 assess all risks associated with the loading and unloading work to ensure safety. Any necessary contingency plans should be incorporated into the written instructions for operations of the facility. It is imperative that the integrity of the safety control systems not be compromised by the source loading and unloading procedures. The loading and unloading of the radioactive sources on arrival at the facility or on dispatch from it are potentially hazardous operations and shall be undertaken under close radiation protection supervision. Safety in these operations depends on cooperation 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 in on the site resides with the operating organization.

PART VIII
EMERGENCY PLANNING, PREPAREDNESS AND RESPONSE

This section focuses on identification of possible situations of emergency or accidents, their prevention, preparation for and mitigation of them.

8.1 Potential Exposure

Safety Assessment

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 appropriate authority AELB.

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

The safety assessment shall be documented and revised by an independent expert recognized and approved by the appropriate authority when:

i. Modification of the radiation sources and/or its facilities are made:
ii. Operational experience or information on accidents or errors indicates that the safety assessment should be reviewed; and
iii. 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 76).

The licensee shall incorporate:

i. Defense-in-depth measures to cope with identified events, and evaluate the reliability of the safety system, (including administrative and operational procedures, and equipment and facility design).
ii. The operational experience and lessons learned from accidents and errors into the training, maintenance and quality assurance programmes.

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 but not limited to, as appropriate:

(a) identification of the reasonably foreseeable accidents, incidents or occurrences and their predicted consequences;
(b) communication procedures, including an emergency call out list;
(c) recommended actions for specified situations; this includes 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;
(d) a statement regarding immediate life saving actions;
(e) statutory responsibilities and the names of persons able to take actions to satisfy them;
(f) availability of emergency equipment, including a list of the equipment that should be available, and its location;
(g) 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);
(h) where appropriate, an outline of the post-emergency procedures designed to restore normal operating conditions.

Emergency procedures shall be concise, easily followed instructions. They shall describe what will be indicative of a situation requiring emergency actions, specify the immediate action to be taken to minimize radiation exposure to persons in the vicinity of the irradiator, and allow for the development of the 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 plans has to be implemented and shall arrange for staff training and emergency drills, as 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, 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.

The licensee shall provide emergency and first aid equipment. 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 situations. This will include ambulance, fire, police,

hospital services, local and national authorities, etc. In the event of an accident it is the duty of the Licensee to initiate the emergency procedures and coordinate the initial response of the emergency services and other bodies and to inform the appropriate authority and all relevant parties.

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

(a) a jammed source with the source assembly failing to return to its shielded positions;
(b) part of the sources assembly detached and left in an unshielded position;
(c) malfunction or deliberate defeat of the safety control system;
(d) leakage of the source; and
(e) fire inside the shielded room.

The plan shall contain names and telephone numbers of the next responsible officer to be contacted. Notice shall be posted inside the facility; they should show:

(a) how to contact the RPO or an alternative person who should be notified immediately of any emergency;
(b) how to call the AELB, fire brigade and medical services; and
(c) the location of emergency equipment.

Emergency equipment shall be kept in a clearly labeled cabinet in a readily accessible place. A list of the emergency equipment shall be fixed 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 source should be used during training exercise.

8.2 Accident Response

In responding to an accident the Licensee shall:

(a) Limit radiation exposure; both Individual and collective.
(b) Regain control of the situation in order to restore the site to its normal conditions.
(c) Treat the injured and overexposed.

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

(a) evacuating the area containing the hazard;
(b) warning persons in the immediate vicinity of the accident;
(c) rendering first aid to any person who may be injured;
(d) notifying the RPO;
(e) evaluate cause and extent of the hazard; and
(f) set up appropriate barriers notices, etc. 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 actions to protect workers and public. This will include:

(a) constructing temporary shielding ;
(b) evacuate the immediate area ;
(c) erect barriers to restrict access ; and
(d) recovery of the source should be undertaken in accordance with pre-planned procedures which take into consideration the doses likely to be incurred.

8.3 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 shall inform the AELB of the incident. It should be recognized that the press and the public may require information about the accident in general, and arrangements should be made for handling such inquiries.

IAEA Safety Series No. 91 (Emergency Planning and Preparedness for Accidents Involving Radioactive Materials Used in Medicine, Industry, Research and Teaching, 1989) 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 11 summarizes the Transport Regulations; Section lll 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 Vlll draws attention to the need to provide accurate and authoritative information to the public.

8.4 Accident Reports

Any accident must be notified to the appropriate authority AELB within 24 hours of the incident. The licensee shall submit to the AELB a detailed written report of the incident within 30 days after such incident and the report shall contain:

i) a description of the apparatus, substance or material involved, including its kind, quantity and its chemical and physical forms, wherever appropriate;
ii) the possible radiation exposure to individuals, circumstances under which the exposures could have occurred, the extent of potential hazard to members of the public;
iii) the actions which have been taken, or will be taken, to recover the licensed apparatus, substance or material;
iv) the procedures or measures which have been or will be adopted to prevent a recurrence of the loss or theft of the licensed apparatus, substance or material;
v) any other information which the licensee deems necessary.

8.5 Special Emergency Procedures for Gamma Irradiators

Removal of Damage or Leaking Source

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

If an actual source leak has occurred in Category III or IV gamma irradiator, the use of the irradiator must be terminated by the licensee 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 where appropriate, assistance should be sought to the following as appropriate): the AELB the manufacturer of the device the supplier and the installer of the source (if different from the manufacturer of the device), a person authorized to remove the defective source. Special permission to remove and transport the source should be obtained from the AELB.

Removal of the defective source should be immediate once the decision is made and should be performed by, or under the supervision and in the physical presence of the RPO or the Consultant RPO.

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 the 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 the excessive heating of the product boxes (e.g. by increasing the ventilation);
(c) Inform the radiation protection adviser and officers, plant management, AELB and manufacturer if necessary according to the established reporting procedure
(d) Access 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.

These actions 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) and Emergency Planning and Preparedness for Accidents Involving Radioactive Material Used in Medicine, Industry, Research and Teaching (Safety Series No. 91, 1989).

8.6 Lessons Learned from Accidents in Irradiation Facilities[11]

Since 1950s, ionizing radiation sources have been used in more than 160 gamma irradiation facilities and over 600 electron beam facilities in operation all over the world. Generally, the safety record has been good; however, fatalities and serious injuries have occurred. If control is lost and protection compromised, the high dose

[11] International Atomic Energy Agency, Lessons Learned from Accidents in Industrial Irradiation Facilities, IAEA, Vienna, 1996

rates at these facilities can cause lethal exposures within seconds or minutes as described in **Annex V**.

8.7 Lessons have been Learned from the Findings of Investigations into Severe Accidents at Gamma and Electron Beam Irradiation Facilities. (refer to Annex VI)

8.8 Major Causes of Accidents

Three contributory elements were apparent in each accident.

(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.

(b) 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.

(c) Someone acted inappropriately because of misinformation or lack of knowledge, or a decision was made to ignore conflicting information.

8.9 Prevention and Remedial Actions

(a) Licensee

The licensee is responsible for the possession and use of the irradiator and, thus, for its operation in accordance with the AELB regulations and approvals, permits or authorizations and appropriate international safety standards such as Safety Series No. 107[12].

Therefore, the licensee bears primary responsibility for the safety and safety of the irradiator. It is the responsibility of “the Person Responsible to the License (OBTL)” in that organization to recognize the safety significance of its operation. OBTL needs to exercise leadership in developing and maintaining an attitude or rigor and thoroughness towards safety, which permeates the entire organization.

The licensee needs:

i. To notify the AELB as soon as possible of the intent to purchase an irradiator and to apply for license.

[12] International Atomic Energy Agency, Radiation Safety of Gamma and Electron Irradiation Facilities, Safety Series No. 107, IAEA, Vienna (1992).

ii. To achieve competency with Safety Series No. 107 through appropriate training, in advance of commissioning the facility; training shall include all levels of the organization intended to interact with the facility.

iii. To appoint an RPO to give relevant advice, particularly for training.

iv. To seek, if necessary, the advice of the manufacturer for the preparation of the environmental assessment study and the safety hazard assessment.

v. To prepare, document, implement and audit a preventive maintenance programme.

vi. To ensure that all operational, maintenance and safety related instructions are available in the local language.

vii. To prepare, document, implement and audit an emergency plan, including training, as approved by the AELB.

viii. To establish an audit system whose content is in agreement with supplier and the AELB recommendations.

ix. To apply an approval from the AELB of any intended user modifications affecting safety prior to its implementations.

x. To conduct a safety system review at least annually and to document the results, which should be made available to the AELB for review; if a warning notice from the supplier or the AELB is received by the licensee, the review should be held as soon as possible.

xi. To implement additional safety devices consistent with the supplier's advice so that all the equipment is current with the latest regulatory requirements.

PART IX
GLOSSARY

9.1 Absorbed dose

The absorbed dose, D. The fundamental dosimetric quantity D, defined as:

$$D = \frac{\mathrm{d}\bar{\varepsilon}}{\mathrm{d}m}$$

where ***dε*** *is the mean energy imparted by ionizing radiation to matter in a volume element and* ***dm*** *is the mass of matter in the volume element.*

9.2 Activity

The quantity *A* for an amount of radionuclide in a given energy state at a given time, defined as:

$$A(t) = \frac{\mathrm{d}N}{\mathrm{d}t}$$

where d*N* is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval d*t*.

The unit of activity is the becquerel (Bq)
1 Bq = 1 disintegration per second (dps)

This replaces the curie as the unit of activity
1 Ci= 3.7×10^{10} dps;
1 Bq = 2.7×10^{-11} Ci

9.3 Becquerel (see 9.2)

9.4 *Bremsstrahlung*

Ionizing radiation produced by the deceleration of electrons in the vicinity of nuclei.

9.5 Contamination

The presence of radioactive material in or on a material or the human body or other places where they are undesirable or could be harmful.

9.6 Dose

A measure of the energy deposited by *radiation* in a target.

9.7 Dose equivalent

The product of the absorbed dose delivered by each type of radiation averaged over a tissue or organ and the radiation weighting factor for the same type of radiation.

9.7.1 Incident

Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

9.8 Radiotoxicity

The potential of radioactive material, when introduced into the body, to cause damage to living tissue by absorption of energy from the radiation it emits.

9.8.1 Source container

A component that encloses a radioactive source (see 9.14) and provides, by attenuation and by distance some protection of individuals from the high radiation levels close to the radioactive source.

Annex I

DOSE LIMITS FOR OCUPATIONAL AND PUBLIC EXPOSURE

The following is reproduced from the Radiation Protection (Basic Safety Standards) Regulations 1988.

OCCUPATIONAL EXPOSURE

Dose limits

1. 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[13];
   (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[14] (hand and feet) or the skin of 500 mSv in a year.

2. For apprentices and for students of 16 to 18 years of age who are training for employment involving exposure to radiation and for students of 16 to 18 who are required to use sources in the course of their studies, and the occupational exposure shall be so controlled to ensure 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 of the skin of 150 mSv in a year.

[13] 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.

[14] 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.

Special Circumstances

3. Where special circumstances exist which require a temporary change in the dose limitation requirements of the Radiation Protection (Basic Safety Standards) Regulations 1988, the Licensee shall apply to the AELB for such a temporary change where:

   (a) the dose averaging period mentioned in para 1(a) may exceptionally be up to 10 consecutive years as specified by the AELB, 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 AELB 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

4. The estimated average dose to the relevant critical groups of members of the public that are attributed to practice 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.

Annex II

QUALIFIED OPERATOR TRAINING PROGRAM

1. **Basic Radiation Protection:**
   (a) Structure of the atom:
   Radioactivity.
   Half-life.
   Ionization.
   Radiation and contamination.
   (b) Units of radioactivity, dose and dose rate:
   SI units and scientific notation.
   (c) Protection from external radiation:
   Time, Distance, Shielding.
   (d) Outline of legislative and license requirement
   (e) Use of monitoring instruments and Personal dosimeters
   (f) Emergency procedures
   (g) Review of incidents and accidents at irradiation facilities

2. **Irradiation Facility:**
   (a) Layout and design of facility.
   Source and product movement sequences.
   Including tour of all areas.
   (b) Facility operational and administrative procedures
   Including demonstration of correct procedures for entry to irradiation cell.

Annex III

ROUTINE CHECKS TO BE CARRIED OUT BY RPO

The frequency with which these checks should be undertaken will depend on the nature of the facility, its age 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 to ensure 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 record
   Radiation monitoring instruments test records
   Leakage test records
   Check availability of local rules and procedures

2. Monitors
   Hand held monitor available, battery o.k.?
   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)

Controls console. Checks against list of installed signals. Operating correctly?

5. General observations

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

6. Radiation survey record

Carry out radiation survey of the facility according to a pre-determined plan, record the results and compare with previous and standard results.

Annex IV

Bibliography

1. Atomic Energy Licensing Act 1984 (Act 304).

2. Radiation Protection (Licensing) Regulations 1986 [P.U.(A)149].

3. Radiation Protection (Basic Safety Standards) Regulations 1988 [P.U.(A)61].

4. Radiation Protection (Transport) Regulations 1990 [P.U.(A)456].

5. IAEA, Practice Specific Model Regulations: Radiation Safety of Non-Medical Irradiation Facilities (Interim report for comment), TECDOC Series No. 1367, Vienna, 2003.

6. IAEA, Radiation Safety of Gamma and Electron Irradiation Facilities, Safety Series No. 107, Vienna, 1992.

7. IAEA, Manual in Panoramic Gamma Irradiators (Categories II and IV), IAEA-PRSM-8, Vienna, 1993.

8. IAEA, Manual in Self Contained Gamma Irradiators (Categories I and III), IAEA-PRSM-7, Vienna, 1993.

9. IAEA, Lessons Learned from Accidents in Industrial Irradiation Facilities, Vienna, 1996.

10. IAEA, Safety Assessment Plans for Authorization and Inspection of Radiation Sources, TECDOC-1113, Vienna, 1999.

11. IAEA, Occupational Radiation Protection, Safety Guide RS-G-1.1, Vienna, 1999.

12. International Organization for Standardization, ISO 2919, Radiation Protection – Sealed Radioactive Sources – General Requirements and Classification (1999)

Annex V

Lessons Learned from Accidents in Irradiation Facilities:

a. Stimos, Italy: May 1975 (put everything under new Annex V)

An unskilled worker employed to load sacks on to a conveyor entered an irradiation cell by crawling through and along an access opening used to accommodate the conveyor. The conveyor was empty, but a high activity Co-60 source was in an 'unshielded' position; the irradiator was unattended. The worker received doses in the range of 8 – 24 Gy to various parts of the body, and died 13 days later.

b. Kjeller, Norway: September 1982

Upon hearing an alarm ringing, a maintenance technician switched it off at the irradiator control panel, opened the door to the irradiation chamber and entered. A green light at the control panel indicated that the source was 'shielded', but the radiation monitor indicated high radiation levels. The worker remained in the irradiation chamber for several minutes and was inadvertently irradiated. He died of radiation injuries 13 days later.

c. San Salvador, El Salvador: February 1989

At 02:200 hours an operator on night shift heard the source transit alarm ringing, which indicated a fault. This resulted in the source rack being automatically lowered from the irradiation position into the storage pool. In spite of following the reset procedure, the alarm continued ringing, which meant that the rack holding the source has not returned to the 'fully-down' position. The operator manipulated the 'source-down' microswitch to induce a green light on the control panel and to signal that the source rack was down. He then manipulated the control panel and to simulated monitor detection of a safe background radiation level, although the radiation monitor had been removed about 5 years before. After waiting for some minutes, he entered the irradiation chamber, but did not check the radiation level on the portable radiation monitor. Unable to free the source rack by himself, the operator brought in 2 untrained workers from another department to help remove the boxes and to lower the rack. When the rack was lowered into the storage pool, the workers saw the blue glow of Cerenkov radiation and hurriedly left the irradiation chamber. All the workers soon became ill and were taken to hospital. The most exposed worker, who had initially been exposed about 1 hour earlier that the other workers, eventually had a leg amputated, but died shortly thereafter. The second had both legs amputated, but recovery was rapid with good prognosis. The third had chronic residual effects, but the symptoms were much less severe and the prognosis for full recovery was good.

d. Sor-van, Israel: June 1990

When a product transport jam occurred, a gamma radiation alarm sounded, but the 'source down' light came on. At the time, the irradiator was unattended, so the duty operator was informed at home. On arrival at the facility, the operator activated power to the control console and 3 signals were shown:

i) the product jam warning light.
ii) the 'source down' signal.
iii) the gamma radiation alarm.

Contrary to the operating procedures, written in English (not the local language), the operator decided to deal with the matter without calling his supervisor. The operator decided that the 'source down' signal was correct, so he disconnected the cable from the radiation monitor to the alarm circuitry. This silenced the alarm, but he still had to open the door by performing a radiation monitor test. However, there was an established trick to simulate this test by manipulating the console controls. Carrying the console key attached to the portable radiation monitor but did not check it against a radioactive check source mounted on the door. The portable radiation monitor was not functioning on the low dose range to which the operator had switched. He saw that a carton had hammed the source rack. (The facility had not installed the source shroud recommended by the source supplier.) He did not notice that the source was in the 'up' position and not in the water of the storage pool. He left the room and returned with a cart to remove the damaged cartons. The operator took fright when he felt a burning sensation in his eyes and a pounding sensation in his head. Despite intensive medical care, he died of radiation effects 36 days after exposure.

e. Nesvizh, Belarus: October 1991

An operator was exposed to Co-60 radiation following a jam in the product transport system. The precise actions of the operator were not known, but certain facts are clear. The key to raise the source was in the main operating console after the accident, and it is likely that entry into irradiation chamber was accomplished without removing the key. This same key was required to operate a mechanism that controlled a movable floor that covered a pit at the maze entrance leading to the irradiation chamber. After the accident, the movable floor section was found in the open position and it is assumed that the operator was able to cross the pit by stepping on to the motor used to drive the movable floor section. The operator apparently took a portable dose rate monitor with him because it was later found at the point where the maze entrance joins the irradiation chamber. The monitor was confirmed to be in correct working order. There is a possibility that the source movement mechanism has jammed, but after the accident the source was found in the 'fully shielded' position. The source transfer mechanism was tested and found to be operating satisfactorily. It seems probable that the source was in the 'safe' position when the operator entered the irradiation chamber. Since the key was in

the console, the source could have been raised by accidental depression of the exposure button, by a component failure, or because of a fault in the logic control system. The operator reported feeling a headache and pain in his joints and gonads after about 1 minute inside the irradiation chamber. He then saw the source, ran out of the irradiation chamber and told his assistant that he had been irradiated. Despite intensive medical treatment, he died 113 days after exposure. There are many unknown facts as to the actual circumstances of this accident; however, it is clear that the specified operating procedures were not followed and that the safety features were circumvented.

f. Illinois, USA: February 1965

A worker entered a room in which a linear accelerator was operating by crawling under an interlocked door, the bottom half of which had been removed to permit installation of a conveyor system. Doses to the right side of the worker's body were very high. His right arm was eventually amputated above the elbow and his right leg above the knee. Other details of the facility safety systems and safety instructions to the worker were not given in the documentation.

g. Maryland, USA: December 1991

The radiation source was of a 3 MV potential drop accelerator design for producing high electron beam currents for processing of materials. During maintenance on the lower pressure plate, the operator placed his hands, head and feet in the beam. This was done with the filament voltage of the electron source turned off, but with the full accelerating potential on the high voltage terminal. The operator's body, especially his extremities and head, was exposed to electron dark current. Three months after the accident, the four digits of the operator's right hand and most of the four digits of his left hand had to be amputated. Hair thinning on the scalp was also observed after 2 weeks, with no re-growth after 6 months. Although the initial facility design included redundant interlocks and systems to prevent entry into the irradiation chamber when the accelerator was operating, the management and employees had systematically removed, disabled or circumvented the safety systems. Also, senior operators appeared to lack understanding of the operation of the electron source and the existence of a cold or dark current even when the filament was not powered. While this dark current was orders of magnitude lower than normal operating procedures, it was sufficient to produce dose rates of 0.4-13 Gy/s to various parts of the operator's body.

h. Hanoi, Vietnam: November 1991

A physicist returned to the irradiation chamber of an electron beam linear accelerator to readjust the position of a sample. Another researcher, believing the physicist had left the irradiation chamber, told the operators that the experiment was ready and that the machine could be switched on. The facility was not equipped with any access interlocks or warning signals, and the physicist continued to

manipulate the sample while the accelerator was operating at an energy of 15 MeV. The second researcher became concerned and, after shouting the physicist's name and failing to get a reply, he asked the operator to turn off the accelerator. The physicist had placed his hands within 5 – 30 cm of the tungsten target about three times during the 2-4 minutes the accelerator had been on. Estimates of the dose to the physicist's hands were difficult to make, since at the time of the accident there were no calibrated radiation measuring devices at the facility. The physicist sustained serious radiation injuries to his hands; ultimately, the right hand and two fingers of the left hand had to be amputated.

Annex VI

Lessons Learned from the Findings of Investigations

(a) Redundant and diverse safety systems could have prevented most accidents. For example, in all the overexposure, the operator places ultimate reliance on access barriers and/or interlocks governed by the source rack position, or on condition signals alone.

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

(c) The management of the operating organization can quickly lose control of the employees' level of knowledge and performance unless systematic audits are conducted and frequent training is provided. For example, in several facilities, the personnel involved in accidents had employed tricks to circumvent the safety systems.

(d) Management practices or attitudes resulted in the degradation of safety systems and operating procedures. It appears that product and production costs sometimes took precedence over safety. This was particularly evident when oversight from regulatory authority was absent or weak. For example, toleration by management of the removal or defeat of radiation activated interlocks played a major role in some accidents.

(e) Personnel adequately trained to handle routine operations were not acknowledgeable 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, personnel involved in accidents routinely failed to appreciate the necessity of making a radiation survey with a demonstrably operational radiation monitor.

CONTRIBUTORS TO DRAFTING AND REVIEW

Dr. Muhamad Lebai Juri	Malaysian Nuclear Agency
En. Mohd. Sidek bin Othman	Malaysian Nuclear Agency
Tn. Hj. Yaziz bin Yunus	Sterilgamma (M) Sdn. Bhd.
Tn. Hj. Anuar bin Mokhtar	Department of Safety and Health
Dr. Mohd. Samudi bin Yasir	Universiti Kebangsaan Malaysia
Dr. Faraizah bt. Abd. Karim	National Blood Centre
Pn. Monalija bt. Kostor	Atomic Energy Licensing Board
Pn. Marina bt. Mishar	Atomic Energy Licensing Board
En. Nik Mohd Faiz bin Khairuddin	Atomic Energy Licensing Board

BODIES FOR THE ENDORSEMENT OF CODE OF PRACTICE

Standing Safety Committee, Atomic Energy Licensing Board

Orang Besar Daerah Sepang: YDM Prof. Madya Dato' Dr. Tengku Jamaluddin Tengku Mahmud Shah Al-Haj; *Malaysian Nuclear Agency:* Dato' Dr. Rehir Bin Dahalan; *Penang General Hospital:* Dato' Dr. Mohamed Ali Bin Abdul Kader; *Atomic Energy Licensing Board*: YM Raja Dato' Abdul Aziz Raja Adnan; *Universiti Kebangsaan Malaysia:* Prof. Dr. Ismail Bahari; *Universti Sains Malaysia:* Prof. Dr. Abdul Aziz Bin Tajuddin; *MOSTI Legal Advisor:* Tuan Hasbullah Adam; *SIRIM Bhd.:* Dr. Khazali Bin Haji Mohd. Zin; *Ministry of Health:* En. Lee Peter; *Malaysian Nuclear Agency:* En. Mohd Yusof Bin Mohd Ali; *Department of Safety and Health:* Tuan Haji Anuar Bin Mohd Mokhtar; *Atomic Energy Licensing Board:* En. Mohd Pauzi Bin Mohd Sobari; *Atomic Energy Licensing Board:* En. Mohd Yasin Sudin; *Atomic Energy Licensing Board:* En. Hamrah Mohd Ali; *Atomic Energy Licensing Board:* En. Hasmadi Hassan; *Atomic Energy Licensing Board:* Pn. Azlina Mohammad Jais