

Radiology Compliance Branch
RADIATION PROTECTION SECTION



Division of Health Service Regulation • N.C. Department of Health and Human Services

SHIELDING PLAN REVIEW AND POST INSTALLATION RADIATION SURVEY REQUIREMENTS

These guidelines are to assist X-ray facilities and service providers to meet the Rules of 10A NCAC 15 related to X-ray facility shielding.

SHIELDING PLAN REVIEWS

RULE .0603(b) Plan Review

Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing X-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant must ensure the qualified expert will submit the recommendations to the agency.

Shielding plan reviews are an analysis of a proposed location of an X-ray unit for safety and compliance with the applicable Rules of [10A NCAC 15](#). **The design of a proposed X-ray location must include engineered controls that will maximize radiation safety to the public, patients and the unit operators.** A well-planned design will reduce the safety burden on the x-ray operator and allow more focus on patient care.

OBTAINING A SHIELDING PLAN REVIEW

A registered qualified expert must conduct a shielding plan review. The facility must provide the qualified expert the room dimensions, unit specifications and information on the planned use and location of the X-ray unit. The qualified expert will analyze the information to determine the minimum construction materials required for protection of the X-ray operator, nearby patients and anyone outside the exam room. A list of registered qualified experts is located on the Radiation Protection Section (RPS) website at:

[Shielding Design Plan & Survey Service Providers](#)

MEDICAL X-RAY UNITS

Shielding plan review requirements for **medical use, dental extra oral and veterinary units** depend on the type and planned use of the X-ray units. Dental extraoral units include cephalometric, tomography and dental CT units. All planned locations for the X-ray units, except for standard mammography and bone density units, require a shielding plan review prior to equipment installation. **Mammography 3D Tomosynthesis and Stereotactic require a shielding plan review.**

A "Class III – Medical" service provider (qualified expert) may complete medical radiographic unit shielding plan reviews. A "Class IV – Medical" service provider may complete medical fluoroscopic unit shielding plan reviews.

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Installing, Replacing or Adding X-ray Equipment

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A "Class III – Veterinary" service provider may complete veterinary radiographic unit shielding plan reviews. A "Class IV – Veterinary" service provider may complete veterinary fluoroscopic unit shielding plan reviews.

The shielding plan must indicate the location for the X-ray control that is:

1. Permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure;
2. and provide visual indication observable at or from the operator's protected position whenever X-rays are produced.

The plans should outline a design that is equivalent to the recommendations in the National Council on Radiation Protection and Measurements Report No. 147 *Structural Shielding Design for Medical X-ray Imaging Facilities*.

DENTAL INTRAORAL X-RAY UNITS

Shielding plan review requirements for **dental intraoral units** depend on the type and planned use of the X-ray unit. All planned locations for dental X-ray units require submission of a shielding plan review prior to equipment installation. A "Class III – Dental" service provider (qualified expert) must complete dental intraoral X-ray unit shielding plan reviews.

Extraoral installations ie **cephalometric, tomography and dental CT** are medical units and may require additional building materials to prevent excessive radiation outside the X-ray room. Shielding plan reviews for dental extraoral medical units, including must be completed by a "Class III – Medical" service provider. Refer to the medical X-ray units section for additional guidance.

Dental panoramic units also require submission of a shielding plan review prior to equipment installation. A "Class III – Dental" service provider (qualified expert) must complete panoramic X-ray unit shielding plan reviews. Panoramic unit installations must at a minimum provide primary and secondary barriers for each direction the primary beam is directed during exposures.

Most walls provide adequate protection for intraoral and panoramic installations. The designs of many intraoral rooms utilize "open bay" configurations that have inadequate barriers for radiation protection. These types of rooms may have open areas between adjacent rooms that do not block scattered radiation or will allow individuals to enter the room during X-ray exams.

Shielding plan reviews for "open bay" rooms must include instructions that will address how the registrant will ensure the operator will control areas that are not adequately protected by barriers. These instructions are known as "administrative controls". Administrative controls are special operating procedures that must be detailed in the facilities' written radiation protection program. Administrative controls should be developed through discussions among the facility, qualified expert and unit installer to determine the most effective methods to prevent unnecessary radiation exposure to the X-ray operator, nearby patients and anyone outside the exam room. For example, the administrative controls could include the operator monitoring an unsafe area or simply instructing the operator to stand in a position behind a barrier if the control location allows the operator to stand unprotected during exposures. The qualified expert may also suggest the use of mirrors or door locks as administrative controls.



The use of administrative controls may increase the risk of radiation exposure to the general public or the operator compared to protective barriers. The facility should discuss the potential hazards with the qualified expert prior to incorporating administrative controls into a planned X-ray room design.

The shielding plan must indicate the location for the X-ray control in which the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure. Plans should also show how the chair will be positioned during X-ray exams.

The plans should outline a design that is equivalent to the recommendations in the National Council on Radiation Protection and Measurements Report No. 177 *Radiation Protection in Dentistry*.

SUBMITTING SHIELDING PLAN REVIEWS

A shielding plan review with a [Shielding Plan Review Form](#) must be submitted to the Radiation Protection Section (RPS) for acknowledgement. All forms are available on our website www.ncradiation.net. The plans and forms should be emailed to shieldingdesign@dhhs.nc.gov. They may also be mailed to Radiation Protection Section, 1645 Mail Service Center, Raleigh, NC 27699-1645.

Shielding plan reviews are evaluated in the order they are received by the Section. This process is typically completed within 30 business days of receipt of the plan.

SHIELDING PLAN REVIEW ACKNOWLEDGMENT

RPS will review the submitted documents and acknowledge the shielding plan reviews that are complete and appear to adhere with the Rules of [10A NCAC 15](#). RPS will issue a letter to confirm the plan has been acknowledged. The facility must not have the X-ray unit installed until receipt of the acknowledgement letter.

The acknowledgement review process is typically completed within 30 days of RPS receiving a complete form. A facility planning to install X-ray units should contact a qualified expert as soon as possible and should arrange to have shielding plan reviews submitted to RPS at least one but not earlier than six months before the expected installation date. This will allow time for adjustments to the plans if they are necessary. RPS will process shielding plan reviews in the order they are received by the Section.

WHEN A NEW SHIELDING PLAN REVIEW AND ACKNOWLEDGEMENT IS REQUIRED

Most uses of X-ray equipment require the facility to obtain a shielding plan review and plan acknowledgement. The facility must maintain the shielding plan review and acknowledgment for each unit in use at the facility.

Shielding plan reviews are required for the following:

- ❖ Units to be installed for medical, veterinary and dental use (excluding bone density and mammography)
- ❖ Mobile units in medical, veterinary and dental facilities routinely used as fixed units.



- ❖ Renovations to an existing room that affect the barriers or moves the X-ray unit
- ❖ An increase in the actual use of the unit compared to the planned use in the acknowledged plan
- ❖ An increase in the occupancy of rooms adjacent to the X-ray room compared to the occupancy in the acknowledged plan
- ❖ Upgrading a dental panoramic unit to a pan/cephalometric, pan/tomography or pan/CT

Shielding plan reviews are not required for the following:

***These installations do not require a shielding plan review submission but will require a post installation survey within 30 days of the initial operation of the unit.**

- ❖ Standard Mammography and bone density units installed in a controlled room with a door that must be closed during exams (Post installation survey must be completed). **Mammography 3D Tomosynthesis and Stereotactic require a shielding plan review.**
- ❖ Industrial units
- ❖ Replacement of an existing unit with an acknowledged plan if:
 1. The new unit is the same machine type
 2. The new unit will produce similar or less radiation than the replaced unit
 3. There has been no reconfiguration of the room or adjacent rooms since the acknowledged plan
 4. Patient imaging work load has not increased since the acknowledged plan
- ❖ Licensed therapy rooms for cancer treatment (with a current Radioactive Materials Branch License) *X-ray units installed in these rooms other than the accelerator must be registered with the X-ray Registration Branch. The units are also subject to the applicable x-ray Rules and inspections outlined in 10A NCAC 15. A plan and acknowledgement would be required if the license is terminated.

POST INSTALLATION RADIATION SURVEY

Post installation radiation surveys must be completed on-site by a registered service provider. The surveys must be completed within 30 days of the initial operation of the X-ray unit. The service provider must provide the facility with documented results of the survey and inform the facility of any findings that are not in compliance with the X-ray Rules. The facility must maintain the documentation of the survey until the unit is removed from its location.

Most dental intraoral and panoramic installations will not require a survey, although the Section may determine it to be necessary for certain designs. The plan acknowledgement letter will remind the facility when a survey is required.

SHIELDING PLAN REVIEW DISCLAIMER

Acknowledgements of shielding plans are based upon the information provided to our agency from the facility or the service provider. Acknowledgements do not exclude compliance issues that may be discovered during an inspection due to incomplete information depicted on the drawings or recommendations submitted on the shielding plan.



CHECK LIST FOR SHIELDING PLAN REVIEW SUBMISSIONS

Completed Shielding Design Form

- Name & address of the facility and the date on each page of the shielding plan review

- The shielding plan review must include:
 - Shielding requirements for primary and secondary barriers
 - Identification of primary and secondary barriers
 - Identification of protective barriers (dental only)
 - Identification of existing or proposed construction material
 - Scaled drawing(s) of room(s)
 - Recommendations for administrative controls to enhance radiation protection

- Drawing(s) must include:
 - Location & identification of the system's components including each control, exposure switch and image receptor
 - Identification and illustration of:
 - scale size (i.e. 1/4", 1/8", etc.)*Must be provided in inches
 - all adjacent areas including corridors (and areas beyond any corridor)
 - identify each window and door
 - walls vs. counters
 - view window and or mirror system
 - the minimum height and width of barriers and distance to the wall (for barriers that do not connect to another wall or the ceiling)

- Floor plan or drawing illustrating the location of the X-ray room in the facility

Notes:

***Rooms with multiple tubes** – the location of the tubes must be indicated

***Intraoral and panoramic units:** If administrative controls are necessary to meet the intent of the shielding rules, the recommended controls must be thoroughly addressed in the shielding plan review. (The facility's written radiation protection program must also address these administrative controls)

