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What You Should Know Before and After Installing, Replacing or Adding X-Ray Equipment or Making Structural Changes to the X-Ray Room or Increasing the Workload

Plan Reviews “Shielding Designs”

Plan Review Requirements

Rule .0603 of the regulations requires that a shielding design/plan review shall be:

- ❖ Performed by a qualified expert registered to perform the service in NC (See Service Provider Requirements).
- ❖ Submitted to the Radiation Protection Section (RPS).
- ❖ Acknowledged by Radiation Protection PRIOR to installation. Upon receipt of the shielding design/plan review an acknowledgment letter and application or
- ❖ Notification of Registration (NOR) will be mailed to the contact person listed on the plan review.
- ❖ The facility is required to maintain a copy for their records and for review during inspections.

When a New Plan Review is Required

A new plan review is required in the following situations:

- ❖ If the equipment and controls are not located in the same orientation as demonstrated on the plan review or area radiation safety survey.
- ❖ When the x-ray room has been modified structurally (windows, doors, or dressing rooms) or if equipment has been added in the room (i.e. adding a vertical bucky is a modification).
- ❖ When an adjacent area to the x-ray room is modified.
- ❖ The output has increased on the unit.
- ❖ The workload, occupancy or use factors used in the original plan review have been exceeded.
- ❖ There has been a change of ownership and equipment has been replaced.

When an Existing Plan Review Can Be Used

An existing plan review prior to installation can be used with replacement equipment, when all the following conditions are met:

- ❖ The original plan review has been submitted and acknowledged by RPS.
- ❖ The room has not been modified, no structural changes to existing shielding, wall, doors or windows in the room (i.e. adding a vertical wall bucky is a modification).
- ❖ All equipment components (control, table, upright bucky) are in the same orientation as the old unit and as demonstrated on the plan review.
- ❖ The output has not increased on the unit.
- ❖ The workload, occupancy and use factors used in the original plan review has not been exceeded. **(New owners must consult with a registered service provider to determine if all conditions are met. There is no grandfather of units or facilities).**

Area Surveys

Post Installation Area Survey Requirements

Rule .0603 of the regulations require that a post-installation radiation survey shall be:

- ❖ Performed by a qualified expert registered to perform the service in NC (See Service Provider Requirements).
- ❖ Must be performed within 30 days of initial operation of the x-ray unit.
- ❖ The facility is required to maintain a copy for their records and for inspection purposes.

When a New Area Survey is Required

A new post-installation radiation survey is required in the following situations:

- ❖ A new unit or replacement unit is installed.
- ❖ When equipment or components are changed, this includes but is not limited to: replacement with identical types of equipment, equipment component changes or software upgrades that affect the occupancy factor or changes to adjacent rooms.
- ❖ If the equipment and controls are not located in the same orientation as demonstrated on the plan review or area radiation safety survey.
- ❖ When the x-ray room has been modified structurally (windows, doors, or dressing rooms) or if equipment has been added in the room (i.e. adding a vertical bucky is a modification).
- ❖ When an adjacent area to the x-ray room is modified.
- ❖ The **output has increased** on the unit.
- ❖ The **workload, occupancy or use factors** used in the original plan review **have been exceeded**.

Service Providers

Service Provider Requirements

Rule .0205 of the regulations requires that each person who is engaged in the business of installing or offering to install radiation machines and machine components or is engaged in the business of furnishing or offering to furnish any equipment services; including selling or servicing x-ray equipment, performing shielding designs/plan reviews and post installation surveys in this state, to any agency licensee or registrant, shall meet the following conditions:

- ❖ Be registered with the agency **PRIOR** to furnishing or offering to furnish any of these services

Federal Rule 21 CFR Part 1020 and NC Rule .0206 of the regulations require the registered installer to:

- ❖ Submit a copy of the Food and Drug Administration (FDA) Report of Assembly Form (FDA Form 2579) within 15 days of the installation on all new and replaced equipment or equipment components, on units designed for diagnostic (human uses) purposes to the following:
 - Facility
 - FDA
 - State (Radiation Protection Section)

- ❖ Install the equipment according to the acknowledged plan review.