

Revised January 19, 2005

Ohio Department of Health Regulatory Guide for Fluoroscopy Equipment

Purpose:

Handlers of fluoroscopic radiation-generating 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 *only 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.

General Administration Requirements

Chapter 3701:1-66-02 of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following general administrative requirements:

- ❑ 3701:1-66-02(B) Only a licensed Practitioner within his/her scope of practice may order the intentional irradiation of human beings for the purpose of dental, veterinary, and medical diagnosis.
- ❑ 3701:1-66-02(D)(1) The Department may use interview or observation to determine that handlers of radiation-generating equipment assure that every individual who performs radiologic procedures on human beings hold the appropriate license as required by Chapters 4773 and 4715 of the Revised Code and the Rules adopted thereunder.
- ❑ 3701:1-66-02(D)(2) The Department may use interview or observation to determine that handlers of radiation-generating equipment assure that every individual who is licensed to perform radiologic procedures is adequately instructed in the registrant's safe operating procedures and can demonstrate competency in the safe use of the equipment.
- ❑ 3701:1-66-02(E) If fluoroscopic radiation-generating equipment does not meet the provisions of this rule or any applicable equipment requirement of Chapter 3701:1-66 of the OAC, the equipment shall not be 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) Radiation-generating units must bear a warning label on the control panel that cautions individuals that radiation is produced when the unit is energized.

Quality Assurance Requirements

Chapter 3701:1-66-04 (A)(B) of the OAC requires handlers of fluoroscopic radiation-generating 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:
 - 3701:1-66-04(B)(1) The frequency of and the procedures for the evaluation of the radiation-generating equipment to ensure compliance with this rule;
 - 3701:1-66-04(B)(2) Any radiation monitoring requirements such as procedures for the use of area and personnel monitoring, occupational exposure limits, radiation surveys and maintenance of records;
 - 3701:1-66-04(B)(3) How and when the Director of Health will be notified following an occupational overexposure to radiation;
 - 3701:1-66-04(B)(4) Radiation safety procedures for all radiation-generating equipment handled;
 - 3701:1-66-04(B)(5) Operator training to assure competency in the safe operation of radiation-generating equipment;
 - 3701:1-66-04(B)(6) Identify the location, boundaries and purpose of a restricted area and describe the location and type of radiation-generating 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;
 - 3701:1-66-04(B)(7) Indicate the quality control tests (e.g. repeat film analysis, evaluation of film/screen contact, etc.) to be performed and the frequency of the quality control test;
 - 3701:1-66-04(B)(8) The Ohio Radiologic License or a copy of the license for each individual operating radiation-generating equipment as required by Chapters 4773 and 4715 of the Revised Code.
- 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 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.

Chapter 3701:1-66-02(J) of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following quality assurance requirements:

- ❑ 3701:1-66-02(J)(1) Radiation-generating equipment certified pursuant to 21 Code of Federal Regulations (CFR) Part 1020 and used on humans must be maintained in compliance with 21 CFR. This maintenance can include such things as calibrations, radiation safety surveys, preventive maintenance 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:
 - 3701:1-66-02(J)(2)(a) Model and serial numbers of all major radiation-generating equipment components and the user's/operator's manual;
 - 3701:1-66-02(J)(2)(b) Records of surveys, calibrations, maintenance and modifications made to the radiation-generating equipment;
 - 3701:1-66-02(J)(2)(c) A copy of all correspondence with the Department regarding each radiation-generating unit.
- ❑ 3701:1-66-02(J)(3) Improper film processing can cause unnecessary radiation exposure to the patient, the operator, ancillary personnel and the general public. For registrants who use fluoroscopic radiation equipment with spot film devices and develop 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 utilized, 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) Darkrooms shall be provided with a method to assure that light does not accidentally enter the darkroom while developing films.
 - ❑ 3701-1-66-02(J)(7) Radiographic film must be stored in a cool, dry place and protected from stray radiation and light.

- ❑ 3701:1-66-02(J)(8) Film cassettes and intensifying screens must be periodically checked, cleaned and replaced as needed to assure good diagnostic radiographic quality.
- ❑ 3701:1-66-02(J)(9) Expired film shall not be 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 3701:1-66-07(D) of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following quality assurance requirements:

- ❑ 3701:1-66-07(D)(1) Handlers of fluoroscopy equipment must utilize a Radiation Expert (RE) (veterinarians are not required to use a RE to meet the requirements of paragraph (D)(1) and (D)(4) of this rule).
- ❑ 3701:1-66-07(D)(1) The RE must perform the following tests on new fluoroscopy installations prior to patient exposure:
 - Spot film compliance test as specified in rule 3701:1-66-07(D)(2);
 - Fluoroscopic image quality test as specified in rule 3701:1-66-07(D)(4);
 - Tests to determine Entrance Exposure Rates (EER) as specified in rule 3701:1-66-07(D)(5).
- ❑ 3701:1-66-07(D)(2) The RE shall assure that the spot film device meets the specifications of this rule.
- ❑ 3701:1-66-07(D)(3) After the initial evaluations of the fluoroscopic unit have been performed, the tests and evaluations in (D)(1) of this rule must be performed annually.
- ❑ 3701:1-66-07(D)(4) The RE must develop written procedures and perform image quality evaluations that include the time intervals and system conditions for the evaluation of image quality. The written records of all image quality evaluations performed must be maintained between inspections.
- ❑ 3701:1-66-07(D)(5) Measurements of EER must be performed as specified in rule 3701:1-66-07(A)(8).
- ❑ 3701:1-66-07(A)(8) The maximum entrance exposure rate must be measured with a block of at least two millimeters thick lead-equivalent intercepting the entire useful beam. EER limits must be determined as follows:
 - 3701:1-66-07(A)(8)(a) If the source is below the X-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle;
 - 3701:1-66-07(A)(8)(b) If the source is above the X-ray table, the exposure rate must be measured 30 centimeters above the tabletop with the end of the beam-limiting device or spacer cone as close as possible to the point of measurement;
 - 3701:1-66-07(A)(8)(c) C-arm type units must be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any Source to Image Distance (SID);
 - 3701:1-66-07(A)(8)(d) For fixed SID lateral fluoroscopes attached to the X-ray table, the maximum EER must be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the table.

- ❑ 3701:1-66-07(D)(5)(a) The RE must perform the EER test annually or after any maintenance that might affect the exposure rate.
- ❑ 3701:1-66-07(D)(5)(b) Results of the EER measurements must be stated in Roentgens per minute (R/min) and include technique factors used to determine the results, the name of the individual performing the measurements and the date of the measurements.
- ❑ 3701:1-66-07(D)(6) An area radiation survey must be completed by a RE upon installation or after any change in the structural shielding or fluoroscopic equipment that may cause a significant increase in radiation hazard.
- ❑ 3701:1-66-07(D)(7) The individual responsible for radiation protection must obtain a written report of the area radiation survey from the RE and a copy of the report must be made available to the Director upon request.

Radiation Safety Requirements

Chapter 3701:1-66-02 of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following radiation safety requirements:

- ❑ 3701:1-66-02(H)(1) The registrant shall develop safe operating procedures for the fluoroscopic radiation-generating equipment and assure that all operators are competent in the safe use of the radiation-generating equipment. The instruction must be documented.
- ❑ 3701:1-66-02(H)(2) Gonad shielding of not less than 0.25 millimeter lead-equivalency must be utilized on human patients who have not passed the reproductive age and for procedures in which the gonads are in the useful beam.
- ❑ 3701:1-66-02(H)(3) All individuals required for the procedure must be protected by either a lead apron or whole-body protective barrier of not less than 0.25 millimeter of lead-equivalence.
- ❑ 3701:1-66-02(H)(4) Refer to rule 3701:1-66-07(C).
- ❑ 3701:1-66-02(H)(5) Assure that only the patient is exposed to the useful beam for diagnostic purposes as ordered by a licensed practitioner.
- ❑ 3701:1-66-02(H)(6) When a patient requires auxiliary support during an exposure, the handler must assure the following:
 - 3701:1-66-02(H)(6)(a) Mechanical holding devices are used as the procedure permits;
 - 3701:1-66-02(H)(6)(b) Safe operating procedures must indicate the requirements for selecting someone to hold and the corresponding holding procedure;
 - 3701:1-66-02(H)(6)(c) If a radiation worker is to be the holder, the worker must be instructed in personal radiation safety and protection (as documented in the safe operating procedures). Protective clothing of not less than 0.25 millimeter lead-equivalency must be worn;
 - 3701:1-66-02(H)(6)(d) 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;
 - 3701:1-66-02(H)(6)(e) There must be an adequate number of protective aprons and gloves available for those persons involved in the X-ray exam.
- ❑ 3701:1-66-02(I)(1) Provide structural shielding to assure that no person other than the patient being examined receives a total effective dose equivalent in excess of the limits prescribed in rules adopted pursuant to Chapter 3748 of the Revised Code.
- ❑ 3701:1-66-07(B) Handlers of fluoroscopic radiation equipment must provide secondary barriers in all walls, floors and ceilings.

Equipment Standards

Chapter 3701:1-66-02 of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following equipment standards:

- ❑ 3701:1-66-02(G)(2) Leakage radiation from the diagnostic tube housing measured at one meter in any direction from the source shall not exceed 100 milliRoentgens in one hour.
- ❑ 3701:1-66-02(G)(3) A “technique” chart must be provided and posted near the control panel. The technique chart must provide:
 - 3701:1-66-02(G)(3)(1) Patient’s body part and anatomical size; or part thickness; or age in the case of pediatrics and the technique factors to be utilized for each.
- ❑ 3701:1-66-02(G)(4) The half-value layer (HVL) of the useful beam for a given radiation-generating 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 that are permanently between the source and patient shall be included when determining minimal HVL.
- ❑ 3701:1-66-02(G)(6) If one exposure switch controls multiple radiation-generating tubes, a clear indication of the tube making the exposure must be on the control panel and on or near the tube housing prior to exposure.
- ❑ 3701:1-66-02(G)(7) The radiation-generating tube must remain stable during exposures unless tube movement is a design of the unit.
- ❑ 3701:1-66-02(G)(8) Technique factors must be indicated prior to X-ray initiation and must be visible from the operator’s position.
- ❑ 3701:1-66-02(G)(9) All position locks, holding and centering devices must function as designed by the manufacturer.

Chapter 3701:1-66-07 of the OAC requires handlers of fluoroscopic radiation-generating equipment to meet the following equipment standards:

- ❑ 3701:1-66-07(A)(1) Unless the Food and Drug Administration has granted a variance for the source-to-skin distance (SSD) of the specific fluoroscopic stationary system, the SSD shall not be less than 38 centimeters on stationary units manufactured on or after Aug. 1, 1974. The SSD shall not be less than 35.5 centimeters on stationary fluoroscopic systems manufactured prior to Aug. 1, 1974.
- ❑ 3701:1-66-07(A)(2) The fluoroscopic image assembly must be provided with a primary barrier that intercepts the entire useful beam at any source-to-image distance (SID). The exposure shall be prevented when the primary barrier is not in the path of the entire useful beam.
- ❑ 3701:1-66-07(A)(3) Fluoroscopic equipment must be provided with intensified imaging. Intensified imaging includes digital detectors.
- ❑ 3701:1-66-07(A)(4) Fluoroscopy equipment shall meet the following field limitation specifications:
 - 3701:1-66-07(A)(4)(a) Neither the length nor width of the X-ray field in the plane of the image receptor shall exceed the length or width of the visible area of the image receptor by more than 3 percent of the SID;
 - 3701:1-66-07(A)(4)(b) The sum of the excess length and the width shall not exceed 4 percent of the SID. Compliance shall be determined with the beam axis perpendicular to the plane of the image receptor;

- 3701:1-66-07(A)(4)(c) Beam-limiting devices shall be provided with a means for stepless adjustment of the X-ray field;
- 3701:1-66-07(A)(4)(d) At the greatest SID stepless adjustment shall provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters.
- 3701:1-66-07(A)(5)(a) A preset-cumulative timer shall be provided on the fluoroscopy unit to preset cumulative exposure time. The maximum cumulative time of the timer shall not exceed five minutes without resetting.
- 3701:1-66-07(A)(5)(b) When the exposure time reaches a maximum of five minutes, the timer shall terminate the exposure or emit an audible signal to the operator. The audible signal shall continue to sound during the radiation exposure until the timer is reset.
- 3701:1-66-07(A)(6) X-ray production shall be controlled by a device that requires continuous pressure by the operator for the entire exposure.
- 3701:1-66-07(A)(7)(a) The entrance exposure rate at the point where the center of the useful beam enters the patient for fluoroscopy equipment with automatic or with both automatic and manual exposure rate control shall not exceed ten Roentgens per minute (10 R/min) at any combination of tube potential and current.
- 3701:1-66-07(A)(7)(b) The entrance exposure rate at the point where the center of the useful beam enters the patient for fluoroscopy equipment with manual exposure rate control shall not exceed five Roentgens per minute (5 R/min) at any combination of tube potential and current.
- 3701:1-66-07(A)(7)(c) The entrance exposure rate at the point where the center of the useful beam enters the patient for fluoroscopy equipment with high-level control and the high-level control is activated shall not exceed 20 Roentgens per minute (20 R/min) at any combination of tube potential and current.
 - 3701:1-66-07(A)(7)(c)(i) Fluoroscopy equipment provided with high-level control shall have a special means to activate the high-level control;
 - 3701:1-66-07(A)(7)(c)(ii) A continuous audible signal shall be available to indicate that high-level control is activated.
- 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

Radiation-generating 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 "l."