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CHAIRMAN

Ref: AERB/RSD/MDX/SC-Amendment/2012/14285 November 26, 2012

Sub: Amendment to AERB Safety Code on Medical X-ray Equipment and Installations [AERB/SC/MED-2 (Rev.1), 2001]

The amendment to the first revision of AERB Safety Code on Medical X-ray Equipment & Installations is hereby issued incorporating the revised regulatory requirements of AERB in the Diagnostic Radiology practice.

The Revision of the Code on Medical X-ray Equipment and Installations is currently underway and the revised safety code will be published in the near future. This Amendment to the Code is issued in the Interim period reflecting the restructured regulatory process in the backdrop of experience gained in the past in regulation of the AERB stake holders of this practice.

The Amendment enclosed herewith brings out the sections where the requirements are revised and shall be read in conjunction with the parent Code. The Amendment shall have the same mandatory status as the parent document [AERB/SC/MED-2 (Rev.1), 2001].

(Chairman, AERB)

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Amendment to AERB Safety Code for Medical Diagnostic X-ray Equipment and Installations, [Code No. AERB/SC/MED-2, (Rev.01), 2001]

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Amendment to AERB Safety Code for Medical Diagnostic X-ray Equipment and Installations, [Code No. AERB/SC/MED-2,(Rev.01), 2001]

1. Section1.1, 1.2 and 6.10

Existing requirements: Reference of Radiation Protection Rules 1971 in Section1.1, 1.2 and 6.10

Revised requirements: *Reference of Atomic Energy (Radiation Protection) Rules 2004, in Section1.1, 1.2 &6.10*

2. Section 3.1 Location of X-Ray Installation

Existing requirements: Rooms housing diagnostic X-ray units and related equipment shall be located as far away as feasible from areas of high occupancy and general traffic, such as maternity and paediatric wards and other departments of the hospital that are not directly related to radiation and its use. In case the installation is located in a residential complex, it shall be ensured that(i) wall(s) of the X-ray rooms on which primary X-ray beam falls is (are) not less than 35 cm thick brick or equivalent, (ii) walls(s) of the X-ray room on which scattered X-ray fall is (are) not less than 23 cm thick brick or equivalent, and (iii) there is a shielding equivalent to at least 23 cm thick brick or 1.7 mm lead in front of the door(s) and windows of theX-ray room to protect the adjacent areas, either used by general public or not under possession of the owner of the X-ray room.

Revised requirements: *Rooms housing diagnostic X-ray units and related equipment shall be located as far away as feasible from areas of high occupancy and general traffic, such as maternity and paediatric wards and other departments of the hospital that are not directly related to radiation and its use.*

3. Section 3.3& 3.4 Room size and shielding

Existing requirements: The room housing an x-ray unit shall not be less than 18 m^2 for general purpose radiography and conventional fluoroscopy equipment. The size of room housing the gantry of the CT unit shall not be less than 25 m^2. Also, not more than one unit of any type shall be installed in the same room, and no single dimension of these x-ray rooms shall be less than 4 m.

Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray unit so that doses received by workers and the members of public are kept to the minimum and shall not exceed the respective annual effective doses as prescribed by the competent authority. Appropriate shielding shall also be provided for the dark room to ensure that the undeveloped X-ray films are not exposed to more than 10 µGy per week. The important dose limits are given in Appendix-I.

Revised Requirements: ***Section 3.3 Room layout requirements:***

The room housing an x-ray unit shall have an appropriate area to facilitate easy movement of staff, patient positioning. Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray unit so that doses received by workers and the members of public are kept to the minimum and shall not exceed the respective annual effective doses as prescribed by the competent authority. Appropriate shielding shall also be provided for the dark room to

ensure that the undeveloped X-ray films are not exposed to more than 10 µGy per week. The important dose limits are given in Appendix-I.

4. Section 3.7 **Control Panel**

Existing requirements: The control panel of diagnostic x-ray equipment operating at 125 kV_p or above shall be installed in a separate room located outside but contiguous to the x-ray room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient. In case of x-ray equipment operating up to 125 kV_p, the control panel can be located in the x-ray room. The distance between the control panel and the x-ray unit/chest stand shall not be less than 3 m.

Revised requirements:

a) The control panel of CT and interventional radiology (IR) equipment shall be installed in a separate room located outside but adjoining to CT/IR room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient.

b) In case of room housing general purpose radiography and fluoroscopy equipment, chest stand shall be located in x-ray room such that no significant stray radiation reaches at control console/entrance door.

5. Section 3.10 **Dark Room**

Existing requirements: The dark room shall be located adjacent to the x-ray room such that no primary or secondary x-rays reach inside the dark room.

Revised Change: The dark room shall be located such that no significant primary or secondary x-rays reach inside the dark room.

6. Section 4.5 **Mobile Equipment**

Existing requirements: A mobile x-ray unit shall be used with appropriate safety measures to distance from occupied areas and temporary shields shall be employed for the purpose. Fluoroscopy shall not be carried out with mobile equipment.

Revised requirements: *Mobile x-ray equipment, when used as fixed x-ray equipment, shall comply with all the requirements of those of fixed x-ray installation. Movement of mobile x-ray equipment shall be restricted within the institution for which it is registered. The distance between operator and x-ray equipment shall not be less than 2 m during exposure. Operator shall always use radiation protection devices such as protective apron while operating the x-ray equipment.*

7. Section 5.1.1 **Safety Personnel**

Existing requirements: Every X-ray department shall have a Radiological Safety Officer (RSO) having qualifications as prescribed in Appendix-III and approved by the competent authority. The RSO may either be the employer himself/herself or a consultant or a full/part-time employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his/her X-ray installation.

Revised requirements: Every X-ray department shall have a Radiological Safety Officer (RSO) having qualifications as prescribed and approved by the competent authority from time to time. The RSO may either be the employer himself/herself or a consultant or a full/part-time employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his/her X-ray installation.

8. Section 5.1.2 **Radiologist**

Existing requirements: All installations having more than two x-ray units, or even a single X-ray unit with fluoroscopy facility, and all establishments performing special procedures, shall have the services of a qualified radiologist. The qualification and experience shall be as given in Appendix-III

Revised requirements: *All installations having x-ray unit with fluoroscopy facility, and all establishments performing special procedures, shall have the services of a qualified radiologist or related medical practitioner, with adequate knowledge of radiation protection for interpretation and reporting.*

9. Section 5.1.3 **X-ray Technologist**

Existing requirements: All x-ray installations shall have either a radiologist or a qualified x-ray technologist to operate the x-ray unit. The minimum qualification and experience for x-ray technologist shall be as given in Appendix-III

Revised requirements: *All x-ray installations shall have a radiologist/related medical practitioner or a qualified x-ray technologist, with adequate knowledge of radiation protection, to operate the x-ray unit*.

10. Section 5.1.4 **Service Engineer**

New requirement: All manufacturers, suppliers and service agencies of diagnostic x-ray equipment shall have qualified service engineers for installation, servicing and maintenance of the equipment. The minimum qualifications for service engineers shall be as prescribed and approved by the competent authority from time to time

11. Section 5.2.1 **Responsibilities of Manufacturer**

Existing requirements: The manufacturer or supplier of x-ray equipment shall make available to the actual user detailed procedures for routine quality assurance tests, exposure charts, operating manuals and a copy of safety/regulatory documents as may be issued by the Competent Authority from time to time. The manufacturer or supplier shall provide appropriate servicing and maintenance facilities during the useful life-time of the x-ray equipment. In case of CT, the manufacturer shall provide the required phantoms for dosimetry and image quality checks.

Revised requirements: ***Responsibilities of Manufacturer of x-ray equipment:***
The indigenous manufacturer shall be responsible for obtaining a-priori Licence for commercial production from the competent authority. The manufacturer shall obtain import permission for x-ray tubes and inserts.

He shall maintain data of testing of x-ray tubes and equipment. He shall make premises available for inspection by the competent authority.
Indigenous manufacturer shall also obtain Type Approval certificate from the competent authority for the prototype of every model of equipment before manufacturing on a commercial scale.
The manufacturer shall be responsible for ensuring compliance with terms and conditions of Licence and Type Approval.

Responsibilities of Supplier of x-ray equipment:

The supplier shall be responsible for obtaining Authorization from the competent authority. In case the supplier intends to market equipment of foreign make, he shall obtain NOC for import, for the prototype, from the competent authority and demonstrate it for Type Approval, prior to marketing in the country.
The supplier shall be responsible for supply of type approved diagnostic x-ray equipment, installation, commissioning, carrying out acceptance testing/quality assurance as part of commissioning of x-ray equipment; servicing and maintenance during the useful life-time of diagnostic x-ray equipment; supply of radiation protection devices such as protective barrier, protective apron, lead rubber flaps etc. as applicable. In case of computed tomography equipment, the supplier shall provide the required phantoms for dosimetry and image quality checks.

The supplier shall be responsible for ensuring compliance with terms and conditions of Authorisation and type approval certificate issued by the competent authority.

12. Section 6.2 Type Approval/ No Objection Certificate

Existing requirements: Prior to marketing the x-ray equipment the manufacturer shall obtain a Type Approval Certificate from the competent authority for indigenously made equipment. For equipment of foreign make, the importing/vending agency shall obtain a No Objection Certificate (NOC) from the competent authority, prior to marketing the equipment. Type Approval/NOC shall be issued only if the equipment satisfies the safety specifications of this Code and the standards in force, as demonstrated by actual type testing of the equipment. Only type-approved and NOC-validated equipment shall be marketed and used in the country. Format of application for NOC/Type Approval is given in Appendix-IV.

Revised requirements: ***Type Approval/ No Objection Certificate(NOC)***

a) *Prior to marketing the x-ray equipment the indigenous manufacturer/ local supplier of imported equipment shall obtain a Type Approval Certificate from the competent authority, on demonstration of performance of the prototype of x-ray equipment.*

b) *Import of prototype of x-ray equipment, meant for Type Approval, shall be carried out by the local supplier only after obtaining NOC for import for Type Approval, from the competent authority.*

c) *Type Approval/NOC will be issued only if the equipment satisfies the safety specifications of this Code and the standards in force.*

d) Import of every Type Approved x-ray machine by supplier or any other importing agency, shall be carried out only after obtaining NOC for import of x-ray equipment, from the competent authority.

e) Only type-approved and NOC-validated equipment shall be marketed and used in the country.

f) For import of x-ray tube(s), the importing agency shall obtain NOC for import of x-ray tubes from the competent authority. The NOC shall be granted only if the x-ray tube conforms to the relevant national/international standards or equivalent.

Format of application for NOC/Type Approval is given in Appendix-IV.

13. Section 6.3 Approval of Layout

Existing requirements: No x-ray unit shall be commissioned unless the layout of the proposed x-ray installation is approved by the competent authority.

Section 6.5 Commissioning of x-ray Equipment

Existing requirements: No x-ray equipment shall be commissioned unless it is registered with the competent authority.

Revised requirements: ***Section 6.5: Operation of X-ray equipment****: No diagnostic x-ray equipment shall be operated unless licensee obtains license and/or registration from the competent authority.*

14. Appendix-II THE X-RADIATION WARNING SIGN

Revised requirement: As per AERB Directive No. 02/2011
Ref. No. CH/AERB/ITSD/125/2011/1508 dated April 27, 2011

15. REGULATORY CONTROLS: New Sections (6.11 and 6.12) to be added for Licence and Authorization

New requirements:

a) 6.11The manufacturer of diagnostic x-ray equipment/ x-ray tube shall obtain licence for commercial production of diagnostic x-ray equipment from the competent authority.

b) 6.12 The suppliers of diagnostic x-ray equipment and agencies associated with servicing & maintenance and quality assurance services of diagnostic x-ray equipment shall obtain authorization from the competent authority.

16. Existing requirements: Appendix IV, V, VI and VII

Revised changes: Appendix IV, V, VI, and VII to be removed. Will be replaced by SG/G-3 "Consenting Process for Radiation Facilities" and as per guidelines displayed in the website by AERB from time to time.