

OHIO DEPARTMENT OF HEALTH REGULATORY GUIDE for RADIOGRAPHIC X-RAY EQUIPMENT

Purpose:

Handlers of radiographic X-ray equipment are required to comply with several quality assurance and general administration rules contained within the Ohio Administrative Code (OAC). This regulatory guide may be used to assist the handler in gaining compliance with these rules. Please remember this is *merely a guide*....it is not intended to identify all possible means of gaining compliance, nor is it intended to limit the registrant's decisions regarding compliance issues. Any questions concerning this guide should be directed to the Ohio Department of Health (ODH), Radiologic Technology Section at 614-644-2727; written inquiries may be sent to the Ohio Department of Health, Bureau of Radiation Protection (BRP), Radiologic Technology Section, 246 North High Street, Columbus, Ohio 43215 or through the BRP's e-mail address: bradiation@odh.ohio.gov. Various ODH Web sites are identified at the end of this document so you may access the rules, forms and other information.

QUALITY ASSURANCE / RADIATION PROTECTION PROGRAM **Rules 3701:1-66-02 & 3701:1-66-04(A)(B)**

Each registrant must develop and maintain a site-specific, *written* quality assurance program. This program may address several items in writing, but it must contain at least the following:

- How often the X-ray units will be evaluated and calibrated;
- Data and test results of equipment evaluation, maintenance logs, incident reports;
- Biennial calibration certificates for testing equipment used to perform area radiation surveys, calibrations and evaluations;
- A complete inventory of X-ray equipment to include location and description of each unit;
- A written report of an area radiation survey performed by a radiation expert prior to patient use or after any change in the X-ray equipment, location or workload which might cause a significant increase in radiation hazard.
- Document and/or maintain for review by ODH:
 - Model & serial numbers of all major X-ray components;
 - User's/operator's manual;
 - Calibrations, radiation safety surveys, preventive maintenance (PMs) (such as that performed by a service company) and quality control (QC) tests;
 - A copy of all correspondence with ODH regarding each X-ray unit (including previous inspection report).
- Procedures for the use of area and personnel monitoring, occupational exposure limits, radiation surveys and maintenance of records;
- How and when the Director of Health will be notified following an occupational over exposure to radiation (ODH ph# 614-644-2727);

- Specific radiation safety procedures for all X-ray equipment handled; (i.e. who can order X-rays, who can operate the X-ray equipment, where the operator stands during exposure, patient holding policy, door opened or closed, restrictions for other personnel during exposure) (*Safe operating procedures*);
- Policy for and documentation of X-ray equipment operator training to assure competency in the operating procedures. Documentation shall include instructor's name, instruction date and instruction content;
- Properly identify the location, boundaries and purpose of a restricted area and identify the location (room name) and type of X-ray equipment within the facility. Indicate the potential health hazards of being in a restricted area (i.e. cancer, cell mutation, tissue damage, reddening of the skin) (*Instruction to Workers / Individuals documentation*);
- Indicate the QC tests to be performed and their frequencies to include, at a minimum: documentation of processing solution preparation and maintenance; cassette / screen or cassette / CR plate erasure procedure; film development temperature;
- QC procedures shall include: Personnel responsible for monitoring and performing quality control tests; a brief description of how to perform the test; a list of the test equipment needed; how the test results will be documented;
- Proof that each individual operating X-ray equipment has an appropriate Ohio Radiologic license for the procedures performed. (Note: For digital or CR systems, GXMO's must have appropriate clinical modules listed on license).

FILM PROCESSING REQUIREMENTS – Rule 3701:1-66-02(J)(3-9)

**Not applicable for digital or CR

Each registrant must assure processing solutions are prepared and maintained properly so full film development is achieved within the time frame specified by the film manufacturer. The following must be maintained:

Manual Processing

- Mechanically rigid, corrosion-resistant processing tanks must be utilized;
- Solution temperature must be maintained between 60 and 80 degrees Fahrenheit. Film developing must either be performed according to the film manufacturer's recommendations or according to the time-temperature chart in this rule. *Chart must be posted*;
- A properly functioning thermometer and a timer.

Automatic Processors and Other Closed Processing Systems

- Time – Temperature Immersion chart posted in darkroom or documentation available;
- Document processing according to the recommended time-temperature relationship; If the processor does not have a built-in temperature gauge, the facility must provide documentation showing periodic temperature measurement.

**Any deviations from the above listed requirements (both manual and automatic processing) must be documented to demonstrate that the requirements of this rule are met or exceeded, such as extended processing.

Darkroom, pass boxes, film and cassettes

- Pass boxes must exclude light and provide adequate shielding from stray radiation to prevent exposure of undeveloped film;
- The darkroom must be light tight with proper safe lighting;
- Daylight film handling boxes must not allow fogging of the film;
- Assure no light accidentally enters the darkroom while undeveloped films are being handled or processed (Lock door, sign on door, written procedures, light above door comes on);
- Assure X-ray film is stored in a cool, dry place and is protected from stray radiation and light;
- Assure expired film is not used for diagnostic radiographs;

GENERAL ADMINISTRATIVE REQUIREMENTS

Rule 3701:1-66-02(F-H)

- Each X-ray unit shall have a warning label that cautions individuals that radiation is produced when it is energized.
- Where one exposure switch controls multiple X-ray tubes, a clear indication of which tube is making exposures must be on the control panel and on or near the tube housing.
- The X-ray tube must remain stable during exposures, unless tube movement is a design of the unit.
- Technique factors must be indicated and visible prior to X-ray initiation. These factors must be visible from the operator's position.
- All locks, holding and centering devices must function as designed by the manufacturer.
- An accurate "technique" chart must be provided and posted near the control panel, and contain at least the following information relating to X-ray exams performed:
 - Body part and anatomical size or part thickness, pediatric age (if applicable), and suggested technique factors for each;
 - Film type and size or film/screen combination to be used;
 - Type and focal distance of the grid to be used;
 - Source-to-image distance (SID) to be used.
- Assure all persons required to be in the X-ray room other than the patient are protected by either a lead apron or whole-body protective barrier.
- Policy to indicate when mechanical holding devices are to be used.
- Documentation to indicate that no individual shall be used routinely to hold patients or films, unless declared necessary by a licensed practitioner and documented in the registrant's safe operating procedures.
- Policy to indicate how to select a holder and radiation safety training if the holder is a radiation worker. *(All holders must be at least 18 years old)*

Rule 3801:1-38-10 (A)(1) Handlers shall post the following documents:

- All applicable rules in Chapter 3701:1-38 of the OAC. If rules are not printed, instruction must be provided on how they can be accessed (i.e. saved to a CD or online). If the online method is selected, Internet access at the facility must be available to all staff members;

- Current “Certificate of Registration” (if issued);
- Safe Operating Procedures;
- Current ODH, BRP issued form titled “Notice to Employees.”

Rule 3701:1-38-11(D)(3) Handlers shall document review of the radiation protection program content and implementation at least every 12 months (i.e. sign-off sheet in front of QA manual).

EQUIPMENT REQUIREMENTS - Rule 3701:1-66-05

The vast majority of these tests are performed by a service engineer or physicist. It is not required that registrants understand each item, just confirm these items are being checked and are in compliance with the regulations.

- Useful beam shall be limited to the area of clinical interest [manual collimation or positive beam limitation (PBL) device].
- Means to terminate the exposure at a preset time interval for manual exposure control (except when time is less than 0.5 second).
- Prior to exposure for automatic exposure control (AEC), the control panel must indicate the selection of the AEC mode, the density and which detector positions are to be used.
- For AEC mode, there must be a visual signal when the exposure has terminated at the back-up limit and the system shall require that manual resetting take place before further exposures are made.
- Visual indication when X-rays are produced and an audible signal when the exposure has terminated.
- Means to align the center of the X-ray field with image receptor within 2 percent of the SID.
- Equipment installed after 2/15/01:
 - Shall have a means for independent adjustment of the X-ray field size in two dimensions (including mobile units);
 - Shall have a means to visually define the perimeter of the X-ray field to within 2 % of the SID (including mobile units);
 - Shall have a means to indicate the x-ray beam is perpendicular to the image receptor;
 - Shall have a means to indicate the SID. For units with a fixed SID, the distance shall be permanently marked;
 - Shall have a means to numerically indicate the field size. Numerical indications shall be accurate within two percent;
 - For equipment with only one image receptor and a fixed SID, a means to limit the X-ray field to the size of the image receptor and align the X-ray field with the image receptor accurately within 2 %.
- Equipment installed prior to 2/15/01:
 - Shall have a means to limit the X-ray field to the image receptor within 2 % of the SID when the field is perpendicular (including mobile units);
 - Shall provide a clear indication of any removable or fixed apertures that are used to meet requirements for SID and alignment (including mobile units).

- Exposure switch must be a ‘dead-man’ type and not capable of being operated outside of the shielded area.
- Timing device shall be accurate within +/- 10 % of the indicated value and reproducible within a 0.05 coefficient of variation (COV).
- kVp shall be accurate within +/- 10 per cent of the indicated value and reproducible within a 0.05 COV.
- Radiation exposure shall be reproducible within a 0.05 COV
- mA linearity must be within 10 % for two consecutive tube current settings.
- PBL shall prevent X-ray production when X-ray field dimensions exceed 3 % of the SID (stationary units only). Five second allowance for PBL to set. X-ray field can be made small than the image receptor, but not larger.
- Portable or mobile radiographic units and all units used for veterinary purposes:
 - Means shall be provided to allow the operator to be a least six feet from the tube housing during exposures or provide a protective barrier at 6.5 feet high to stand behind;
 - Operator must wear lead apron of 0.25 mm of lead during exposures when not behind a protective barrier;
 - Tube housing assembly shall remain stable (not hand held) during exposures.

Radiologic Technology Section Websites

X-ray Equipment Registration and Inspection:

<http://www.odh.ohio.gov/odhPrograms/rp/xequip/xequip1.aspx>

Radiologic License:

<http://www.odh.ohio.gov/odhPrograms/rp/rlic/rlic1.aspx>

Certified Radiation Expert:

http://www.odh.ohio.gov/odhPrograms/rp/cr_exp/cr_exp1.aspx

Health Care Facility Licensing and Inspection:

http://www.odh.ohio.gov/odhPrograms/rp/hc_fac/hc_fac1.aspx

Ohio Department of Health

<http://www.odh.ohio.gov/>

Please Note: For all Website addresses within the “Radiologic Technology Section,” the character before “.aspx” is the numeral “1”(one) and not the alpha character “l”