REGULATORY GUIDE B6

X-RAY FACILITY SHIELDING PLANS

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Table of Contents

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Each facility possessing x-ray units requiring shielding plans must submit the appropriate information and comply with Regulations 61-64, X-Rays (Title B). This guide is intended to help facilities in complying with Title B regulations.

SUBMISSION OF SHIELDING PLANS

(See RHB 4.4)

Shielding plans are required to be reviewed and submitted by a registered Class III, Class IV, Class VII or Class IX vendor. A facility may not submit their own shielding plan unless they are also registered as a Class III, Class IV, Class VII or Class IX vendor. Shielding plans will not be accepted from unregistered vendors. A list of registered vendors is available at the DHEC website. Before a plan can be reviewed, a fee of $62.50 must be paid. The $62.50 should be sent in the form of a check or money order made out to SCDHEC, and submitted with the shielding plan.

SHIELDING PLAN REQUIRED

(See RHB 4.4.4)

All new installations of x-ray equipment must have an accepted shielding plan. In addition, any facility that is modifying an existing facility must also have an accepted plan.

Shielding plans are required for:

1) All diagnostic medical x-ray units installed at new facilities.

2) Relocation of a unit within a facility.

3) All installations of therapeutic x-ray or accelerator units.

4) All installations of x-ray equipment at veterinary offices.

5) All industrial x-ray units used in shielded room configurations.

6) All dental cephalometric, TMJ and Dental CT units.

7) Table bone density units (or area survey if prior approval is granted)

8) Mobile and portable radiographic units with a permanent cassette holder as addressed in RHB 4.4.4.6

9) Any space utilized as a radiation area for greater than 5 consecutive days

Shielding plans may be required for:

1) Modifications to an existing accepted installation, such as moving the operator's barrier, or installing vertical cassette holder.

2) Changes to an accepted plan that may affect the shielding requirements, such as changing the film/screen system used, etc.

The only units that generally do not require shielding plans to be submitted are dental intraoral units, most industrial and analytical x-ray equipment, and peripheral bone density units. In those cases where a plan may or may not be required, please contact the Department for assistance. **DO NOT** assume that a new plan is not needed.

EQUIPMENT REPLACEMENT

(See RHB 4.4.2)

A shielding plan may or may not be required when x-ray equipment (i.e. control, generator, or entire machine) is replaced.

1) A shielding plan is not required upon the replacement of x-ray equipment with like equipment and when there are no other changes that would render the original shielding plan inaccurate. This must be determined by a Class III, IV, V, VII, VIII, or IX vendor. The vendor must notify the Department on DHEC Form 2779. No fee is required for the submission of an equipment notification form. This notification must be submitted to the Department prior to the replacement.

2) A shielding plan is required when the replaced unit has increased capabilities that would render the original shielding plan inaccurate. This must be determined by a Class III, IV, V, VII, VIII, or IX vendor.

3) A shielding plan is required when the parameters of the original shielding plan change to an extent that the original shielding plan is no longer accurate. This must be determined by a Class III, IV, V, VII, VIII, or IX vendor.

4) A shielding plan is required when the original shielding plan is not available.

DEPARTMENTAL REVIEW OF SHIELDING PLANS

(See RHB 4.4.4.2)

The Department will review shielding plans for adequacy according to the National Council of Radiation Protection and Measurements, Report Number 147 "Structural Shielding Design for Medical X-ray Imaging Facilities;" the National Council of Radiation Protection and Measurements, Report Number 145 "Radiation Protection in Dentistry;" or an equivalent reference.

After review and acceptance of a shielding plan, the Department may require additional modifications if an analysis indicates the possibility of an individual receiving a dose in excess of the applicable limits.

After a plan is reviewed and accepted, the Department issues a shielding acceptance letter. This letter should be retained by both the vendor and the facility for future reference.

DESIGN REQUIREMENTS

Attached are the design criteria for new x-ray equipment installations. All installations in new facilities are required to meet these criteria. If the design criteria cannot be followed, such as replacement of equipment in an existing facility, the registrant may offer alternative design criteria to the Department for acceptance**.** The alternative design must afford the same degree of safety as the specified criteria. If a particular installation cannot reasonably meet the required design criteria, the shielding plan should be submitted to

the Department along with a letter stating why the criteria cannot be met. The Department will give consideration for alternate designs provided that the intent of the regulations is being met.

In addition, the following conditions must be met:

1) All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of at least 2.13 meters or 7 feet above the floor.
2) Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.
3) The operator's position at the control must be permanently mounted in a protected area.

Mobile and Portable X-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation as discussed in RHB 4.4.4.6. Mobile and Portable X-ray systems which are used in a single location for a period of greater than 5 consecutive days shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4, as discussed in RHB 4.8.8. A shielding plan is also required when any space is utilized as a radiation area for more than 5 consecutive days.

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEW

(See RHB 4.4 and Appendix B)

The following information must be provided to the Department for review and acceptance of a shielding plan:

1. Plans shall show, at a minimum, the following:

   a) The general direction of the useful beam, location of any windows and doors, the location of the operator's booth, the location of the x-ray control panel, and the location of the wall bucky or chest board, if applicable.

   b) The structural composition and thickness or lead equivalency of all walls, doors, partitions, floor, and ceiling of the room concerned.

   c) An accurate drawing of the room(s) concerned.

   d) The type of occupancy of all adjacent areas inclusive of space above and below the room concerned. If there is an exterior wall, the distance to the closest area where it is likely that individuals may be present must be given.

   e) The type x-ray equipment and the maximum technique factors.

   f) Location of the darkroom and the area where the film will be stored. Any shielding which will be used to protect the film must be noted. Include the type of film bin and the type and thickness of the material from which it is constructed. If no film bin will be used, this must also be noted. The use of digital image acquisition should be indicated.

2. Information on the anticipated workload of the x-ray system. Give the number of exposures per week. This is the total number of exposures, not patients, taken each week. This figure should include allowances for future growth so that shielding will continue to remain adequate.

3. Individual barrier shielding specifications and descriptions of all assumptions that were used in the shielding calculations.

A Check or Money Order payable to SCDHEC in the amount of $62.50 must be submitted along with the Shielding Plan Review Application.

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH
(See RHB 4.4.10)

1. SPACE REQUIREMENTS

a) The operator must have 7.5 square feet (0.697 m^2) of unobstructed floor space in the booth.

b) The operator's booth may be any geometric configuration with no dimension less than 2 feet (0.61 m).

c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.

d) The booth shall be located or constructed such that attenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth.

2. STRUCTURAL REQUIREMENTS

a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

b) When a door or moveable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

3. X-RAY CONTROL PLACEMENT

a) The x-ray control shall be fixed within the booth and shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examination table.

b) The x-ray control shall allow the operator to use the majority of the available viewing windows.

4. VIEWING SYSTEM REQUIREMENTS

a) Each booth shall have at least one viewing device which will be placed so that the operator can view the patient during each exposure, and allow the operator to have full view of any occupant of the room. The device should also be placed so that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

b) When the viewing system is a window, it must have at least 1 square foot (0.0929 m^2) of viewing area. The design of the booth shall be such that the operator's position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 m) from the edge of the

booth. The view window must have the same lead equivalence as that required in the booth's wall in which it is mounted.

c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the same general requirements as discussed in (a) above.

d) When the viewing system is by electronic means, the camera shall be so located as to accomplish the general requirements of (a) above, and there shall be an alternate viewing system as a backup for the primary system.

MAMMOGRAPHY SHIELDING REQUIREMENTS

A shielding plan or radiation area survey, which is acceptable only if prior approval is given, is required for mammography units. Shielding plans must be submitted and accepted by this Department prior to installation, or a written request must be made by a Class V, VII, or IX vendor to perform a post-install survey in lieu of a shielding plan.

Both shielding plans and requests for post installation radiation area surveys require the submission of a shielding review fee of $62.50 and shielding plan review application.

POST INSTALLATION REQUIREMENTS

(See 4.4.7.1)

X-RAY EQUIPMENT SHALL NOT BE INSTALLED OR OPERATED BEFORE A SHIELDING PLAN FOR THE UNIT HAS BEEN ACCEPTED BY THE DEPARTMENT.

The acceptance letter will indicate if an as-built drawing or a post-install survey is required after installation of the x-ray unit.

1. AS-BUILT DRAWINGS (4.4.7.1)

Within 30 days after construction and installation are complete, the facility shall ensure that "as-built" drawings are submitted to the Department. The drawings must indicate the composition of the walls, floor, ceiling, windows and doors. The drawings must also indicate the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided, as well as the location and composition of the film bin, if present. Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy by a Class III, Class IV, Class VII, or Class IX vendor.

2. AREA SURVEYS (4.4.6)

A radiation area survey must be submitted to the Department within 30 days of installation. This survey must be performed by a Class V, Class VII, or Class IX vendor, registered with the Department. Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy.

A complete survey shall include the following:

a) An accurate drawing of the room indicating the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided.

b) Indication of the composition of the walls, floor ceiling, windows, and doors.

c) The location and composition of the film bin, if applicable.

d) An evaluation of the adequacy of each protective barrier, the operator's location, and the film storage area, if appropriate.

QUESTIONS

If you have questions, please feel free to call or write:

SC Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

REGULATORY GUIDES

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B - Facilities Utilizing Analytical or Industrial X-ray Equipment
B5 – Complying with Title B - Vendors
B6 – X-Ray Facility Shielding Plans
B7 - Complying with Title B - Mammography
B8 - Complying with Title B - Bone Densitometers
B9 - Complying with Title B - Veterinary Facilities
B10- Complying with Title B - Hospitals
B11 – Complying with Title B – Therapy Facilities

Visit our web site at: http://www.scdhec.gov/Health/FHPF/HealthFacilityRegulationsLicensing/X-RayFacilitiesRadioactiveMaterials/X-RayFacilities/