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A Study on the Regulatory Requirements to Establish a Gamma Irradiation Chamber in a Hospital

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I. Introduction

Gamma Irradiation Chambers (GIC) or Blood Irradiators are being extensively used in various universities, academic and research institutions for research and development purposes. Ionizing radiation can modify the physical, chemical and biological properties of the irradiated materials. Gamma-ray emitters like cobalt-60 became popular radiation sources for medical and industrial applications. Gamma Irradiation Chambers are also used in hospitals and blood banks for irradiation of blood and blood products/components, for clinical and research purposes. Gamma radiation is broadly used for the sterilization of medical equipment, micronized amniotic membrane injectable products, and food samples[1].

Gamma processing has several advantages over other treatment methods; for example, sterilization of health care products using either ETO or wet steam as a sterilant. Tissues like bone, skin, amniotic membrane and soft tissues obtained from a human donor can be used for repair or reconstruction of the injured part of the body. Gamma irradiation technology is an effective method for sterilization of biological tissues and ensuring the safety of tissue allografts. Considering that the GIC possess radioactive material or radiation generating equipment (X-ray device), certain requirements have to be met to ensure the safety of radiation workers, members of the public and environment.

II. Objective

To enlist the various Regulatory requirements to establish a gamma irradiation chamber in a hospital.

III. Methodology

Latest textbooks and literature was reviewed to identify the various acts and regulations pertaining to gamma irradiation Chamber.

IV. Results

1. Application in the prescribed format
2. No Objection Certificate (NOC)' from the Competent Authority
3. Procurement permission obtained through the online portal, www.aerb.gov.in/eLORA
4. The requirements for availability of manpower and safety infrastructure as stated below:

(a) Radiological safety officer (RSO)
(b) Personnel monitoring devices (e.g. TLD)
(c) Radiation monitoring devices (e.g. radiation survey meter)
(d) Emergency response plans and procedures (EPP)
(e) Security plan for the facility
(f) Provision /commitment for safe disposal of spent/disused sources.

5. Source manufacturer or supplier should maintain records relating to the sealed source(s) and provide this information to meet the requirements of licensing, transportation, etc. The records should include the following:

(a) Make, model number and identification number of source (s), the contained radioisotope, activity, and date of measurement
(b) The physical and chemical form
(c) Sealed source classification certificate (e.g. AERB/ISO/ANSI)
(d) Bend test certificate, as per applicable standard
(e) Leak test certificate, as per applicable standard

(f) Contamination test certificate, as per applicable standard.
(g) Special form test certificate if required by the transportation authorities

6. The receipt of GIC unit with a source should be submitted with full details of radioactive source pencil nos. as soon as the GIC received by the Institute.
7. After installation of the GIC unit by the manufacturer /their authorized supplier, the applicant should obtain the Licence in the form of Authorization from the Competent Authority for the operation of the GIC unit.
8. Prior to obtaining the license, a separate fund should be earmarked by the employer (in the form of bank guarantee) towards expenditure for removal and transport of sources if required.
9. Type Approval testing of the equipment to AERB.

V. Others

1. The employer should have responsibilities listed in Rule 20 of the Atomic Energy (Radiation Protection) Rules, 2004
2. The licensee should have responsibilities listed in Rule 21 of the Atomic Energy (Radiation Protection) Rules, 2004
3. The RSO shall have responsibilities listed in Rule 22 of the Atomic Energy (Radiation Protection) Rules, 2004
4. The licensee should prepare emergency response plans, as per Rule 33 of Atomic Energy(Radiation Protection) Rules, 2004

VI. Siting and Layout Requirements for Gamma Irradiation Chamber

The site layout for installation of Gamma Irradiation Chamber (GIC), should meet the following requirements:

a) The room for the installation of GIC should be an exclusive room having provisions of lock and key arrangement for preventing access by unauthorized personnel.
b) This room for GIC installation may be of normal brick wall construction. However, it should be ensured that radiation levels outside the room housing GIC unit shall not exceed the AERB specified limit of 1 μSv/h.

c) The room should have the following features:
(i) Preferably located on the ground floor for ease of installation
(ii) Adequate room size to house the GIC unit
(iii) Door size – adequate enough for taking the unit (assembled) inside the room
(iv) Floor loading capacity – as per the weight and base size of the unit.

VII. Conclusion

Establishing a gamma irradiation chamber in a hospital requires an understanding of radiation safety. Radiation is a double-edged sword. So every organization taking up the task of establishing and running a GIC should adhere to the regulatory guidelines strictly for the safety of patients, radiation workers, public and environment.

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