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Ohio Department of Health Regulatory Guide For Veterinary 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 that this is *merely a guide* and 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, Radiologic Technology Section at 614-644-2727, written inquiries may be sent to the Ohio Department of Health, Bureau of Radiation Protection, Radiologic Technology Section, Post Office Box 118, Columbus, Ohio 43216-0118 or through the bureau's e-mail address: bradiation@odh.ohio.gov. Various Ohio Department of Health Web sites are identified at the end of this document so that you may access the rules, forms and other information.

Quality Assurance Requirements

Chapter 3701:1-66-02(J) of the OAC requires handlers of radiographic X-ray equipment to meet the following quality assurance requirements:

- 3701:1-66-02(J)(1) Maintenance of X-ray equipment to assure quality assurance with 21 Code of Federal Regulations (CFR) may include such things as calibrations, radiation safety surveys, preventive maintenance (such as that performed by a service company) and quality control tests. Documentation of such maintenance must be maintained between inspections.
- 3701:1-66-02(J)(2) The following information must be documented and maintained for review by the Ohio Department of Health (Department) and may be kept in a log or manual:
 - Model and serial numbers of all major X-ray components;
 - User's/operator's manual;
 - Records of surveys, calibrations, maintenance and modifications made to the X-ray equipment;
 - A copy of all correspondence with the Department regarding each X-ray unit.
- 3701:1-66-02(J)(3)(a) Improper film processing can cause unnecessary radiation exposure to the patient, the operator, ancillary personnel and the general public. For registrants who use radiographic X-ray equipment and record images on radiographic film (analog image receptors), the following provisions apply:

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 be performed either according to the film manufacturer's recommendations or according to the time-temperature chart in this rule;

- A thermometer to determine developer temperature and a timer to determine developing time must be utilized.

Automatic Processors and Other Closed Processing Systems

- Film developing must be performed either according to the film manufacturer's recommendations or according to the time-temperature chart in this rule;
 - The developer temperature and the length of time the film is immersed in the developing tank must be documented and posted either in the darkroom or on the automatic processor;
 - 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.
- 3701:1-66-02 (J)(4) If provided, pass boxes must exclude light and provide adequate shielding from stray radiation to prevent exposure of undeveloped film.
 - 3701:1-66-02(J)(5) The darkroom must be light tight with proper safelighting that will meet compliance with this rule. Daylight film handling boxes must not allow fogging of the film.
 - 3701:1-66-02(J)(6) Assure that no light accidentally enters the darkroom while undeveloped films are being handled or processed.
 - 3701-1-66-02(J)(7) Assure that X-ray film is stored in a cool, dry place and is protected from stray radiation and light.
 - 3701:1-66-02(J)(8) Assure that film cassettes and intensifying screens are periodically checked and cleaned and replaced as needed to assure good diagnostic radiographic quality.
 - 3701:1-66-02(J)(9) Assure that expired film is not used for diagnostic radiographs.
 - 3701:1-66-02(J)(10) Assure that processing solutions are prepared and maintained properly so that full film development is achieved within the time frame specified by the film manufacturer.

Chapter 3701:1-66-04 (A)(B) of the OAC requires handlers of radiographic X-ray equipment to meet the following quality assurance requirements:

- 3701:1-66-04(A) Each registrant must develop and maintain a written quality assurance program.
- 3701:1-66-04(B) The registrant's quality assurance program may address several items in writing, but it must contain at least the following:
 - The frequency of and the procedures for the evaluation of the X-ray equipment to ensure compliance with this rule;
 - Any radiation monitoring requirements such as 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;
 - The radiation safety procedures for all types of X-ray equipment handled;
 - X-ray equipment operator training to assure competency in the operating procedures;
 - Identify the location, boundaries and purpose of a restricted area and describe the location and type of X-ray equipment handled. Individuals who are likely to work in a restricted area or who may receive an annual whole body dose of 100 millirem must receive instruction regarding the potential hazard of being in a restricted area;

- (Signatures of the individuals receiving this instruction document would suffice as proof that the "Instruction" was given);
- Indicate the quality control tests (e.g. repeat film analysis, evaluation of film/screen contact, etc.) to be performed and their frequencies.
- 3701:1-66-04(B)(9) At the time of the state inspection the following items must be readily available for review;
- A complete inventory of X-ray equipment to include location and description of each unit;
 - All quality assurance documents as required under this rule;
 - Data and test results of the evaluation of each X-ray unit and its shielding and surroundings;
 - Copies of each X-ray machine operator's state/dental radiologic license, as applicable;
 - Records required for each type of X-ray unit indicating the following:
 - ⇒ Personnel responsible for monitoring and performing quality control tests;
 - ⇒ A brief description of the procedures to be used for each quality control test to be performed;
 - ⇒ A list of the equipment to be used for each quality control test;
 - ⇒ The manner in which the performance of quality control tests will be documented;
 - ⇒ Biennial calibration certificates or cross-calibration documentation for instrumentation used to perform area radiation surveys, calibrations and evaluations, as appropriate for each type of radiation-generating equipment.

General Administration Requirements

Chapter 3701:1-66-02 of the OAC requires handlers of radiographic X-ray equipment to meet the following requirements:

- 3701:1-66-02(E) Assure that radiographic X-ray equipment that does not meet any provision of this rule or any applicable equipment requirement of Chapter 3701:1-66 of the OAC, is not operated for diagnostic purposes unless the Director or a Radiation Expert makes a determination that the non-compliance will not pose a radiation risk and arrangements have been made to promptly correct the non-compliance.
- 3701:1-66-02(F) Assure that each X-ray unit bears a warning label which cautions individuals that radiation is produced when it is energized.
- 3701:1-66-02(G) The registrant may utilize a qualified individual (e.g. Radiation Expert, Certified Radiation Expert, etc.) and shall assure that each radiographic X-ray unit meets the following equipment standards:
 - Leakage radiation from the diagnostic tube housing shall not exceed 100 milliRoentgens in one hour when measured according to this rule;
 - A "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;
 - ⇒ Grid type and focal distance (if applicable);
 - ⇒ Source-to-image distance (SID) to be used.

- The half-value layer (HVL) of the useful beam for a given X-ray tube potential shall not be less than the values shown in table 1 (http://www.odh.ohio.gov/Rules/Final/Chap1_66/Fr66_02.PDF) of this rule. The filtration contributed by all materials which are permanently between the source and patient shall be included when determining minimal HVL;
 - For X-ray systems that utilize variable kVp and filtration, a device which links the kVp and filtration shall prevent an exposure unless the half-value layer required by the above rule is met;
 - Where one exposure switch controls multiple X-ray tubes, prior to X-ray initiation, 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 prior to X-ray initiation and must be visible from the operator's position;
 - All locks, holding and centering devices must function as designed by the manufacturer.
- 3701:1-66-02(H) Handlers of radiographic X-ray equipment shall meet the following radiation safety requirements:
- The registrant shall develop safe operating procedures (including any restrictions for the safe use of the X-ray equipment) for the radiographic X-ray equipment, document instruction in those procedures and assure that all operators are competent in the safe use of the X-ray equipment;
 - Assure that 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 not less than 0.25 millimeter lead-equivalency;
 - Assure that only the patient is exposed to the useful beam for diagnostic purposes as ordered by a licensed practitioner;
 - Assure the following when a patient requires auxiliary support during an exposure:
 - ⇒ Mechanical holding devices are used as the procedure permits;
 - ⇒ The safe operating procedures must indicate the requirements for selecting someone to hold and the corresponding holding procedure;
 - ⇒ Instruction in personal radiation safety and protection (as documented in the safe operating procedures) is required if a radiation worker is selected to hold and the appropriate protective clothing of not less than 0.25 millimeter lead-equivalency must be worn;
 - ⇒ Adequate number of protective aprons and gloves are available for those persons involved in the X-ray exam.
 - Assure that procedures and auxiliary equipment designed to minimize patient and radiation worker exposure are commensurate with the needed diagnostic information and shall be utilized as follows:
 - ⇒ When grids are used, they must be positioned properly and used within the proper focal distance for the SID.
- 3701:1-38-10(A)(1) Handlers shall post the following documents:
- Current "Certificate of Registration" (if issued);
 - All applicable rules in Chapter 3701:1-38 of the Ohio Administrative Code;
 - The Ohio Department of Health (ODH), Bureau of Radiation Protection issued form titled "Notice to Employees;"
 - Safe Operating Procedures.
- 3701:1-38-11(E)(3) Handlers shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

ODH WEB SITES

Ohio Department of Health: <http://www.odh.ohio.gov>

Draft Rules: <http://www.odh.ohio.gov/Rules/rulesdraft.html>

Pending Rules: <http://www.odh.ohio.gov/Rules/rulespend.html>

Final Rules: <http://www.odh.ohio.gov/Rules/rulesfinal.html>

Ohio Department of Health Forms: <http://www.odh.ohio.gov/Forms/Formquery.asp>

Additional ODH Forms: http://www.odh.ohio.gov/ODHPrograms/XEQUIP/reg_guid1.htm

Anderson's Ohio Administrative Code:
<http://onlinedocs.andersonpublishing.com/oac>

Anderson's Ohio Revised Code:
<http://onlinedocs.andersonpublishing.com/revisedcode>

Radiologic Technology Section

Radiologic License:
<http://www.odh.ohio.gov/ODHPrograms/RLIC/rlicl.htm>

Certified Radiation Expert:
http://www.odh.ohio.gov/ODHPrograms/CR_EXP/cr_expl.htm

X-ray Equipment Registration and Inspection:
<http://www.odh.ohio.gov/ODHPrograms/XEQUIP/xequipl.htm>

Health Care Facility Licensing and Inspection:
http://www.odh.ohio.gov/ODHPrograms/HC_FAC/hc_fac1.htm

Please Note: For all Web addresses within the Radiologic Technology Section, the character before ".htm" is the numeral "1"(one) and not the alpha character "I."