

# **GOVERNMENT OF INDIA**

# **AERB SAFETY GUIDE**

# X-RAY GENERATING EQUIPMENT FOR RESEARCH, EDUCATION, INSPECTION AND ANALYSIS



# **AERB SAFETY GUIDE: AERB/RF/SG/XGE**

# X-RAY GENERATING EQUIPMENT FOR RESEARCH, EDUCATION, INSPECTION AND ANALYSIS

Atomic Energy Regulatory Board Mumbai - 400094 India

December, 2025

Order for this Guide should be addressed to:

The Chief Administrative Officer Atomic Energy Regulatory Board Niyamak Bhavan Anushakti Nagar Mumbai - 400094 India

#### **FOREWORD**

The Atomic Energy Regulatory Board (AERB) was constituted in 1983, to carry out certain regulatory and safety functions envisaged under Section16, 17 and 23 of the Atomic Energy Act, 1962. AERB has powers to lay down Safety Standards and frame rules and regulations with regard to the regulatory and safety requirements envisaged under the Act. The Atomic Energy (Radiation Protection) Rules, 2004, provides for issue of requirements by the Competent Authority for radiation installations, sealed sources, radiation generating equipment and equipment containing radioactive sources, and transport of radioactive materials.

With a view to ensuring the protection of occupational workers, members of the public and the environment from harmful effects of ionizing radiations, AERB Regulatory Safety Documents (REGDOCs) establish the requirements and guidance for all stages during the lifetime of nuclear and radiation facilities and transport of radioactive materials. These requirements and guidance are developed such that the radiation exposure of the public and the release of radioactive materials to the environment are controlled; the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation is limited, and the consequences of such events if they were to occur are mitigated.

The Regulatory Documents (REGDOCs) apply to nuclear and radiation facilities and activities giving rise to radiation risks, the use of radiation and radioactive sources, the transport of radioactive materials and the management of radioactive waste.



Fig. 1 Hierarchy of Regulatory Documents (REGDOCs)

Safety Codes establish the objectives and set requirements that shall be fulfilled to provide

adequate assurance for safety. Safety Standards provide models and methods, approaches to achieve those requirements specified in the Safety Codes. Safety Guides elaborate various requirements specified in the Safety Codes and furnish approaches for their implementation. Safety Manuals detail instructions/safety aspects relating to a particular application. The hierarchy of Regulatory Documents depicted in Figure.1.

The recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) are taken into account while developing the AERB REGDOCs. .

The principal users of AERB REGDOCs are the applicants, licensees, and other associated persons in nuclear and radiation facilities including members of the public. The AERB REGDOCs are applicable, as relevant, throughout the entire lifetime of the nuclear and radiation facilities and associated activities. They also form the basis for AERB's core activities of regulation such as safety review and assessment, regulatory inspections and enforcement.

Persons engaged in handling of X-ray generating equipment for research, education, inspection and analysis are required to obtain Licence from AERB under Atomic Energy (Radiation Protection) Rules, 2004. This Guide elaborates the requirements to be met by persons engaged in manufacturing, supply and operation of X-ray generating equipment for research, education, inspection and analysis, for protection of people and environment and safety of sources (generators). The requirements are given in AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/RF/SC, 2025. This Safety Guide is effective from the date of its issue.

Consistent with the accepted practice, 'should' and 'may' are used in the Guide to distinguish between a recommendation and a desirable option respectively. Appendix is an integral part of the document, whereas annexure and bibliography are included to provide further information on the subject that might be helpful to the user(s).

The initial draft was prepared by an In-House Working Group (IHWG) of AERB, which was then reviewed by the Task Force (TF) with specialists drawn from technical support organizations and institutions, and other consultants.

The Comments obtained from domain experts and relevant stakeholders have been suitably incorporated. The Safety Guide has been reviewed and concurred by the AERB Advisory Committee on Nuclear and Radiation Safety (ACNRS).

AERB wishes to thank all individuals and organizations who have contributed to the preparation, review and finalization of the Safety Guide. The list of experts, who have participated in this task, along with their affiliations, is included for information.

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# SPECIAL TERMS AND INTERPRETATION (Specific to the Present Guide)

# **X-ray Generating Equipment**

Equipment capable of generating X-rays for intended/specific application.

# **ABBREVIATIONS**

AERB Atomic Energy Regulatory Board

EPR Emergency Preparedness and Response

NOC No Objection Certificate

OEM Original Equipment Manufacturer

PCB Printed Circuit Board

PXS Portable X-Ray Scanner

RPP Radiation Protection Programme

RSM Radiation Survey Meter

RSO Radiological Safety Officer

XBIS X-ray Baggage Inspection System

XRD X-ray Diffractometer

XRF X-ray Fluorescence Device

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#### 1. INTRODUCTION

#### 1.1. General

Radiation sources have many beneficial applications in medicine, industry, research and agriculture. The radiological consequences to workers, public and environment that may arise from these applications have to be assessed and, as necessary, minimized. Activities having bearing on the safe operation of X-ray generating equipment, therefore, are subject to regulation for radiation safety.

AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/RF/SC, 2025, issued under the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, stipulates the regulatory requirements for compliance by radiation facilities.

X-ray generating equipment are widely used for several applications in industries, research centres, academic institutions/universities, for reseach, analysis, training as well as for scanning of materials/packages for security and other purposes. Self-shielded X-ray based equipment viz X-ray Baggage Inspection System (XBIS) & CT based X-ray Baggage Inspection System (CT-XBIS) are used for scanning of baggage. X-ray based Food Scanners and mail scanners are used for the scanning of the manufactured food products for quality control and scanning of mail packages respectively. X-ray Fluorescence Device (XRF) (cabinet and hand-held Type) and X-ray Diffractometer (XRD) are used in various industries, research centres, and in academic institutions/universities for research and analysis purposes to investigate / identify the materials and their composition. X-ray Printed Circuit Board (PCB) Analyzers are used for checking the quality of PCB in electronics industry. Portable and hand held X-ray scanners are used by security personnel for imaging of suspicious items in the field. Cabinet type equipment are used for Non-destructive Testings (for example Tyre inspection, casting inspection etc.).

Electron microscopes are used in research and academic institutions. The X-rays generated in an electron microscope, are generally well shielded by the microscope and the associated housing. Electron beam welding machines are used in various engineering

applications for welding, which use electrons as primary (radiation) heat source. The secondary radiation (viz X-rays) emitted from electron beam welding machine is required to be shielded, to protect the operators and others. Most of these units are self-shielded (or cabinet type). X-ray generating equipment can be procured and handled in India only by the users duly authorized by AERB. Most of the above equipments emit low intensity X-ray radiation and radiation levels are generally less than  $1\mu Sv/h$  at 10 cm from the accessible surface of the equipment.

# 1.2. Objective

The objective of this document is to provide guidance in order to meet the relevant regulatory requirements prescribed in AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/SC/RF, 2025, by specifying relevant procedures and elaborating radiation safety requirements in the design, manufacture, supply, installation, operation and decommissioning.

#### 1.3. Scope

X-ray generating equipment covered in this guide are those generating X-rays in the kilovoltage range (generally in the range of 30 kV-300 kV), as described in para 1.1. This Safety Guide elaborates the radiation safety provisions as applicable to manufacturers, suppliers and users of X-ray generating equipment for research, education, inspection and analysis (denoted as XGE in this Guide). It also applies to the persons involved in servicing and maintenance of such equipment.

This guide excludes the following:

- (i) Any application/equipment containing radioactive source;
- (ii) X-ray irradiation chamber;
- (iii) X-ray based industrial radiography (other than self-shielded units);
- (iv) X-ray based nucleonic gauging devices;
- (v) X-ray generating equipment used for human imaging;
- (vi) X-ray/Accelerator based vehicle/cargo/container scanning systems.

The above practices are covered in other Safety Guides. Equipments which are exempted from regulatory control for use and disposal, as per relevant notifications, are also out of the scope of this guide.

#### 2. RADIATION PROTECTION AND SAFETY

#### 2.1. General

In this chapter, the radiation protection principles viz, Justification, Optimization and Dose Limits are outlined. Although care for radiation safety is taken in the design of the equipment itself, it is essential that the user should have adequate knowledge about safe handling of these equipment. The licensee (employer) has the prime responsibility for protection and safety of radiation workers, public and environment at all times and should comply with the regulatory requirements.

#### 2.2. Justification

Justification is the process of assessing the benefits **derived** from the practice involving exposure to ionizing radiation **over the potential risk associated with it**.

The employer should ensure that no practice or activity involving exposure to radiation is performed, unless it produces more benefit than any harm it may cause.

While justifying a practice, the justification process should consider all aspects of the practice, including manufacture, assembly, its use by end user and decommissioning.

Before using any XGE covered in this guide, the employer should explore any other available options which do not involve the use of ionizing radiation.

# 2.3. Optimization

Licensee should ensure that procedures are in place for the protection of personnel, the public and the environment. Licensee must also ensure that doses are kept as low as reasonably achievable, with economic and social factors being taken into account (the principle of optimization) and always within the prescribed dose limits (see para 2.4).

The optimization process should also consider minimizing the number of individuals exposed and the magnitude for likelihood of exposure. The radiation protection measures should be customized to meet the need of the institution. The management structure of the institution, policies, responsibilities, procedures and arrangements should be in place to control radiation hazard, to optimize radiation protection measures, to prevent/reduce exposures, and to mitigate the consequences of incidents associated with the practice.

#### 2.4. Dose Limits

The licensee should ensure that the exposure to worker or public due to the authorized practice is so restricted that neither the effective dose nor the equivalent dose (to specified tissues or organs) exceeds the dose limits prescribed by Atomic Energy Regulatory Board (AERB) from time to time. The dose limits for occupational exposure and relevant public exposure should never be exceeded. The dose limits prescribed by AERB are reproduced in Appendix-I.

The dose limits apply to all users of radiation sources including short-time contract workers, research workers, and students. For exposure of students and researchers in the age group of 16 to 18, using an XGE in the course of their studies, the dose limits for Apprentices and Trainees, as provided in Appendix-I, are applicable.

The dose received from natural background radiation and medical exposures are not part of the dose limits.

# 2.5. Management for Safety

In order to achieve overall safety during handling of an XGE, an effective management system should be in place so that the safety requirements, which include human performance, quality, protection of the environment, promotion of safety culture, assessment of safety performance and lessons learned are fulfilled.

A Radiation Protection Programme (RPP) should be established by the institution to ensure radiological safety during normal operation, maintenance, decommissioning, and in emergency situations as stated below:

- (i) the radiation exposure of both workers and the public is kept as low as reasonably achievable (ALARA principle);
- (ii) the probability of events giving rise to significant exposures and the magnitude of such exposures are kept as low as reasonably achievable;
- (iii) the radiation exposure to both workers and the public are kept below the dose limits prescribed by AERB from time to time;

(iv) a safety culture is fostered and maintained amongst all the workers involved in the operation of XGE. This is necessary to encourage a positive attitude towards protection and safety and to discourage complacency / negligence.

The licensee and the institution operating an XGE, through its management, should establish and implement technical and organizational measures to ensure protection and safety for handling the XGE. Organizational and technical measures should include the following:

- (i) The licensee should have overall responsibility of overseeing radiation safety, and that operation of XGE is carried out in accordance with the regulatory requirements;
- (ii) The licensee should prepare an SOP for each equipment type, with the guidance of the manufacturer/supplier and ensure that the XGE are operated in accordance with the Standard Operating Procedures (SOP);
- (iii) Development, implementation and assessment continually improve the quality management system, which defines the responsibilities of all relevant persons and which also details out the requirements of the institution, personnel and equipment.
- (iv) Availability of suitable facilities and equipment to ensure safety during operation of the XGE.

The responsibilities of various personnel are specified in Appendix V.

# 3. DESIGN OF RADIATION SOURCES, EQUIPMENT AND INSTALLATION

#### 3.1. General

The design requirement for an XGE and radiation installation play a major role in ensuring radiation safety while using X-ray equipment. While designing, provisions should be made to minimize any undue exposure to personnel and occurrence of incident or emergency situations. This chapter is applicable to all stakeholders such as manufacturer, supplier and the end user of XGEs.

# **3.2.** Sealed Source (Not Applicable)

In order to maintain consistency amongst all 15 practice specific guides, the chapters, sections and sub-sections in all the 15 practice specific guides, including this safety guide have been maintained same. The section on 'Sealed Source' is not relevant to XGEs, hence is not applicable to this guide.

# **3.3.** Source Housing (X-ray tube housing)

Source housing is the shielding provided to a device containing an X-ray tube. The housing is designed such that the radiation level outside the useful beam remains within the limits for leakage radiation levels, specified by AERB. The X-ray tube should be incorporated within a specially designed housing that provides adequate shielding. Equipment-wise limits for leakage radiation levels are provided in Appendix-IV.

#### 3.3.1 Source Housing integrity

The design of source housing of XGE should meet the national/international standards including marking and labelling. The source housing is to be so designed so as to retain the integrity of shielding under all conditions.

# 3.3.2 Securing of X-ray Tube in the Housing

The source housing or device, wherever applicable, is required to have a mechanism such that the X-ray tube is kept secured within the housing and its removal is possible only using special tools by trained individuals.

#### 3.3.3 Radiation Symbol and Warning Sign

A radiation symbol or warning sign should be conspicuously and prominently displayed on the X-ray tube housing and outer surfaces of the equipment, wherever applicable.

The equilateral triangle radiation symbol with 'CAUTION-X-RAY' as the warning sign should be used for X-ray tube housing and X-ray generating equipment. Specifications of radiation symbol and warning sign are stipulated in the safety directive issued by AERB, which is reproduced in Appendix-II.

# 3.4. Design of Radiation Equipment

The design of the XGE should meet the requirements of relevant national/international standards (such as IS, CE, IEC or equivalent). Conformity of the XGE with national/international standard should be established, and an authenticated report in this regard should be submitted by the manufacturer/supplier to AERB for obtaining type approval of the equipment. Paragraphs 3.4.1 to 3.4.6 below, elaborate the design requirements of different types of XGE. The regulatory requirements for safety may be periodically amended based on updated technology and safety standards, and on operational feedback from the users.

It is the responsibility of the manufacturer/supplier to ensure that the XGE meets the current requirements. In respect of already supplied equipment, manufacturer/supplier should ensure that (a) the revised requirements are duly complied with, wherever feasible and (b) the updated safety requirements are brought to the notice of the users of such equipment.

# 3.4.1 Design of X-ray based Equipment

Radiation generating equipment consists of X-ray tube(s) housed under adequate shielding, electrical cable and control panel. Depending on equipment type, these components may be housed inside a single equipment or may be configured separately. Design of the X-ray based equipment is required to meet the applicable test requirements from radiation safety point of view. In addition, the design of an XGE should comply with the applicable regulatory requirements for conventional safety, relating to hazards such as fire, mechanical and electrical, for the purpose of its intended use, prescribed by the relevant competent authorities. Equipment should be subjected to Type Approval Tests as per the national/international standards. Details related to the basic radiation safety performance tests, allowable leakage limits and required safety features are provided in Appendix-IV.

In respect of equipment for which AERB has published safety standards, it is required that the design specifications meet such standards; otherwise, the applicable national/international standards should be complied with. For such equipment, if national/international standards are not available, the manufacturer should ensure that the design of the X-ray equipment complies with the standards of the country of origin. In case such standards are not available, the equipment design should meet the objectives of standards for similar equipment.

The self-shielded X-ray units like XBIS, CT-XBIS, Food Scanners Inspection systems, XRF (Cabinet Type), PCB Analyzers, XRD, cabinet type equipment for non-destructive testing, Electron Beam Welding Machine, etc., do not require any room shielding. However, the equipment design should be such that the beam cannot be switched "ON", unless the door of the cabinet/shutter/window is completely closed. The shielding incorporated around the source housing itself, should ensure that the radiation level at 10 cm from any accessible external surface (e.g. cabinet) of the equipment is within the limit  $(1 \, \mu \text{Sv/h})$ .

In several other types of equipment such as XRF (Hand-Held Type), the object to be examined is kept in an open place. For such devices, the primary radiation beam should have very small dimension (few millimeters) and necessary interlocks should be provided to prevent any accidental energizing of the equipment.

Some of the equipment are intended to be used in open field conditions, such as portable X-ray scanners used by government agencies such as law enforcement, security etc. exclusively for detection of suspected objects. For these types of equipment, the dose per scan/exposure should not exceed 5  $\mu$ Sv at a distance of 30 meters in any direction from the X-ray generator, measured without placing any object and image in the beam. Such portable scanners used in the open field, should have the provision for remotely operating the device from a distance of at least 30 meters from the scanner.

All the handheld devices should have proximity sensor, so that the beam does not get switched "ON", unless the object to be scanned is present at the desired distance from the equipment. Such equipment should also give audio/visual indication, when the X-ray beam is in "ON"... All the hand held/ portable X-ray equipment should have a preset

timer, such that after the lapse of the preset time, the beam gets cut off automatically, to avoid unnecessary exposure.

The design of the table top equipment used for analysis of material (e.g. gold purity analyser), should be such that beam cannot be switched "ON", unless the door of the cabinet/shutter/window is completely closed.

All the cabinet/self-shielded type equipment should be equipped with warning lights to notify the beam status (ON/OFF).

# 3.4.2 Fail-Safe Mechanism

Design of the XGE, should be such that the X-ray beam gets de-energised automatically in the event of any malfunctioning, and should remain de-energised, until the equipment is reset manually and restarted from the control panel.

If the equipment operation is interrupted using emergency switches/stop-button/other-mechanism, the equipment should get de-energised and the X-ray beam turns- OFF immediately and it should remain so, until it is reset.

#### 3.4.3 Safety Interlocks

Wherever an XGE is controlled by electrical or any other system, it should be so designed that any unsafe condition can be prevented by suitable safety interlock systems.

Some examples of typical interlocks for XGE are described below:

Emergency Push Button: Provision of emergency push-button should be made in the XGE. For equipment used in fixed locations such as XBIS, PCB Analyser and Cabinet type systems, emergency Push Button (e.g. mushroom switches) should be provided at various locations, such as control panel and cabinet surfaces. The number of such buttons to be provided depends on the equipment size. For large size equipment, these buttons may be provided at the rear and side surfaces also, which should be easily identifiable and accessible during an emergency. Necessary instructions for using these buttons should be displayed near these buttons.

**Door Interlocks**: The door interlock functions on the simple principle that X-ray beam cannot be in energised state whenever any of the interlocked doors is open. Door

interlocks should be so provided, that the X-ray beam cannot be in an energised state, when any of the interlocked doors is open. If the door is opened while the equipment is in use, the X-ray beam should switch OFF autoimatically.

For the fixed installation, where the equipment is intended to be manufactured/tested inside a room with biological shielding, interlocks should be provided to the doors of the room.

In a cabinet type equipment, interlock should be provided to the product entrance / exit door and service door. For equipment, where lead flaps are used to limit the radiation level at product entry-exit points, interlocks should, wherever feasible, be so provided that X-ray beam cannot be energized unless flaps are in the intended position.

**Proximity Sensors/Other Sensors**: For handheld devices used for analysis and inspection, proximity sensors should be provided, which allows energizing of the X-ray unit only when the object to be analysed/inspected is at the intended distance from the equipment. For X-ray baggage inspection systems and other similar equipment, sensors should be provided in such a way that, X-ray beam is turned OFF automatically, if any material (to be scanned) is not present on the conveyer belt for a preset duration.

#### 3.4.4 Emergency Control Mechanism

Wherever the XGE is controlled by electrical or any other system, a readily identifiable and accessible means should be provided to control any emergency condition so that the equipment attains the safe condition.

#### 3.4.5 Conventional Safety

Apart from radiation safety, conventional safety aspects such as fire, mechanical, electrical, and environmental safety are important. The requirements of conventional safety are to be met as mandated by the relevant authority, to prevent hazards and/or personal injury. The "No Objection Certificate" or "Type Approval" of X-ray generating equipment, issued by AERB would take effect only if all the other applicable NOCs pertaining to conventional safety are also available.

#### 3.4.6 Control Panel

All the handheld devices and most of the self-shielded devices have control panel as an

integral part of the equipment. Operation of the control panel (and hence equipment) should be password-protected or key controlled to prevent unauthorized operation. If the operating parameters (kV, mA etc.) of the equipment are not fixed, these values should be displayed on the control panel. ON/OFF switch or button on the control panel should have clear and visible markings.

#### 3.5. Shielded Enclosure

A shielded enclosure is an enclosed space engineered to contain ionizing radiation and to provide adequate shielding for persons working/present in the vicinity. A shielded enclosure or similar arrangement is essential for testing of the XGE during its manufactureg or repair. This enclosure should be designed and constructed such that the radiation level outside the enclosure is within the limits specified by AERB. The limits on the radiation level outside the enclosure are derived from annual dose limits for workers and members of public. Approval of the design of the XGE testing facility should be obtained by the employer/licensee from AERB prior to commencement of construction work.

The design requirement for enclosure includes the room(s) where the equipment is handled/tested/studied, and it should preferably be located at one end of the building. This enclosure should be used exclusively for the intended studies and should not be accessed by persons not associated with the activities. Wherever feasible, this enclosure should be located away from the main entrance to the premises.

Prior to the use of an enclosure, a radiation protection survey should be carried out all along the walls and the entry point(s) to locate any void and reduced density/dimension of the shielding material, and that the protective barriers are designed appropriately from radiation safety view point. Any change in the approved building and the layout design should be carried out only with the prior approval of AERB.

#### 3.5.1 Structural Shielding

During development, manufacturing and testing phases of any XGE or X-ray tube without the shielded casing, the radiation exposure level around the unit may be higher than that around the finished product. Hence, testing of such units during manufacturing process should be carried out in an enclosure with structural shielding or local shielding

of appropriate material and of adequate thickness.

Safety of the workers and the office staff must be taken into account while testing such units. The area should have restricted access and warning light (red blinking light) should be installed around the shielded enclosure to indicate that the radiation device is 'ON' and testing is in progress.

The structural shielding wall should preferably be made of concrete and/or brick. The size of the enclosure should be so designed as to comfortably manage the intended activities. The thickness of the shielding should be such that the radiation level outside the enclosure does not exceed the prescribed dose limit for workers and members of the public.

Shielding thicknesses should be calculated such that the weekly radiation dose does not exceed 400  $\mu Sv$  for workers and 20  $\mu Sv$  for members of public (consistent with the annual dose limits) for the maximum workload. Occupancy may be full, partial or occasional. There may be a need for a controlled area outside an enclosure, where necessary radiation protection measures are to be implemented for exposure control.

The primary/direct beam will require comparatively thicker barrier (primary barrier) as compared to scattered and leakage radiations. The shielding thickness of the wall could be optimized by restricting the primary beam dimensions, which can often be achieved by collimating the beam.

Sufficient shielding is to be provided against scattered radiation and also the leakage radiation, which is transmitted through the X-ray tube housing. Although the scattered radiation has lower energy than the primary radiation, leakage radiation has the same energy as the primary radiation but with reduced intensity.

# 3.5.2 Control Room

In general, self-shielded units are provided with a control console attached to the unit. In certain cases where the radiation beam is used inside a well shielded enclosure, a separate control room with appropriate protective barrier is essential for the safety of the operator.

In manufacturing/testing facilities, the control panel should be located in a separate room, however if it is not possible, the X-ray generating equipment should be operated from a safe distance, taking advantage of available protective shielding.

# 3.5.3 Conduit/Opening

In case the X-ray equipment is having energy more than 200 kV, underground conduits should be provided to lay thecables between the control room and the exposure room. There should not be any through and through opening or hole in any of the walls of the exposure room. A conduit of appropriate diameter should be provided in the wall to lay the control cables of X-ray device from the control console to the exposure room. The conduit should be so provided in the specified wall that it prevents direct streaming of radiation from the exposure room to the control room. Conduit for electrical cables may also be provided underground to avoid direct streaming of radiation from the exposure room to the control room.

#### 3.5.4 Door Interlock

The door of shielded enclosure for material or personnel entry should be provided with an electrical interlock, to prevent inadvertent operation of the equipment when the door is opened or improperly closed.

#### 3.5.5 Audio-Visual Indicator

When the radiation equipment is in exposure 'ON' condition inside the enclosure, there should be an audio and/or visual indication. The arrangement for audio indicator can be made using an audio system directly connected to the X-ray equipment or its control system. Similarly, for a visual system, red bulb/LED may be connected. The audio system should be such that the sound is clearly audible to the operator and persons present nearby, and for visual system the exposure 'ON' indication should be clearly visible to operator and persons present nearby. The audio and/or visual indicator should be placed conspicuously on the wall of the enclosure near the entry door of enclosure.

#### 3.5.6 Zone Monitor

Zone monitor is used for cautioning when exposure is 'ON' and to sound an alarm when exposure exceeds the preset level. Manufacturing facilities or X-ray tube testing facilities should have a zone monitor for measuring any elevated radiation level in the room and to sound alarm in the event of the radiation level exceeding the preset levels. The location of the zone monitor should be near the entrance to the enclosure to alert the person(s) entering the area.

# 3.5.7 Radiation Symbol and Warning Sign at Entry point

The radiation symbol (see para 3.3.3) should be posted conspicuously and prominently at the entrance of the enclosure. A placard indicating 'RADIATION: RESTRICTED ENTRY' and "RADIATION HAZARD KEEP AWAY" should be displayed, along with its equivalent in Hindi as well as in the local language, alongside the radiation symbol. The placard/warning signs should be made from materials that are durable and should be replaced periodically as necessary. Specifications of radiation symbol, legends to be used in the warning sign are stipulated in the safety directive issued by AERB, which is reproduced in Appendix-II. In case of imported equipment, the radiation warning sign should include the sign as specified in Appendix-II and international symbol.

# 3.5.8 Ventilation System

In order to maintain consistency amongst all 15 practice specific guides, the chapters, sections and sub-sections in all the 15 practice specific guides, including this safety guide have been maintained same. The sub-section on 'Ventilation System' is not relevant to XGE-REIA facility, hence is not applicable to this guide.

#### 4. OPERATIONAL SAFETY

#### 4.1. General

Radiation safety can be achieved broadly by incorporating design safety features and implementing operational controls. Operational safety plays an important role, as it is not always possible to have engineering controls to address all the safety issues.

For operational safety, qualified and trained manpower, proper operating procedures, safety culture among the staff of the facility, compliance with the safe operating procedures, and necessary infrastructure (e.g. protective accessories) are important. The basic principles of radiation safety, viz, time, distance and shielding, should be adopted judiciously while working with an XGE.

In addition, it is important that the procedure/practice-specific safety aspects are considered during the operation of an XGE. The following factors should be taken into account for ensuring safety in the use of XGE:

- (i) Operation of the equipment by trained person;
- (ii) Monitoring of the radiation doses received by the workers (wherever applicable);
- (iii) Availibility of radiation monitoring instruments and radiation safety gadgets/tools (wherever applicable);
- (iv) Use of structural shielding/mobile protective barriers by concerned radiation worker(s) during the manufacturing process;
- (v) Periodic quality assurance of the equipment by user/authorized suppliers;
- (vi) Operation of the XGE as per standard operating procedures/manufacturer's manual:
- (vii) Training of the operating personnel and associated staff in radiation safety aspects;
- (viii) Availability of radiation protection programme, covering all the above aspects, their implementation and conducting periodic review of the same.

#### 4.2. Manpower Requirement

No person under the age of 18 years should be employed as a radiation worker. While employing the workers, the employer should ensure that the workers have appropriate training and instructions in radiation safety, in addition to the qualification required for

performing their intended tasks as prescribed by the relevant agency /authority.

Radiation workers, who are likely to receive an effective dose in excess of three-tenths of the average annual dose limits prescribed by the competent authority shall be designated as classified workers. Such employees shall be informed that they have been so designated.

The XGE manufacturer, supplier and user institutions should have competent professionals/staff to ensure safe, effective and smooth operation of the unit. Personnel viz employer, licensee, Radiological Safety Officer (RSO), radiation worker and trainees/interns, have specific roles and responsibilities with respect to possession/handling of radiation sources. The responsibilities of respective personnel is specified in Appendix -V.

# 4.2.1 Persons Operating the Equipment

Personnel operating the XGE should have basic knowledge of radiation safety and should have received instructions and training on safe operation of the equipment. They should obtain training preferably from the manufacturer/supplier of the device and receive a training certificate.

Training should include, *inter alia*, operation of the equipment, radiation safety aspects, periodic maintenance and common troubleshooting.

Each institution should have identified persons who are trained in safe operation of the XGE. Equipment should not be operated by the trainees, researchers or students unless their course curriculum requirement specifically mentions the same. In such cases, the equipment should be operated only under the supervision of the trained operator or the Radiological Safety Officer (RSO). The number of staff members and their qualifications should be in compliance with the requirements prescribed by the relevant authority specific to each practice. Guidance on manpower requirement for equipment under the scope of this guide is provided in Appendix-III.

# 4.2.2 Radiological Safety Officer

A Radiological Safety Officer (RSO) should be designated and available at the manufacturing facility. The supplier of the XGE should ensure compliance with the requirements specified in AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/ RF/SC, 2025.

For user institutions of XGE-REIA, a suitably trained person may be identified and assigned by the licensee to discharge the duties of RSO.

# 4.2.3 Consideration for persons who are not Employees of a Licenced Facility

Visiting persons (e.g. academic appointees, research workers) who are not employees of the licenced facility may use the XGE in the said facility, however the licensee should ensure that such persons are provided with the same level of protection and safety as those employed by the licenced facility.

The responsibilities of the visiting persons, and employer of the licensed facility (where the visiting persons use the XGE), should be clearly specified in contractual arrangements. The contractual arrangement between the employer of the visiting persons and the employer of the licensed facility should include the following:

- (i) Ensuring that the level of protection and safety of the visiting persons who may use the XGE is at least equivalent to those of the employees of the licensed facility;
- (ii) Assessment and maintenanace of the records of the doses received by the visting persons, their current annual effective dose and the cumulative effective dose prior to commencing work with radiation sources at the licensee's facility;
- (iii) Details of radiation protection programme of the licensee, contact information of the RSO and other responsible person(s) for radiation protection;
- (iv) Clear allocation and documentation of the responsibilities for protection and safety, of the employer of the visting persons and those of the licensee of the licensed facility where the persons have come to work.

#### 4.3. Trainees

Persons undergoing training or apprenticeship who are required to use the equipment, may be permitted to work only under the direct supervision of an identified trained person. It should be ensured that the radiation dose to trainees/apprentices between 16-18 years of age, who use equipment in the course of their studies, does not exceed the

dose limits of Apprentices and Trainees, as provided in Appendix-I. Dose limits for trainees and apprentices above 18 years are same as those for occupational workers.

# 4.4. Protection and Safety Tools

Access to the X-ray tube should be, wherever possible, only by means of special tools that require special procedure and should be available only with the authorised service and maintenance personnel.

# 4.4.1 Personnel Monitoring

The levels of radiation around most of the XGEs are generally so low that personnel monitoring for end users is not warranted. In some cases, workplace monitoring may be sufficient to ensure protection of operators, other workers and public. Dose rate around the equipment should be measured by the manufacturer/supplier during installation; requirement of personnel monitoring may be recommended to the users by manufacturer/supplier/RSO, wherever required.

Workers involved in manufacturing, servicing, testing and repair of XGEs, are required to avail personnel monitoring services (PMS). The approved personnel monitoring device should be obtained from accredited laboratories and availed on a quarterly basis. The licensee should ensure that workers use the personnel monitoring badges (i.e. TLD badges) properly and radiation dose control measures are implemented effectively so as to keep doses as low as reasonably achievable and always within the prescribed dose limits. The licensee should ensure that the used TLD badges are returned at the beginning of every monitoring period to the Personnel Monitoring Service providing agency.

The dose records of the above mentioned workers are required to be maintained and such records should be made available during regulatory inspections by AERB. The employer should furnish dose records annually to each worker in his employment and also as and when requested by the worker. Detailed instructions for proper use of TLD are given in AERB website (https://aerb.gov.in/english/aerb-advertisement).

# 4.4.2 Investigation of Reported Excessive Exposure Cases

The XGE under the scope of this guide are usually of low hazard potential and hence the chances of excessive exposure are remote. However, workers, operators, engineers

working in the manufacturing facility (dealing with the testing of equipment) or service engineers servicing these equipment may get exposed to a dose in excess of regulatory limits if safety systems/measures are not implemented.

In order to ensure that the radiation dose to the workers does not exceed the dose limit, an investigation level of 15 mSv in a monitoring period (i.e. three months in the case of XGE-REIA) is recommended. If the dose recorded by the personnel monitoring badge of any personnel exceeds the above mentioned level, the Licensee should submit an investigation report including a statement from the personnel reported to be excessively exposed, to AERB. The investigation should focus on identifying the causes that led to the exposure, and on failures if any in the standard operating procedures or safety systems. The investigation report would be reviewed and evaluated by AERB. The genuineness of the dose received by the personnel would be decided based on the findings of the report submitted, inspections conducted at the site, and interviews with the individuals exposed.

In case the reported dose in a monitoring period is greater than 100 mSv (although extremely unlikely), biological dosimetry i.e. Chromosomal Aberration (CA) test of the exposed individual(s) should be conducted, if directed by AERB, for deciding the genuineness of the dose. CA test should be carried out at AERB recognized laboratories only.

# 4.4.3 Personnel Protective Equipment

Use of specific personnel protective equipment (PPE) such as lead-apron, thyroid shield, lead-equivalent spectacles etc. are not envisaged for normal operation / manufacturing of XGEs under the scope of this guide.

#### 4.4.4 Radiation Monitoring Instrument

The radiation monitoring instrument should be so chosen that it is suitable for the type of radiation, radiation energy and its sensitivity and accuracy. Most of the equipment under the scope of this guide emits low intensity X-ray radiation and radiation levels are less than  $1\mu Sv/h$  at 10 cm from the accessible surface of the equipment. Therefore, routine monitoring of such equipment may not be required. Periodic monitoring and QA

of these equipment should be carried out by the manufacturer/suppliers/RSO or other qualified agencies to verify the degradations in the system, if any, and records should be maintained.

The manufacturing facility/supplier should maintain functioning radiation survey meters (RSM) suitable for measuring the X-rays dose rate. The survey meter should be capable of measuring the dose rate in the range of 0.1  $\mu$ Sv/h to 10 mSv/h. Periodic radiation protection surveys should be conducted using an appropriate and properly calibrated survey meter. The RSM should remain in good working condition and should have valid calibration at all times.

Radiation monitors should be calibrated before their first use, after any repair and at intervals not exceeding two years or at such frequency as specified by the manufacturer. The pre-use test should include the instrument's overload performance to ensure that it operates correctly up to the maximum credible dose rate it may encounter. Response check of portable radiation meter should be carried out before every use.

Calibration of monitoring instrument should be carried out once every two years by laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) or other agencies recognized by AERB, and a certificate of calibration should be obtained and maintained for regulatory review. The monitoring instrument received after calibration should be checked for performance as mentioned above. The readings so obtained should be recorded and kept for future reference.

# 4.4.5 Measuring Instrument

In order to maintain consistency amongst all 15 practice specific guides, the chapters, sections and sub-sections in all the 15 practice specific guides, including this safety guide have been maintained same. The sub-section on 'Measuring Instrument' is not relevant to XGE-REIA facility, hence is not applicable to this guide.

# 4.4.6 Handling Tools

Normally no special handling tools are requried for handling of XGEs.

#### 4.4.7 Mobile Shield/L-Bench

In a manufacturing facility of radiation generating equipment, a mobile shield may be used during operation or testing of the unit to optimize radiation protection and reduce exposure to the workers.

#### 4.5. Operation of Radiation Equipment

Prior to operation of the XGE, the operator should ensure that necessary arrangements are in place to offer adequate protection to the workers and members of public around the equipment/installation and also to the environment. The operator should be familiar with all the safety features of the equipment to ensure that the occupational and public exposures are kept, as low as reasonably achievable and within the prescribed limits.

General safe practices for handling of XGEs include the following:

- (i) No Person should place himself or any part of their body within the path of the primary beam;
- (ii) Warning lights and audible signals should be checked to confirm their normal functioning, before switching 'ON' the X-ray generator;
- (iii) Personal access to the XGE should be controlled; only authorized persons should be permitted access to the X-ray equipment;
- (iv) Faulty equipment should be promptly taken out of service;
- (v) User should report any damage or suspected malfunction of the XGE to the employer;
- (vi) Shielding or interlocks should never be tampered with.

For portable scanners used for security purposes, adequate area should be cordoned off so that the total dose to a person present near the boundary of the cordoned 'OFF' area (30 m from X-ray generator) does not exceed 5  $\mu$ Sv per scan, taking congnizance of the annual dose limit for public being 1mSv.

#### 4.6. Source/Equipment Location and Storage

# 4.6.1 Change of Premise/Location

Manufacturing, servicing, testing and operation of the XGE should be carried out only at the premises/location specified in the application for approval. In case of the need for change of premise/location, prior approval from AERB should be obtained.

#### 4.6.2 Transfer of Equipment

The employer/licensee should not loan, sell, gift or otherwise transfer an XGE to another person/institution without obtaining prior permission from AERB.

# 4.6.3 Safe and Secure Storage

The manufacturer/supplier of XGEs should securely store the equipment in the designated area to ensure its safe handling. Inventories of equipment should be maintained and verified periodically. Records of equipment supplied to users should be maintained by the supplier.

# 4.6.4 Security of Radioactive Material

In order to maintain consistency amongst all 15 practice specific guides, the chapters, sections and sub-sections in all the 15 practice specific guides, including this safety guide have been maintained same. The sub-section on 'Security of Rdioactive Material' is not relevant to XGE-REIA facility, hence is not applicable to this guide.

#### 4.6.5 Source handling in other's Premise/Facility

The manufacturer/supplier of XGEs should specify the location where the equipment will be operated for the purpose of type approval testing. If the manufacturer is required to test the equipment in others' premises, while manufacturing, prior persmission for the same should be obtained from AERB.

# 4.7. Safety Checks, Quality Assurance and Maintenance

# 4.7.1 Safety Check

XGEs have certain inbuilt safety systems such as, fail-safe mechanism, interlocks, timers, couplings, emergency stop buttons, and radiation monitoring systems in order to reduce radiation exposure to workers and members of the public. These safety systems should be checked periodically and its frequency should be determined based on the nature and probability of its failure. The frequency of checks of all safety system may not be the same and a graded approach is to be followed in determining the frequency of checks for safety systems. Failure of a critical system that is more important for safety may give rise to radiation risk. The frequency of checks of these systems should be more than that for other safety systems. The manufacturer of radiation generating equipment should specify all required safety checks and their frequencies in the safety manual. It should mention the safety checks to be done by users and those to be performed by the

manufacturer/supplier or service providers. Records of all checks carried out should be maintained. In the event of any defect being detected in the radiation equipment, it should not be used until it has been repaired and found fit for use.

The manufacturer/supplier should provide safety manual to the end user for proper and safe use of the equipment.

# 4.7.2 Tests for Quality Assurance

The manufacturer of XGEs should develop a manual on Quality Assurance Programme (QAP) for their products and adhere to the same. This manual may include, management systems, manufacturing process, QA tests at different stages, QC checks, servicing and maintenance procedures, and guidance for suppliers and distributors. Manufacturers should follow the Quality Assurance Programme during the manufacturing process and records of all the QA tests should be maintained.

The operating institution should also prepare a manual for safety or follow the manual provided by manufacturer/supplier.

#### 4.7.3 Servicing and Maintenance

Servicing and maintenance are required for smooth functioning of the XGE. The servicing and maintenance of the XGE should be carried out as specified in the manual provided by the manufacturer. Radiation exposure may occur during servicing and maintenance of radiation generating equipment; therefore, it should be performed only by the persons trained and certified by the original equipment manufacturer.

In an XGE, use of spare parts and accessories meeting original specifications of the unit is very important from radiation safety view point. Replacement of components should meet the design specifications of national/international standards.

# 4.8. Safe Management of Disused Sources / Decommissioning of Equipment

Decommissioning is the process by which an XGE is finally taken out of operation in a way that it can no longer be re-energized. When the XGE is no longer in use, the facility should decommission the equipment as per the instructions provided by the manufacturer/supplier and procedure laid down by AERB. The decommissioning should be carried out by authorized suppliers/competent agencies.

Licensee should ensure that all components such as X-ray tube (including Beryllium), lead used as shielding material in the X-ray tube housing and electrical wastes should be disposed off in accordance with the procedure prescribed by the relevant authorities.

# **4.9.** Transport of Radioactive Material (Not applicable)

In order to maintain consistency amongst all 15 practice specific guides, the chapters, sections and sub-sections in all the 15 practice specific guides, including this safety guide have been maintained same. The section on 'Transport of Rdioactive Material' is not relevant to XGE-REIA facility, hence is not applicable to this guide.

# **5. MEDICAL EXPOSURE (Not Applicable)**

In order to maintain consistency amongst all 15 practice specific guides, all the chapters, sections and sub-sections in the 15 practice specific guides, including this safety guide have been maintained same.

The chapter on 'Medical Exposure' is kept intentionally blank since the same is not relevant to 'X-ray generating equipment used for research, education, inspection and analysis' hence is not applicable to this guide.

#### 6. HANDLING INCIDENTS/EMERGENCY SITUATIONS

#### 6.1. General

Emergency is a non-routine situation that necessitates prompt action, primarily to mitigate adverse consequences to human life, health and environment. Such incidents are unlikely during the use of XGEs, as several built-in safety features are incorporated in them. However, incidents may occur during manufacturing, servicing, testing or repairing of the equipment. To manage any such incident/emergency conditions, standard procedures should be available with the institutions and duly implemented.

# 6.2. Emergency Preparedness and Response

The manufacturer and supplier should prepare an emergency preparedness and response plan to mitigate the consequences of all foreseeable incidents. Generally an emergency situation may be called off by simply switching off the radiation generating equipment. The emergency response plan should be maintained and updated periodically. All radiation workers associated with the XGE testing should be familiar with these procedures.

The procedures should include names and details of personnel to be contacted during emergency, tools to be utilized and safety instructions.

#### **6.3.** Response to Emergency/Incidents

For X-ray based devices, the emergency procedures are different from those equipments containing radioactive sources, and in most cases the immediate response is to activate emergency stop switches or turn off the power supply.

The licensee, in consultation with the RSO, should ensure that incidents are handled in a manner that the exposures to the personnel are minimized.

#### 6.3.1 Reporting an Emergency

After safe handling of emergency, a report giving the details of response action taken as per the available emergency procedures should be made. The root cause of the emergency situation and the actions to prevent recurrence of such abnormal situation/ incidents in future should also be included in the report. The existing emergency procedures may also

be revised, if required based on the incident that occurred in the facility. AERB should be informed about any such incident and the remedial actions taken.

## 7. PUBLIC SAFETY

## 7.1. General

XGE-REIA units specified in this guide are widely used in public domain. Most of these equipment are self-shielded. Therefore, the potential of hazard is very low during use/application of these equipment. The manufacturer should ensure that the equipments are designed in a manner that both in normal and in accident conditions, the dose to the public is within the prescribed limits (see section 7.2). The dose limits for members of the public prescribed by AERB is given in Appendix-I.

Public exposure may occur among individuals present in, or around the facilities or laboratories where XGEs are used for research and education. Similar is the scenario where equipment is used for screening and for non-destructive examination purpose (e.g. X-ray baggage inspection at airport, hotels, food scanners in the food industry, PCB analyser in electronic industry, etc.). These members of public fall into two categories (i) those working in the laboratory or facilities but are not directly involved in the use of radiation, like administrative support staff; and (ii) those members of the public who are present in or near the radiation facility. All these persons are to be provided with the same level of radiation protection and safety as that required for members of the public.

Students and researchers, may use XGEs intermittently as part of their academic learning, research and study. There is a general expectation that a high level of protection will be provided for younger students. Dose limits for trainees/interns/students of age 16 to 18 years shall be 6 mSv in a year and for those of age above 18 years shall be same as occupational workers.

Licensees should establish a system to ensure that the total annual radiation exposure to students and research workers, including any exposure received by them while using radiation sources at other research organizations, does not exceed the respective dose limits.

During the use of a portable scanner, adequate area should be cordoned off, and people in the vicinity of the cordoned area should be alerted about the operation of the radiation

generator (XGE).

## 7.2. Measures for Public Safety

The manufacturer/supplier of XGEs should provide necessary information/instructions on hazard associated with it to the end users in the form of instructions to handle or, on the products/product cover itself (wherever possible). Specifying "Dos and Dont's" is one of the simple ways to caution public regarding safe use of the equipment.

Self-shielded equipment or laboratory based equipment are provided with adequate builtin-safety systems to make the device safe for operation and safe for public.

However, the manufacturing facility of the equipment should have shielded enclosure (as applicable) along with other built-in-safety systems. Adequate protection against radiation should be provided so that the dose limits prescribed for members of the public (given in Appendix-I) are not exceeded. The radiation exposure of the public from all sources including that due to operation of the XGE in one week should not exceed 20 µSv considering an annual dose limit of 1 mSv.

To ensure public safety, members of the public should not be allowed in the manufacturing facilities beyond the designated place. In addition, the entrance door of the facility should be labeled with a radiation warning symbol.

## 7.3. Protection of Foetus/Child of a breastfeeding Worker

A female worker, on becoming aware that she is pregnant, should notify the employer, licensee and Radiological Safety Officer, so that her working conditions may be modified suitably, if required, to ensure that the dose to the foetus is well within the prescribed limit.

The foetus is considered as member of the public for radiation protection purposes. Thus, procedures should be incorporated in such a manner that ensures that the dose to the foetus is within the prescribed limits for general public.

Protection of lactating mother is not a concern in the case of XGEs covered in this Guide.

## Appendix-I: The Dose Limits for Exposures from Ionising Radiations for Workers and the Members of the Public

(AERB Directive No. 01/2011)

## [Under Rule 15 of the Atomic Energy (Radiation Protection) Rules 2004]

(Ref. No. CH/AERB/ITSD/125/2011/1507 dated April 27, 2011)

In exercise of rule 15 of the Atomic Energy (Radiation Protection) Rules, 2004, the Chairman, Atomic Energy Regulatory Board, being Competent Authority under the said rules, hereby issues an order prescribing the dose limits for exposures from ionising radiations for workers and the members of the public, which should be adhered to Dose Limits.

## 1. General

- (a) The limits on effective dose apply to the sum of effective doses from external as well as internal sources. The limits exclude the exposures due to natural background radiation and medical exposures.
- (b) Calendar year should be used for all prescribed dose limits.

## 2. Occupational Dose Limits

(i) Occupational Workers

The occupational exposures of any worker should be so controlled that the following limits are not exceeded:

- (a) an effective dose of 20 mSv/yr averaged over five consecutive years (calculated on a sliding scale of five years);
- (b) an effective dose of 30 mSv in any year;
- (c) equivalent dose to the lens of the eye of 150 mSv in a year;
- (d) an equivalent dose to the extremities (hands and feet) of 500 mSv in a year and
- (e) an equivalent dose to the skin of 500 mSv in a year.

Limits given above apply to female workers also. However, once pregnancy is declared the equivalent dose limit to embryo/foetus should be 1 mSv for the remainder of the pregnancy.

## (ii) Apprentices and Trainees

The occupational exposure of apprentices and trainees between 16 and 18 years of age should be so controlled that the following limits are 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;
- (c) an equivalent dose to the extremities (hands and feet) of 150 mSv in a year and
- (d) an equivalent dose to the skin of 150 mSv in a year.

## 3. Dose Limits for Members of the Public

The estimated average doses to the relevant members of the public should not exceed the following limits:

- (a) an effective dose of 1 mSv in a year.
- (b) an equivalent dose to the lens of the eye of 15 mSv in a year; and
- (c) an equivalent dose to the skin of 50 mSv in a year.

## **Appendix-II: The Specifications for Radiation Symbol and Warning Sign**

(AERB Directive No. 02/2011)

# [Under Rule 14(3) of the Atomic Energy (Radiation Protection) Rules 2004] (Ref. No. CH/AERB/ITSD/125/2011/1508 dated April 27, 2011)

In exercise of rule 14(3) of the Atomic Energy (Radiation Protection) Rules, 2004, the Chairman, Atomic Energy Regulatory Board, being Competent Authority under the said rules, hereby issues an order prescribing the specifications for the radiation symbol and warning sign.

- 1. Specifications for radiation symbol/warning sign:
  - (i) The radiation symbol for radioactive sources other than medical diagnostic and industrial X-ray radiography equipment should confirm to the specifications given hereunder;
    - (a) The relative dimensions of the trefoils and the central circle should be as shown in Fig.1;
    - (b) The trefoils and the circle should be of magenta colour;
    - (c) The background of the above symbol should be yellow;
    - (d) The symbol should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry, e.g. CAUTION RADIOACTIVITY;
    - (e) Small objects, containing radioactive material may, however, have on them only the aforesaid trefoil symbol engraved in a conspicuous colour when their dimensions do not permit compliance with the above.
  - (ii) The radiation symbol for radiation generating equipment such as medical diagnostic x-ray equipment, industrial x-ray radiography equipment and accelerators should have a warning sign as illustrated in Fig. 2 and the warning sign should conform to the specifications given hereunder;
    - (a) The triangle should be equilateral;
    - (b) The ratio of the outer to the inner sides of the triangle should be 1.5;
    - (c) The area between the outer and inner triangle should be in yellow colour on white background;
    - (d) The printing on the area between the outer and inner triangle and figure inside the inner triangle should be bold, proportional and red in colour;
    - (e) The area between the outer and inner triangle should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry.

## A. RADIOACTIVE MATERIAL SYMBOL



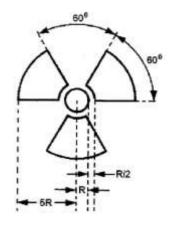


Fig. 1. Radiation Symbol for Radioactive Sources



Fig. 2.
Radiation Symbol and Warning Sign for Radiation Generating Equipments

The X-ray symbol should be displayed on the cabinet/outer enclosure of X-ray generator also at entrances to the installation room in accordance with regulatory requirements.

## **Appendix-III: Qualification Requirement**

## 1. Operator

Each radiation facility, operating XGEs should have qualified/certified operator(s).

## Minimum Qualification for Operator

- (i) Passed 10<sup>th</sup> standard, and
- (ii) Formally trained on radiation safety aspects by the original equipment manufacturer (OEM). If training from OEM is not feasible, appropriate training on radiation safety may be imparted by the Radiological Safety Officer of the supplier/Manufacturer.

## 2. Radiological Safety Officer (RSO):

Each facility involved in the manufacture/supply/servicing including repairs/testing of XGEs, and users of cabinet type equipment for Non-destructive Testings, should have a Radiological Safety Officer.

## Minimum Qualification for RSO

- (i) Basic degree in Science or equivalent from a recognized University/Institution; or
  - Diploma in Engineering from recognized University/Institution;
- (ii) Completed the RSO certification course for scanning facilities, or any other course prescribed by AERB from time to time.

## Appendix-IV: Design Requirements for X-ray Equipment

## 1. Requirements for Self-shielded/Cabinet Type X-ray equipment

(Applicable for Self-Shielded NDT equipment/ X-ray baggage inspection system (XBIS)/CT based baggage inspection system (CTBIS)/Packaged food inspection system (PFIS)/X-ray diffractometer (XRD): Cabinet type/X-ray Fluoresce Equipment (XRF): Cabinet type/ Self Shielded Electron beam welding machine/ Self-Shielded PCB analyser/ any other similar kind of equipment)

Part A: Performance Tests for Self Shielded X-Ray Equipment

Sr. No.	Parameter	Acceptance criteria	Remarks
1	Beam Energy verification\$	Within tolerance value as provided by the manufacturer or within ± 5% of manufacturer's designed value, whichever is less	Measurements to be carried out at declared values of kV
2	Operating tube current <sup>\$</sup> (mA)	± 10 %	Measurement at declared values of mA
3	Radiation leakage level at 10 cm from the external surface of the cabinet	Leakage radiation level not to exceed 1 μSv/h in any direction	Measurement at maximum operable kV and corresponding maximum tube current.  Using hand held radiation survey meter which should have following characteristics;  (i) suitable for the X-ray energy under reference  (ii) should measure background radiation levels - resolution should be at least 0.01 μSv/h  Levels should be measured at multiple points at 10 cm from the accessible surface of the cabinet.

<sup>\$</sup> Applicable for industrial radiography systems only(optional)

Part B: Requirements for Self Shielded X-Ray Equipment

Sr. No.	Component		Requirements
1	Control Console	(i)	Provision for display of;
			(a) Operating tube voltage (kV) and Tube current
			(mA); for systems capable of operating at
			variable energies/current
			(b) Beam status indicator (ON/OFF)
		(ii)	Provision of Key-controlled operation/password
			protected operation of the equipment. Key can be
			removed only when X-rays are in Switch-OFF condition.
		(iii)	Emergency stop switch(es) should be provided at the
			suitable locations.
		(iv)	Appropriate X-rays caution symbol(s) should be
			displayed,
2	On the cabinet of the	(i)	Display of manufacturer's tag indicating
	system		manufacturer's name and address, model number
			serial number.
		(ii)	Appropriate X-rays caution symbol(s) should be
			displayed.
		(iii)	provision of emergency stop switches.
3	Provision of	(i)	Availability of door interlocks (for systems which do
	interlocks		not have product transport system).
		(ii)	Availability of protective drapes (for the systems with
			product transport mechanism). In such systems,
			interlocks should be available at places such as on the
			panel cover, X-ray generator, detector.

# 2. Requirements for Portable X-ray Scanner (PXS) for Security Applications Part A: Performance Tests for the PXS

Sr. No.	Parameter	Acceptance criteria	Remarks
1	Beam Energy	Within tolerance value as provided by the	Measurement at
	verification <sup>\$</sup>	manufacturer or within ± 5% of	declared values of kV
		manufacturer's designed value,	
		whichever is less.	
2	Radiation Output	Within tolerance value as provided by the	Measurement at
	measurement at 1	manufacturer or within ± 5% of	declared kVp and
	meter from the	manufacturer's designed value,	corresponding
	device	whichever is less.	declared tube current.

3	Dose at various	The dose per scan/exposure at 30 m	Measurement at
	points on a 30 m	distance all around the portable scanner	maximum operable kV
	circle around the	without placing any object and image	and corresponding
	device	should not exceed 5.0 μSv,	maximum tube
			current.

\$ optional

**Part B: Requirements for the PXS** 

Sr. No.	Component	Requirements
1	Control	(i) Provision for display of beam status indicator (ON/OFF)
1	Console	(ii) Provision of Key-controlled operation/password protected
	Collsole	` '
		operation of the equipment. Key can be removed only when X-
		rays are in Switch-OFF condition.
		(iii) Emergency stop switch(es) should be provided at the suitable
		locations.
		(iv) Appropriate X-rays caution symbol(s) should be displayed.
2	On the System	(i) Display of manufacturer's tag indicating manufacturer's name
		and address, model number serial number.
		(ii) Appropriate X-rays caution symbol(s) should be displayed.
		(iii) Provision for emergency termination of exposure.
3	Provision of	Equipment should have a provision of remote operation from a
	Remote	distance of at least 30 m from the device (X-ray generator).
	operation	

## 3. Requirements for handheld X-ray Fluorescence (XRF) equipment

Part A: Performance Tests for Handheld XRF Equipment

Sr. No.	Parameter	Acceptance criteria	Remarks
1	Beam energy	Within tolerance value as provided	Measurement at
	verification <sup>\$</sup>	by the manufacturer or within $\pm 5\%$	declared values of kV
		of manufacturer's designed value,	
		whichever is less	
2	Consistency of		Measurement at declared
	exposure rate	$COV \leq 0.05$	kVp and corresponding
			declared tube current
3	Radiation at 5 cm	Leakage radiation shall not exceed 20	Measurement at maximum
	from the accessible	μSv in one hour with maximum	operable kV and
	surface of the	possible exposure	corresponding maximum
	equipment		tube current

\$ Optional

Part B: Requirements for Hand held XRF Equipment

Sr. No.	Component	Requirements
1	Control Console	(i) Provision for display of beam status indicator (ON/OFF)
		(ii) Provision of Key-controlled operation/password protected operation of the equipment. Key can be removed only when X-rays are in Switch-OFF condition.
		(iii) Emergency stop switch(es) should be provided at the suitable locations.
		(iv) Appropriate X-ray caution symbol(s) should be displayed.
2	On the system	<ul> <li>(i) Provision of safety interlocks with respect to removable shield, if any, and proximity sensor.</li> <li>(ii) Display of manufacturer's tag indicating manufacturer's name, address, model number and serial number.</li> </ul>
		<ul><li>(iii) Appropriate X-rays caution symbol(s) should be displayed.</li><li>(iv) Provision for emergency termination of exposure.</li></ul>

## **Appendix V: Responsibilities**

## 1 General

There are various stakeholders involved in handling the radiation sources and equipment in the complete life cycle of the radiation facility. This includes personnel involved in the manufacture, supply, installation, commissioning, operation, maintenance, and decommissioning of the radiation equipment or radiation facility. Responsibilities are assigned to these personnel for radiation safety in the facility under Atomic Energy (Radiation Protection) Rules 2004. All the personnel should understand and perform their responsibilities to ensure radiation safety effectively. The responsibilities of the employer, licensee, RSO, Radiation Worker, Manufacturer and Suppliers of X-ray generating equipment used for research, education, inspection and analysis (henceforth described as XGE-REIA) are provided in this chapter.

## 2 Responsibilities of Licensee (Employer)

The person responsible for any facility or activity that gives rise to radiation risks shall have the prime responsibility for safety. The prime responsibility of ensuring radiation safety in handling an XGE shall rest with the Licensee (Employer) who has obtained the licence and this responsibility cannot be delegated.

## The licensee should:

- (a) ensure compliance to all the applicable provisions of Atomic Energy Act, 1962 and the relevant rules made thereunder, and the requirements stipulated in regulatory documents / conditions referred to or contained in the license or Safety Directives/Orders from AERB or otherwise applicable;
- (b) designate, with the written approval of AERB, a person or persons, as required, having qualifications as specified in this guide, as Radiological Safety Officer (RSO), wherever applicable;
- (c) ensure that relevant provisions of this guide are implemented by the RSO and other worker(s):
- (d) ensure that no person under the age of 18 years is employed as a worker and no person under the age of 16 years is taken as trainee or employed as an apprentice for radiation work;
- (e) provide facilities and equipment to the RSO and other worker(s) to carry out their functions effectively in conformity with the regulatory constraints;
- (f) prior to employment of a worker, obtain the dose records and health surveillance reports, from his/her former employer. Also upon termination of service of worker provide his/her dose records and health surveillance reports on request to his/her new employer;
- (g) extend all assistance to enable the regulatory inspection to be carried out effectively and unhindered;
- (h) arrange for and maintain health surveillance of workers as specified under Rule 24 & 25 of Atomic Energy (Radiation Protection) Rules, 2004;

- (i) arrange for personnel monitoring services (PMS) of radiation workers (as applicable), proper implementation and also to maintain the individual dose records as prescribed by AERB;
- (j) furnish to each worker covered by PMS, dose records, and health surveillance reports of the worker in his/her employment annually, as and when requested by the worker and upon termination of service;
- (k) inform AERB if the licensee or the RSO leaves employment;
- (l) ensure that written procedures and plans are established for controlling, monitoring and assessment of exposure for ensuring adequate protection of workers, members of the public and the environment, during normal operation and emergency situations;
- (m) ensure that periodic safety status report of the facility in the prescribed format is submitted to AERB;
- (n) ensure radiation monitoring is carried out in accordance with this safety guide;
- (o) ensure radiation monitoring equipment is/are regularly inspected, maintained and periodically calibrated at least once in two years and all systems/components are regularly serviced and maintained in good working order as per the manual provided by the manufacturer / designer and records are maintained. Records shall also be maintained for replacement of components, if any;
- (p) ensure periodic tests and inspections of safety systems and control mechanisms are carried out; the records are maintained and are available for inspection by AERB;
- (q) ensure that adequate instruction/training is given to employees concerning any radiation hazards associated with their work, any precautionary measures necessary to limit radiation exposure of persons and to avoid radiation accidents and injuries;
- (r) ensure that necessary supervision is provided to all employees in the performance of their work in accordance with the provisions of this guide;
- (s) in consultation with the Radiological Safety Officer, investigate any case of exposure in excess of regulatory constraints received by individual workers and maintain records of such investigations;
- (t) inform AERB promptly of the occurrence of actual or suspected radiation exposure of personnel in excess of regulatory constraints in prescribed format followed by reports of detailed investigations and follow up actions to prevent recurrence of such incidents;
- (u) ensure that all applicable requirements of other relevant regulatory authorities are met;
- (v) ensure that Standard operating procedures (SOP) are developed and implemented for operation of the XGE. This SOP should include a list of specific Dos and Don'ts;
- (w) QA of the equipment should be performed periodically by the supplier or authorised person;
- (x) ensure that no person is permitted to operate the XGE unless he/she has been adequately trained and is competent to operate the unit in accordance with the safety procedures;

- (y) in case of permanent termination of the use of a XGE due to any reason, decommission the unit with prior permission of AERB;
- (z) keep the documents/history of the XGE-REIA equipment in safe custody;
- (aa) obtain prior permission from AERB in case of transfer of ownership of the XGE; and
- (bb) obtain prior approval from AERB for any modifications in location of installation.

## 3 Responsibilities of Radiological Safety Officer

The role and responsibilities of RSO are elaborated below:

The Radiological Safety Officer should:

- (a) ensure that the relevant provisions of Atomic Energy (Radiation Protection) Rules, 2004, are implemented;
- (b) implement all radiation surveillance measures including display of radiation symbol and warning at the entrance door of the room where the unit is installed and at appropriate location;
- (c) implement continuous display of the radiation symbol, warning, marking and labeling on the unit;
- (d) advise licensee in establishing and maintaining an effective radiation protection programme to ensure safety of workers, members of the public and the environment;
- (e) train the operators and associated servicing / maintenance personnel on basic radiation safety, hazard potential and biological effects of radiation;
- (f) instruct all operators/users on relevant safety measures, provide adequate training in radiation protection and safety methodologies, use of personnel monitoring devices (as applicable);
- (g) ensure that personnel monitoring devices are given to radiation workers in the facility, as applicable, used as required and are securely stored in radiation-free zone;
- (h) ensure that radiation monitoring instruments are kept in proper working condition and are periodically calibrated;
- (i) assist the licensee in developing suitable emergency response plans to deal with emergencies and ensuring appropriate emergency preparedness;
- (i) conduct periodic radiation protection surveys and maintain records;
- (k) furnish to the licensee the necessary particulars for the submission of the periodic reports on safety status of the unit to AERB;
- (l) investigate any situation that could lead to potential exposures and submit report to AERB:
- (m) advise employer on implementation of physical protection measures;
- (n) assist licensee in maintaining personnel monitoring records, analyse personnel exposure records to ensure that there are no abnormal exposure trends;
- (o) prepare the standard operating procedures (SOP) in-line with the instruction manual provided by manufacturer/supplier of the unit;

- (p) assist licensee for periodic servicing and preventive maintenance of the unit as prescribed by manufacturer/supplier and maintain records;
- (q) report on all hazardous situations, including details of immediate remedial actions taken if any is made available to the employer and licensee for reporting to the Competent Authority;
- (r) advice the licensee on the modification in the working condition of female worker after her notification about pregnancy; and
- (s) inform the competent authority when he/she leaves the employment or is relieved of RSO role.

## 4 Responsibilities of Workers (Operator/User)

Worker (Operator/user of an XGE) is the person who is directly involved in day-to-day operation/use of the unit. The worker has recognized rights and duties in achieving radiation safety while handling the radiation source, which call for awareness about the operational as well as safety requirements of the unit. Accordingly, the workers should get training in safe operation, preventive maintenance aspects of the unit from authorized manufacturer/supplier during installation of the unit at the site.

The worker (operator/user) of an XGE should:

- (a) be familiar with the basic design, operation and preventive maintenance of the XGE including procedures for routine operation and handling emergency situations;
- (b) operate the XGE as per the standard operating procedures (SOP) prepared from detailed instruction manual provided by the manufacturer/supplier of the XGE;
- (c) follow all applicable rules and regulations for safe operation of unit;
- (d) maintain the logbook in respect of use and operation of the unit;
- (e) make proper use of protective equipment, radiation monitors and personnel monitoring devices provided (as applicable);
- (f) report to RSO/licensee of any issues related to safe operation of the XGE, including the circumstances that could adversely affect safe operation of the unit;
- (g) be familiar with area security safeguards such as locks, posting signs, warning lights and interlock systems; and
- (h) in case of a female worker, on becoming aware that she is pregnant, notify the employer, licensee and RSO in order that her working conditions may be modified, if necessary.

## 5 Responsibilities of Manufacturer and Supplier

The manufacturer/supplier should:

- (a) ensure that only Type Approved XGE are supplied to the user and the terms and conditions of the Type approval are complied with;
- (b) adhere to the Terms and Conditions of the licence issued for manufacturing and authorization for supply of the XGE;
- (c) supply the unit only to the users authorized by the AERB;
- (d) install the unit only at premises authorized/approved by AERB;

- (e) provide to the user instruction manual in understandable language (English/Hindi) for safe operation, periodic inspection, servicing, preventive maintenance including general description of the unit and detailed operating instructions and procedures;
- (f) provide information to the user in respect of make, model, sr. no. of the unit, beam energies, beam current and dose rate;
- (g) provide appropriate training to the personnel of user institution involved in operation, servicing and maintenance of irradiation unit;
- (h) ensure the availability of essential spare parts of the unit for its useful life;
- (i) provide servicing, maintenance and QA of the unit whenever required;
- (j) assure the supply of generator and spare parts when requested by user, in compliance with regulatory procedures;
- (k) provide safety accessories, as required to the user for the normal operation of the XGE and for handling emergency situations;
- (l) provide written instructions to the user specifying procedures to be followed in an emergency situation that has caused or may cause a radiation hazard to any individual;
- (m) undertake the responsibility for providing technical support in decommissioning of the XGE/facility.

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