ATOMIC ENERGY REGULATORY BOARD

Bombay, the 29th March, 1989

G.S.R. 388- In pursuance of rule 15 of the Radiation Protection Rules, 1971, the Atomic Energy Regulatory Board, hereby specifies the following **radiation surveillance procedures for medical applications** of radiation, namely :-

1. Short title, extend and commencement -

   (1) These procedures shall be called the Radiation Surveillance Procedures for Medical Applications of Radiation, 1989.
   (2) It shall apply to the whole of India.
   (3) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions -- In these procedures, unless the context otherwise requires, -

   (a) "adequate protection" means protection against radiation so provided that the levels of radiation and contamination are kept as low as reasonably achievable and in no case exceed the prescribed operational limits;

   (b) "appropriate" means appropriate in the opinion of the competent authority to ensure adequate protection;

   (c) “authorisation” means written permission of the competent authority to handle radiation equipment;

   (d) “authorised personnel” means personnel with appropriate qualifications and experience necessary to administer radiation or radionuclides to the patient for the specific medical diagnosis or therapy;

   (e) “commissioning” means starting the use of radiation equipment or radiation installation subsequent to performing such tests and measurements as are necessary to confirm the safety and performance of the equipment or installation in accordance with the design intent or specifications;

   (f) "competent authority" means any officer or authority appointed by the Central Government by notification under the Rules;

   (g) “decommissioning” means discontinuation of the use of radiation equipment or radiation installation on a permanent basis, with or without dismantling the radiation equipment, after all radioactive materials have been removed from it;

(h) "employer" means any person who employs radiation workers or who is self-employed as the only radiation worker in a radiation installation;

(i) “external hazards” means health related hazards due to exposure to ionising radiation originating from a source located external to the body of the exposed person;

(j) "handle" means manufacture, possess, store, use, transfer by sale or otherwise, export, import, transport or dispose of;

(k) “internal hazards” means health related hazards due to exposure to ionising radiation originating from a source located internal to the body of the exposed person;

(l) “licensee” means a person who has been granted a licence under rule 3 of the Rules;

(m) "operational limits" means limits on levels of radiation or levels of contamination as the competent authority may by notification, specify from time to time;

(n) “planning” means planning for the provision of appropriate (i) building layout, (ii) radiation shielding, (iii) protection equipment and (iv) operational procedures, to ensure adequate protection in course of handling radioactive material or radiation equipment and performing related operations in the proposed radiation installation;

(o) “quality assurance tests” means conducted to ensure performance and reliability of the radiation equipment in accordance with the design specifications;

(p) “radiation” or “ionising radiation” means gamma rays, x-rays, rays consisting of alpha particles, beta particles, neutrons, protons and other nuclear and sub-atomic particles but not sound or radiowaves, or visible infra-red or ultra-violet light;

(q) “radiation equipment” includes equipment or appliances incorporating radioactive materials, and radiation generating plants and equipment including those generating x-rays, medical accelerators, and neutron generators;

(r) "radiation installation" means any location or facility which in the opinion of the competent authority requires radiation surveillance and includes all locations where radioactive materials or radiation equipment is handled or related procedures and operations are carried out;

(s) "radiation surveillance" means measures that may be specified by the competent authority to provide adequate protection either generally or in any individual case and include the measures and procedure specified in these procedures for medical applications of radiation;

(t) "Radiological Safety Officer" means any person who is so designated by the employer and who in the opinion of the Competent Authority, is qualified to discharge the functions mentioned in the Rules;

(u) “Rules” means the Radiation Protection Rules, 1971;

(v) words and expressions not defined in these procedures, but defined in the Rules shall have the meanings respectively assigned to them in the Rules;

3. Objectives of a radiation surveillance programme :-

(1) The employer shall ensure that all procedures and operations involving radiation installations, radiation equipment and radioactive materials are performed in conjunction with a pre-planned surveillance programme approved by the competent authority so as to ensure adequate protection.

(2) The surveillance programme shall inter-alia, include;

i) the provision of appropriate built-in safety features in respect of both radiation equipment and radiation installations to ensure adequate protection;

ii) the provision and use of appropriate radiation measuring and monitoring devices or instruments; and

iii) the periodic monitoring of all safety related parameters and systems to ensure their continued satisfactory performance.

4. Licence or authorisation: -

(1) Any employer desirous of handling a radiation equipment or radioactive material, shall do so only after obtaining prior permission of the competent authority.

(2) He shall apply to the competent authority for such permission which will be granted to him in the form of either a licence or an authorisation from the competent authority for the handling of such material or equipment.

5. Design safety of equipment :-

(1) All radiation equipment and protective equipment and their accessories shall be appropriately designed and constructed with due regard to their shielding adequacy and operational safety.

(2) All radioactive sources and their associated assemblies shall be designed and constructed with due regard to their containment integrity and radiation safety in normal use as well as in accident conditions.

(3) Protection against external hazards shall be provided by employing a judicious combination of factors such as minimum source handling time, optimal source to user distance and appropriate shielding immediately around the source in the most efficient configuration.

(4) Protection against internal hazards shall be provided by measures such as ensuring appropriate containment of radioactive materials, choosing proper predetermined operating procedures and taking appropriate measures to limit the extent of spread of contamination in the event of accident or spills.

(5) (a) Approval of the competent authority shall be obtained for each type of radiation equipment manufactured in the country.

(b) Approval of the competent authority shall be obtained prior to the import or sale of radiation equipment.

6. Planning of radiation installations :-

(1) The location and planning of a radiation installation shall be such as to ensure adequate protection to the members of the staff, patients and the public.

(2) Appropriate measures to achieve this objective shall include the following measures, namely :

(i) a radiation installation shall have integrated facilities at one location for the handling of radiation equipment and radioactive materials;

(ii) a radiation installation shall be located as far away as feasible from high occupancy areas, paediatric and maternity wards and other facilities of the institution that are not directly related to radiation and its use;

(iii) the layout of a radiation installation and safety equipment shall be so planned that all the radiation handling operations can be performed in a safe manner.

7. Commissioning of a radiation equipment or radiation installations:

Any radiation equipment or radiation installation shall be commissioned only after all aspects including design, planning, construction and operation have been duly approved by the competent authority.

8. Working conditions in a medical radiation installation to be ensured by every employer:-

(1) Only authorised personnel shall administer radiation or radioisotopes to a patient.

(2) Appropriate facilities shall be provided by the employer at all times for storage, dispensing, transport, use including administration and disposal of radioactive materials.

(3) Quality assurance tests shall be performed periodically on all radiation equipment and accessories and records of all these tests shall be maintained properly.

(4) A qualified Radiological Safety Officer shall be appointed by the employer with the approval of the competent authority to implement the radiation protection programme including all in-house radiation surveillance measures and procedures and to discharge the functions under the Rules.

(5) Reasonable care shall be exercised by each radiation worker to protect himself and others by making full use of safety equipment and protection devices prescribed by the competent authority.

(6) Appropriate steps shall be taken to prevent damage to, or loss or misplacement of radioactive materials and such steps shall include –

(i) appropriate source integrity tests for sealed sources as laid down by the competent authority;

(ii) regular stock taking as may be necessary of all radioactive materials including spent sources that may not be in use and are awaiting disposal; and

(iii) appropriate facilities, including availability of radiation measuring instruments, for the search and recovery of lost or misplaced sources;

(7) (a) Spillage of unsealed sources shall be avoided by proper handling procedures approved by the competent authority.

(b) Appropriate decontamination facilities approved by the competent authority shall be provided for ready use in the radiation installation.

(8) Damaged or spent sources shall be effectively isolated and shall not be used further.

(9) The competent authority shall be informed forthwith of any damage, misplacement or loss of sources.

9. Disposal procedures for radioactive effluents :-

(1) The gaseous radioactive effluents resulting from medical applications of radioactive materials may be released to the atmosphere through a fume-hood or other appropriate exhaust system in such a way that the operational limits for contamination in air, laid down by the competent authority, are not exceeded.

(2) Solid and liquid radioactive wastes shall be disposed of in accordance with the guidelines that may be issued by the competent authority.

(3) Cadavers and carcasses containing radioactive materials shall be disposed of under the supervision of the Radiological Safety Officer and in accordance with the guidelines that may be issued by the competent authority.

10. Protection Surveillance to be ensured by every employer :

(1) All radiation workers shall be provided with appropriate personnel monitoring devices.

(2) Appropriate radiation measuring instruments shall be provided for day to day use.

(3) The radiation measuring instruments shall be maintained in good working condition and calibrated regularly.

(4) The Radiological Safety Officer shall impart appropriate radiation protection training to all radiation workers on their employment before they start radiation work and periodic training courses shall be conducted to keep these workers abreast in respect of latest equipment, procedures and work practices.

(5) Patients with removable sealed radioactive sources in their body shall be hospitalised and a careful check shall be maintained on such patients and sources to avoid loss or misplacement of such sources.

(6) Patients administered with unsealed radioactive material or with permanent implants shall be dealt with in accordance with procedures that may be specified by the competent authority

11. Medical Surveillance :

All radiation workers shall be subject to appropriate medical surveillance procedures as may be specified from time to time by the competent authority.

12. Maintenance of records :

(1) The Radiological Safety Officer shall maintain log books showing records of movements of all radiation sources including their arrival, storage, inventory, dispensing, transport, administration, use, removal and disposal.

(2) Log books of personnel doses, area surveys, radiation incidents and remedial actions taken, shall be maintained by the Radiological Safety Officer.

(3) The Radiological Safety Officer shall maintain records of persons authorised to handle radiation equipment and radioactive materials in order to ensure that such equipment or materials are not used by unauthorised personnel.

(4) Records of all medical examinations shall be maintained by the employer with due regard to their confidential nature and medical ethics.

(5) Every employer shall ensure compliance with the above requirements and maintain the records for appropriate periods as may be specified by the competent authority.

13. Decommissioning of a radiation installation or radiation equipment

(1) Procedures for decommissioning of a radiation installation or radiation equipment shall include safe disposal of radiation sources, contaminated objects and materials and decontamination of all affected areas.

(2) The employer shall obtain prior permission from the competent authority for undertaking any decommissioning operation.

14. Codes and Guides :

The competent authority may also issue from time to time, Codes and Guides governing the safety in the various medical applications of radiation in order to enable compliance with these surveillance procedures and other relevant requirements under the Rules.

15. Responsibilities of the employer :

(1) The employer shall be directly responsible for the effective implementation of these surveillance procedures and Codes and Guides issued by the competent authority in his behalf.

(2) The employer shall ensure that all radiation workers in his employment are informed of surveillance procedures and Codes and Guides that may be issued by the competent authority from time to time.

(3) The employer shall comply with any other special radiation surveillance procedure that may be specified by the competent authority from time to time.