

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- (A) Each registrant shall develop, implement and maintain a written quality assurance program. For purposes of this chapter and chapter 3701:1-67 of the Administrative Code, quality assurance program means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities.

**Each registrant must develop a written quality assurance program (procedures) that identifies sound radiation safety practices and promotes the safe operation of radiation-generating equipment.**

- **A well written quality assurance program promotes prompt identification, correction and reporting (if necessary) of deficiencies, deviations, defective equipment or unsafe practices.**
- **This written quality assurance program must be implemented - meaning that the quality assurance program is being carried out by the staff.**
- **The written quality assurance program must be maintained – meaning the quality assurance program must be revised to reflect any changes to radiation safety practices and organized in a written document or electronic document.**

**Inspectors will review the written quality assurance program for appropriateness.**

- (B) The written quality assurance program of each registrant shall address and include records to verify implementation of at least the following:

**The written quality assurance program must contain policies and procedures described in this rule.**

**Records to verify implementation include documenting results of the tests, audits and inspections performed by responsible facility personnel.**

**Inspectors will review the written quality assurance program to verify its appropriateness. In addition, inspectors will review test, audit and inspection results to verify the policies and procedures are being implemented as written.**

- (1) The intervals of and procedures for the evaluation of all radiation-generating equipment to ensure compliance with all applicable rules of this chapter;

**The written quality assurance program must indicate a specific interval at which the radiation-generating equipment is evaluated and calibrated to ensure that the radiation-generating equipment is working according to all applicable requirements of Chapter 3701:1-66 of the Ohio Administrative Code.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

The procedures for such an evaluation may include periodic evaluation by a radiation expert (medical physicist), the performance of manufacture recommended preventative maintenance by appropriately trained personnel, or a combination of the above.

Typical compliance evaluations include testing the reproducibility and accuracy of the radiation output, the accuracy of the beam restriction device (collimators) and the condition of the x-ray beam, according to clinical use factors.

Inspectors will review the written quality assurance program to verify the registrant has committed to a specific evaluation interval and adequate evaluation procedures. In addition, the inspectors will review the actual evaluation records to verify the procedures have been implemented.

**NOTE:** The periodic inspection by the Ohio Department of Health does not meet the evaluation and calibration requirements of this rule. The Ohio Department of Health's inspection is only to verify compliance with the rule requirements.

- (2) Procedures for maintaining compliance with occupational and public exposure limits;

The requirements for occupational and public exposure limits are found in rules 3701:1-38-12 and 3701:1-38-13 of the Ohio Administrative Code (OAC).

Refer to rules 3701:1-38-14(B) and 3701:1-66-02(H)(7) of the OAC to determine if personnel monitoring (badges) are necessary.

- If unnecessary, the written quality assurance program must identify that personnel monitoring is not required and all individuals are to follow all time distance and shielding requirements of the quality assurance program.
- If personnel monitoring is necessary or provided, the written quality assurance program must identify the following:
  - Rule 3701:1-38-14(C) of the OAC, wearing individual monitoring devices (badges): For example:
    - Whole body monitoring, the individual monitoring device must be worn at an unshielded location likely to receive the highest exposure. When an apron is worn, the location is usually the neck.
    - Individual monitoring devices for monitoring dose to the embryo or fetus of a declared pregnant women pursuant to paragraph (H) of rule 3701:1-38-12 of the OAC shall be located at the waist under any protective apron being worn the woman.
  - Rule 3701:1-38-10(C) of the OAC, requirements to provide monitoring records to individuals:

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- **Annually – if the individual’s occupational dose exceeds one millisievert (one hundred millirem) TEDE or one millisievert (one hundred millirem) to any individual organ or tissue.**
- **At the request of a worker formerly engaged in radiation activities controlled by the facility.**
- **When a facility is required pursuant to paragraphs (A) to (C) of rule 3701:1-38-21 of the OAC to report any exposure of an individual to the Director, the facility shall also provide the individual a written report on the exposure data included in the report to the Director.**
- **At the request of an employee who is terminating employment.**

**Inspectors will evaluate the exposure limit monitoring requirements and compare those requirements with the written quality assurance program to verify the procedures are adequate and have been effectively implemented.**

**Note: related topic - you may also refer to rules 3701:1-38-14(A) and 3701:1-66-02(I) of the OAC regarding survey requirements.**

- (3) Procedures for notifying the director when individuals are occupationally over-exposed to radiation, pursuant to Chapter 3701:1-38 of the Administrative Code;

**If individual monitoring devices (badges) are required or provided, the quality assurance program of the facility must include a procedure for notifying the Director of individuals occupationally over-exposed to radiation.**

**The procedure must identify that the Director will be notified in accordance with rule 3701:1-38-21 of the OAC.**

**Inspectors will review the written quality assurance program to verify the requirements of this rule are adequately addressed. In addition, inspectors will review individual monitoring records for the inspection period to verify the procedures have been implemented.**

- (4) Safe operating procedures for each type of radiation-generating equipment to be handled;

**Safe Operating Procedures must be provided for each type of radiation-generating equipment on site. If the facility has several radiographic units that are of the same type, then only one set of safe operating procedures for those units is necessary.**

**The safe operating procedures for radiation-generating equipment are part of the quality assurance program and may include topics such as:**

- **Follow manufacture specification for equipment operation, morning QC if applicable and warm-up**

## **Guidance in Bold Text**

Rule 3701:1-66-04      Effective Date: 02/1/14

### **Quality assurance program**

- **Use devices or administrative procedures to prevent unauthorized use of the radiation-generating equipment 3701:1-38-17**
- **Position of operator during radiation exposures**
  - **Six feet from dental I/O unit when switch is on a cord**
  - **Behind protective barrier and able to see the patient when exposure switch is permanently mounted behind a protective barrier**
- **Use appropriate techniques for patient examinations from a technique chart or preprogramed control panel (3701:1-66-02(H))**
- **Provide appropriate patient shielding during exposure 3701:1-66-02(H)**
- **Proper use of the radiation-generating equipment's collimation to reduce radiation exposure**
- **Proper use of mobile barriers, lead aprons and lead gloves.**
- **Provide appropriate protective apparel for individuals required for the radiographic procedure 3701:1-66-02(H)**
- **Only appropriate licensed individuals may operator radiation-generating equipment to expose human beings. 3701:1-66-02(D)(1)**
- **When multiple tubes are controlled by one exposure switch, the operator must know how to tell which tube is selected 3701:1-66-02(G)(5)**
- **If applicable, proper use of a manual line voltage compensator to maintain appropriate energy**
- **Indication that only licensed practitioners order x-ray examinations**
- **Proper attachment of removable spacer cone on c-arm fluoroscopic equipment**
- **If applicable, limitations on source-to-image distance selection due to grid focal length**
- **The radiation-generating equipment tolerance limits and not to exceed those limits**

**Inspectors will evaluate the facility to determine what operating conditions must be addressed and compare those conditions with the written quality assurance program to verify the safe operating procedures are adequate and have been effectively implemented.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- (5) Training of operators of each type of radiation-generating equipment to be handled in order to assure competency in the operating procedures;

**The written quality assurance program must address operator training specific to each type of x-ray unit operated by a particular individual at the facility.**

**The records for verifying implementation of the operator training program must show a trainer / trainee relationship with sign-off.**

**Inspectors will review the written quality assurance program to verify the training procedures address all types of radiation-generating equipment handled by the facility. The inspector will also review the training records of all individuals that have operated radiation-generating equipment during the inspection period.**

- (6) In addition to the requirements of paragraph (B) of rule 3701:1-38-10 of the Administrative Code, individuals likely to receive an annual occupational dose in excess of one millisievert (one hundred millirem) shall be instructed in the following:

**This rule is applicable to individuals that are likely to receive an annual occupational dose in excess of one millisievert (one hundred millirem).**

- (a) The location, boundaries, and purpose of restricted areas;

**The written quality assurance program must describe the restricted area(s):**

- **A restricted area is an area limited by the facility for the purpose of protecting individuals against undue risks from exposure to radiation.**
- **Clear identification and enforcement of a location (such as a room) as being a restricted area during radiation exposure is acceptable.**
- **Clear identification of the boundaries of open areas as restricted areas must also have methods for operator enforcement to assure those boundaries are maintained during radiation exposure.**
- **Example: the universal three-blade radiation signs are good for clearly outlining boundaries or restricted areas.**

**Inspectors will review the written quality assurance program to verify the instruction identifies the location and boundaries of all restricted areas at the facility. The inspector will also verify the instruction records of individuals that were likely to receive an occupational dose greater than one millisievert during the inspection period.**

- (b) a description of the radiation-generating equipment and its location;

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

**The written quality assurance program must describe the type of radiation-generating equipment and its location:**

**Examples:**

- **An intraoral unit is located in room A**
- **Room A has an intraoral unit**
- **Room A has a computed tomography unit**

**Inspectors will review the written quality assurance program to verify the instruction describes all radiation-generating equipment at the facility. The inspector will also verify the instruction records of individuals that were likely to receive an occupational dose greater than one millisievert during the inspection period.**

- (7) **The quality control tests to be performed, the frequency of the quality control tests to be performed and the personnel responsible for the performance of the quality control tests as applicable to the radiation-generating equipment type and use;**

**The written quality assurance program must indicate the specific intervals at which quality control testing is to be performed and identify the personnel responsible for performing the quality control tests. Radiation-generating equipment manufacturers often provide recommended quality control testing schedules and procedures.**

**At a minimum, quality control testing procedures must address (as applicable):**

- **The temperature of their film developer chemistry [ref. rule 3701:1-66-02(J)(3)(a) or (b) of the Ohio Administrative Code (OAC)].**
- **Film processing solution preparation and maintenance [ref. rule 3701:1-66-02(J)(3)(d), OAC].**
- **Cassette/screen or cassette/computed radiography (phosphorus) imaging plate maintenance [ref. rule 3701:1-66-02(J)(9) of the OAC].**
- **The process that will ensure computed radiography (phosphorus) plates are used frequently enough or erased so as to produce diagnostic quality images [ref. rule 3701:1-66-02(J)(10)(c) of the OAC and manufacturer specifications].**
- **[Fluoroscopy equipment only] Initial and annual quality control tests that must be performed by a radiation expert (medical physicist) [ref. 3701:1-66-07(C)(2)(a), (C)(2)(b) and (C)(2)(c) of the OAC].**
- **[Stereotactically-guided breast biopsy equipment only] Initial and annual quality control tests that must be performed by a radiation expert (medical physicist) [ref. 3701:1-66-08(G) of the OAC].**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

- **[Computerized tomography (CT) equipment only]:**
  - **[Conventional (fan beam) CT]:**
    - **Initial and annual quality control tests that must be performed by a radiation expert (medical physicist) [ref. 3701:1-66-10(C)(1)(a) (C)(1)(b) of the OAC].**
    - **Quality control program that must be performed by the CT technologist and must be approved by a radiation expert (medical physicist) [ref. 3701:1-66-10(C)(1)(e) of the OAC].**
  - **[Cone beam CT]:**
    - **Quality control test procedures, frequencies and tolerance limits developed under the guidance of a radiation expert (medical physicist) [ref. 3701:1-66-10(D)(1), of the OAC].**
    - **Initial and annual quality control tests that must be performed by a radiation expert (medical physicist) [ref. 3701:1-66-10(C)(1)(a) (C)(2), OAC].**
- **[Bone densitometry equipment only] Quality control tests as specified by the manufacturer [ref. 3701:1-66-11(C)(1), OAC].**

The identified responsible personnel may be from within the facility staff, from an outside company or a combination of the two. At a minimum, unless specified by another OAC rule, facility records must list responsible personnel by job description (a list by name may be appropriate, but is not required to meet compliance with this rule).

Inspectors will review the written quality assurance program to verify the registrant has committed to specific quality control testing intervals and adequate quality control testing procedures. In addition, the inspectors will review the actual quality control records to verify the procedures have been implemented.

- (8) Policies regarding the state licensure or certification of each person operating radiation-generating equipment as required by Chapters 4773. and 4715. of the Revised Code;

The written quality assurance program must contain policies that address the process that will be used to ensure each individual who operates radiation-generating equipment holds a valid license or certificate as required by the Ohio Revised Code.

### Example:

- Only individuals appropriately licensed in accordance with Chapter 3701-72 of the Ohio Administrative Code are allow to take x-rays.
- The facility verifies active licenses via the Ohio Department of Health website at <https://odhgateway.odh.ohio.gov/xraylicensure/activelicenses.aspx>
- Add any other procedures the facility does to comply with this rule.

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

**Inspectors will review the written quality assurance program to verify an adequate licensure or certification program. In addition, the inspectors will review actual licensure and/or certification documents for each individual who operated radiation-generating equipment to verify the procedures have been implemented.**

- (9) The dissemination of quality assurance policies and a method to educate affected workers on those policies any policy changes;

**The written quality assurance program must indicate:**

- **How quality assurance policies are provided to all workers that would be affected by those policies.**
- **The method used to provide policy changes to affected workers.**

**Inspectors will review the written quality assurance program to verify adequate dissemination and education on policies and policy changes. In addition, the inspectors interview workers to verify implementation of the procedures.**

- (10) Radiation workers' role and responsibility for following and supporting the quality assurance program;

**The written quality assurance program must identify that the radiation worker is responsible for following and supporting the policies and procedures of the radiation quality assurance program. This support should include enforcing the radiation safety policies and procedures of the quality assurance program.**

**Inspectors will review the written quality assurance program to verify that the radiation worker's role and responsibility have been specified in the quality assurance program and interview workers to verify implementation.**

- (11) Policies regarding personnel protection, including time, distance, and shielding;

**The written quality assurance program must contain policies regarding the judicial use of time, distance and shielding for the purposes of personnel protection.**

**Example:**

- **Other than the patient no one is allowed in the x-ray room during radiation exposures.**
- **When participating in fluoroscopy procedures wear lead aprons and maintain as much distance as possible from the fluoroscopy tube and image intensifier.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- **In line with rule 3701:1-66-02(H)(3) only staff required for the medical procedure:**
  - **Must be positioned such that no part of the body is struck by the useful beam.**
  - **Shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than .25 millimeters of lead equivalent material.**

**Inspectors will review the written quality assurance program to verify that time distance and shielding concepts have been specified.**

- (12) Policies regarding occupational exposure of pregnant workers;

**The written quality assurance program must contain policies regarding the occupational exposure of pregnant workers.**

**At a minimum, the policy must specify the facility will follow the requirements of rule 3701:1-38-10, 3701:1-38-12, 3701:1-38-14 and 3701:1-38-20 of the Ohio Administrative Code (OAC).**

**Inspectors will review the written quality assurance program to verify that occupational exposure of pregnant workers has been addressed in the quality assurance program.**

- (13) Policies regarding radiation safety training for ancillary personnel;

**'Ancillary personnel' are those individuals who are present during the operation of radiation-generating equipment, but not directly involved in the operation. Such individuals may include nurses, surgeons, anesthesiology staff, surgical assistants, speech pathology staff, emergency department staff, etc. However, under conditions where ancillary personnel are occupationally exposed to radiation, basic radiation safety training must be provided.**

**Inspectors will evaluate the facility to determine the extent of occupational exposure received by ancillary personnel and compare those exposure conditions with the written quality assurance program to verify the policies regarding radiation safety training for ancillary personnel are adequate and have been effectively implemented.**

- (14) Policies regarding training for personnel with quality control responsibilities; and

**The written quality assurance program must contain policies addressing training for personnel with quality control responsibilities. The policies may be specific to a particular individual or generally applied to all personnel with a particular job description.**

**Inspectors will review the written quality assurance program to verify the registrant has developed a training program for personnel with quality**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

**control responsibilities. In addition, the inspectors will review actual training records for individuals that have performed quality control testing during the inspection period to verify the program has been implemented.**

- (15) Policies regarding patient protection, including screening for pregnancy, exposure of pregnant patients, patient shielding, patient education, patient identity verification.

**The written quality assurance program must contain policies regarding the topics listed in this rule.**

**Example:**

- **Patient protection – radiation signs posted to identify restricted areas. Sponges and positioning devices used to support patients during examinations.**
- **Screen for pregnancy – patients are screened for pregnancy to identify pregnancy and whether the benefit versus the risk of having a radiation examination versus the benefit of some other testing option.**
- **Policy on exposure of pregnant patient – determination of risk versus benefit.**
- **Patient shielding – policy in line with rule 3701:1-66-02(H)(2).**
- **Patient education – any written information provided to patients such as pamphlets describing the examination, preparation and post instructions, etc....**
- **Policy on identifying the patient – best practice is to use a combination of two methods of identification.**

**Inspectors will review the written quality assurance program to verify that the concepts listed in this rule have been specified.**

- (C) In addition to the requirements of paragraphs (A) and (B) of this rule the quality assurance program of hospital registrants shall comply with the following:

**NOTE: ONLY hospitals as defined in section 3727.01 of the Ohio Revised Code must follow paragraph (C) of the rule. All other registrants may scroll down to paragraph (D) of this rule for further guidance.**

- (1) A certified radiation expert shall conduct oversight and maintenance of quality assurance programs for hospital registrants, by:

**An Ohio Certified Radiation Expert (CRE) must conduct oversight and maintenance of the hospital's quality assurance program for the following categories of radiation-generating equipment:**

- **Therapeutic**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- **Diagnostic other than mammography**
- **Mammography**

**A radiation expert is certified in accordance with rule 3701:1-66-03 of the Ohio administrative Code.**

**A hospital may use a single CRE certified in all applicable categories or a number of CREs to cover all categories.**

**A current copy of the CRE's certificate is required to verify the credentials of the CRE at inspections.**

- (a) Auditing the quality assurance program on an annual basis;

**The CRE of the appropriate category must audit the hospital's quality assurance program at intervals not to exceed one year, plus or minus one month (according the definition of 'annually' found in rule 3701:1-38-01(A)(18) of the OAC. The audit must be completed according to the requirements of rule 3701:1-66-04(C)(6) of the OAC.**

- (b) Performing quarterly reviews;

**The CRE of the appropriate category must perform quarterly reviews in accordance with the requirements of rules 3701:1-66-04(C)(5)(a – e) of the OAC. The definition of 'quarterly' can be found in rule 3701:1-38-01 of the OAC.**

- (c) Completing and submitting all required information with the annual audit form in accordance with paragraph (C)(6) of this rule, and;

**The CRE of the appropriate category is required to provide all attachments and required information with the annual audit form.**

- (d) Serving on the quality assurance committee.

**The CRE must be a member of the hospital's quality assurance committee.**

- (2) Employees working in the radiation areas shall be made aware of the identity, scope of authority, and a method for contacting the certified radiation expert and the individual responsible for radiation protection. This information, or a specific location where this information may be obtained, shall be conspicuously posted in each area where radiation-generating equipment is used.

**Documents containing the information described in this rule must be posted in each area where radiation-generating equipment is used. This can be a central location between x-rays rooms where routine work takes place. The posting is to be placed where individuals who work in the radiation area can observe the postings during their normal work routine.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

**The document must be replaced if the required information becomes illegible.**

**Inspectors will observe the postings and their locations to determine if the requirements of this rule have been met. Inspectors may verify implementation by interviewing employees to see if they are aware of the posting's location.**

- (3) Each hospital registrant shall establish a quality assurance committee for the management of the quality assurance program. The members of the quality assurance committee shall be approved by an executive administrator. Committee meetings may be attended by the members or similarly qualified, designated alternates. The quality assurance committee shall include at least the following members:

**A committee for the management of the quality assurance program must be established by each hospital. Members and alternate members on this committee must be approved by a hospital executive administrator. Attendance by either the committee member or the similarly qualified individual designated as their alternate may count towards meeting the quorum requirements described in paragraph (C)(4) of this rule.**

- (a) A member of the hospital's executive administration;

**An individual employed in the hospital's administration must be a member of the quality assurance committee. According to the definition of "executive administration" found in rule 3701:1-66-01 of the Ohio Administrative code, this individual must have the authority to expend capital funds, approve personnel actions and implement changes to hospital policy and procedure.**

**Inspectors will review documents and interview staff members to determine if a member of the hospital's executive administration is included in the membership of the quality assurance committee.**

- (b) The individual responsible for radiation protection;

**The individual designated by the registrant on their registration must be a member of the quality assurance committee. According to the definition of "individual responsible for radiation protection (IRRP)" found in rule 3701:1-66-01 of the Ohio Administrative code, this individual must have the knowledge and responsibility for overall radiation safety and the quality assurance program at the facility, to include daily radiation safety operations and compliance with the rules.**

**Inspectors will review documents and interview staff members to determine if the individual responsible for radiation protection is included in the membership of the quality assurance committee.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- (c) A radiologist or radiation oncologist;

**An individual who has completed a formal (residency) training program approved by the Residency Review Committee for Radiology**

**of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association must be a member of the quality assurance committee.**

**Inspectors will review documents and interview staff members to determine if a radiologist or radiation oncologist is included in the membership of the quality assurance committee.**

- (d) A certified radiation expert representing each of the following as applicable in each hospital;

(i) Radiation therapy services;

(ii) Mammography, or

(iii) Diagnostic radiography other than mammography; and

**The certified radiation expert(s) of the appropriate category must be a member of the quality assurance committee.**

**Inspectors will review documents to determine if a certified radiation expert representing each of the applicable categories is included in the membership of the quality assurance committee.**

- (e) A management representative of each department of the hospital which has responsibilities involving the handling of radiation-generating equipment.

**A management representative from each department which has responsibilities for handling radiation-generating equipment must be included in the membership of the quality assurance committee.**

- **The department considers any individual who is in a position of authority over any number of other individuals in the represented department to meet the definition of 'management.'**
- **The department considers any department in which radiation-generating equipment is operated without direct support from a department represented on the quality assurance committee to be handling radiation-generating equipment (i.e. a department where miniature c-arm fluoroscopic units are operated by physicians without a radiologic technologist (from Radiology) in the room during any procedure would need to be represented on the quality assurance committee).**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

**Inspectors will evaluate the facility to determine if all departments requiring representation are included in the membership of the quality assurance committee.**

- (4) The quality assurance committee shall meet as often as is deemed necessary to carry out its duties, but at least on a quarterly basis. To establish a quorum at least one-half of the committee's membership must be present either in person or by telecommunication means, and must include the individual responsible for radiation protection for the hospital, and the member of the executive administration of the hospital. In addition, each member must attend at least one quarterly meeting each calendar year. A record of each meeting shall be maintained and distributed to each member which shall include the following:

**At a minimum, the quality assurance committee must meet at least once each quarter according the definition of 'quarterly' found in rule 3701:1-38-01 of the OAC.**

**Although attendance by all members or designated alternates is encouraged, at a minimum, each member or his/her designated alternate must be present for at least one meeting each calendar year.**

**At least one-half of the committee's membership must be present either in person or by telecommunication to establish a quorum. For a committee with an odd number of members, quorum is reached by rounding up (i.e. a 7 member committee would require attendance by 4 members to meet quorum).**

**All meetings require the attendance of the individual responsible for radiation protection and the executive administrator or their approved alternates.**

**A record of the meeting shall be maintained and a process in place to distribute the meeting record to each appointed member of the committee. If the procedure consists of distributing the meeting record at the time of the subsequent committee meeting, but all members are not generally in attendance at all meetings, an alternate means of record distribution must be developed (i.e. e-mail, interoffice mail, etc.).**

**Inspectors will evaluate the meeting records or may interview staff to determine compliance.**

- (a) The date of the meeting;

**Record the date of the meeting.**

- (b) An indication of members present; and

**Identify attendance in the meeting record. This includes attendance by telecommunication.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

Quality assurance program

- (c) A summary of meeting including any recommended actions and ALARA reviews.

**Provide a summary of the meeting and all recommended actions and ALARA reviews.**

**Inspectors will review meeting records to determine if all required components are documented for the meetings that took place during the inspection period.**

- (5) Each quarter, the certified radiation expert shall submit, to each appointed quality assurance committee member, a review of the quality assurance plan which shall contain, as applicable:

**The definition of 'quarter' is found in rule 3701:1-38-01 of the OAC.**

- (a) Radiation safety policy revisions proposed by the certified radiation expert;

**If the certified radiation expert proposes any revisions or radiation safety issues that are not appropriately addressed in the quality assurance program, the revisions or issue must be submitted to the quality assurance committee members.**

**If the CRE does not propose any revisions, it should be documented that no revisions are proposed or identified on the review submitted to the quality assurance committee members.**

**Inspectors will check that the CRE's review of the radiation safety policy was submitted to the quality assurance committee members.**

- (b) A review of occupational exposure records by the certified radiation expert;

**The certified radiation expert must submit to the quality assurance committee members a review of the occupational exposure records.**

**The certified radiation expert must develop a plan such that the actual exposure records are effectively reviewed by the certified radiation expert. If the plan involves review of the actual records by intermediary personnel, the certified radiation expert must ensure the plan educates those reviewers to recognize irregular occupational exposure results. This includes reviewing records for exposure levels that exceed 'ALARA levels' or other irregularities that may indicate improper use.**

**Inspectors will check that the CRE's review of the occupational exposure records was submitted to the quality assurance committee members.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- (c) Radiation safety incidents;

**The certified radiation expert must submit to the quality assurance committee members any radiation safety incidents identified during the quarterly review.**

**If there are no radiation safety incidents, it should be documented that no radiation safety incidents occurred on the review submitted to the quality assurance committee members.**

**Inspectors will check that CRE's quarterly review addressed radiation safety incidents and was submitted to the quality assurance committee members.**

- (d) Radiation-generating equipment performance evaluation summaries to include a description of any issues found; and

**A summary of the radiation-equipment performance evaluations that took place during the reviewed quarter must be included in the review. The summary must, at a minimum, include a description of any issues found.**

**Inspectors will check that the CRE's quarterly review addressed radiation-generating equipment performance evaluations and any issues found.**

- (e) Any corrective actions recommended by the certified radiation expert necessary to comply with the requirements of this chapter.

**If the certified radiation expert identifies any areas of non-compliance with the regulations, the recommended corrective actions to the non-compliance must be submitted to the quality assurance committee.**

**If the certified radiation expert does not identify non-compliances with the regulations, it should be documented on the review submitted to the quality assurance committee.**

- (6) The quality assurance program shall be audited at least annually as defined in paragraph (A)(18) of rule 3701:1-38-01 of the Administrative Code by a certified radiation expert. The certified radiation expert shall develop a written report of the audit findings on forms prescribed by the director and submit the report to the quality assurance committee within thirty days of completing the audit. The quality assurance committee shall review the audit report and implement any corrective actions

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

determined to be necessary. The certified radiation expert shall file the audit report with the director, within ninety days of completing the audit. Every audit report shall include a determination of whether the quality assurance program properly addresses the matters described in this rule and whether it is being carried out in accordance with the written quality assurance program, and any corrective actions to be taken to comply with the requirements of this chapter. The audit report shall become a part of the inspection record.

**A certified radiation expert, certified in each category of radiation-generating equipment handled by the hospital, must audit the hospital's quality assurance program at intervals not to exceed one year, plus or minus one month. Definition of 'annually' found in rule 3701:1-38-01.**

**The annual audit report must include a completed audit form prescribed and include the CRE's:**

- **Determination of whether the quality assurance program properly addresses all requirements of rule 3701:1-66-04 of the OAC and whether the quality assurance program is being carried as written.**
- **Determination of any corrective actions to be taken to comply with the requirements of Chapter 3701:1-66 of the OAC.**

**The certified radiation expert must submit the entire annual audit report to each member of the quality assurance committee within thirty days of completing the audit.**

**The quality assurance committee must review the audit report and implement any corrective actions determined to be necessary. The committee's review and corrective action must be documented to demonstrate occurrence. The good place for this documentation is in the quality assurance meeting minutes.**

**The certified radiation expert must also file the audit report with the Ohio Department of Health within 90 days.**

- (D) At the time of the state inspection the following items shall be readily available for review:

**Routine inspections are scheduled in advance to accommodate facilities by giving them time to plan for the inspection including gathering documents together in one place or at minimum making the documents readily available by other means for inspection.**

**For larger facilities, this may involve the coordination of records from many departments.**

**If documents are not organized or readily available, the inspection will take longer to complete.**

## Guidance in Bold Text

Rule 3701:1-66-04 Effective Date: 02/1/14

### Quality assurance program

- (1) A complete listing of the inventory of radiation-generating equipment, including the location and description of each unit;

**A complete listing of the x-ray equipment to include the location and type of equipment must be available at the time of the inspection.**

- (2) The written quality assurance program as required by this rule shall be maintained in the form of a readily available manual or manuals, either in hard copy printed format or electronic format;

**The written policy and procedures of this rule must be organized in a manual or manuals. This documentation may be in an electronic format on a computer.**

- (3) Data and test results of the evaluation of each unit of radiation-generating equipment and its shielding and surroundings;

**Test results (numerical, if appropriate – kVp, timer accuracy, coefficient of variation, beam size measurements, etc.) must be present for any testing completed during performance evaluations (preventative maintenance, repair, etc.). When radiation-generating equipment fails during an ODH inspection, any corrective action submitted must also show data and test results.**

- (4) Maintenance logs and incident reports for each radiation-generating equipment system;

**All maintenance logs and incident reports of each x-ray unit must be maintained.**

- (5) Current copies of department's licensure verification web page for each individual who is required to possess a license at the facility; and

**A copy of each x-ray machine operator license must be readily available for review. Acceptable documents would be a copy of the licensee's license certificate or a print-out of the license verification page from the licensure website.**

- (6) Instrumentation used to perform area radiation surveys, calibrations and evaluations, as appropriate for each type of radiation-generating equipment, including at least biennial calibration certificates or cross-calibration documentation done within the biennium.

**Ensure companies hired to perform these services provide the calibration certificates of their testing equipment used to perform the services. Often a company will put the information directly on the maintenance document.**