Guidance in Bold Text

3701:1-68-04 Effective 06/30/2023

Non-medical analytical systems

In addition to the applicable rules in this chapter and Chapter 3701:1-38 of the Administrative Code, handlers of analytical systems will comply with the following:

(A) Analytical systems will meet the following equipment standards:

Non-medical analytical systems need to meet the equipment standards of this rule.

(1) Open-beam analytical systems will;

(a) Provide an automatic shut-off feature that prevents any part of a person's body from being exposed to the primary x-ray beam path; or

Open-beam analytical systems need to have an automatic shut-off feature that prevents any part of the body from being exposed to the primary x-ray beam path. This includes extremities, such as fingers.

In accordance with rule 3701:1-68-04(E), hand-held analytical units are exempt from this rule. Hand-held units are not required to have an automatic shut-off feature.

(b) Request a variance from the director to include:

(i) The reason a device or an automatic shut-off feature cannot be used; and

(ii) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that the operators and others in the area will be informed of the absence of safety devices.

If an open-beam system does not have an automatic shut-off feature to comply with this rule, the handler can request a variance to the rule. Using administrative controls for the device is acceptable provided that a variance request has been approved by the Director of Health.

The variance request will include:

- **The reason the device or automatic shut-off feature cannot be used;**
- **A description of alternate methods such as engineering and administrative safety controls that effectively prevent personnel exposure to the primary x-ray beam; and**

Procedures to assure operators and others in the area that may be affected are informed of the applicable protective measures.

(2) Analytical system installed after February 10, 2006, will be provided with a readily visible warning light labeled with the words "X-RAY ON" or symbols having a similar intent, and be located near the x-ray source and its controls and be illuminated when the x-ray source is energized. In addition, open-beam analytical system will be provided with a readily discernible indication of:

Analytical systems installed after February 10, 2006, need to have functioning warning lights located both near the x-ray source and near the x-ray control panel.

The warning lights need to read, "X-Ray On," or have a similar intent and need to illuminate during x-ray exposures.

(a) X-ray source power "on-off" status located near the x-ray source housing, if the primary beam is controlled in this manner; or

If the primary beam of an open beam analytical system is controlled by an "on-off" power source, the open beam analytical system needs to have a discernable indication of the "on-off" status located near the x-ray source housing.

(b) Shutter "open-closed" status located near each collimator on the x-ray source housing, if the primary beam is controlled in this manner.

lf rule 3701:1-68-04(A)(2)(a) does not apply, the open beam analytical system needs to have a shutter with an "open-closed" status located near each collimator on the x-ray source housing.

(3) Except for gauging units, open-beam analytical systems installed after February 10, 2006, will have warning devices, or a system of warning devices, such as lights with fail-safe characteristics.

Open beam analytical systems installed after February 10, 2006 need to have warning devices or a system of warning devices such as redundant lights with fail-safe characteristics.

Fail-safe characteristics: example - when a light bulb for warning device burns out, it prevents the open beam analytical system from generating radiation.

This rule does not apply to gauging units. Also, in accordance with rule 3701:1-68-04(E), hand-held analytical units are exempt from this rule.

(4) All analytical systems will conspicuously display a clearly legible label or labels bearing the radiation symbol and the words "CAUTION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or appropriate words having a similar intent, near any switch or control that directly energizes the unit. Open-beam analytical systems will have an additional warning label on or near the x-ray housing with the radiation symbol with the words "CAUTION - HIGH INTENSITY X-RAY BEAM" or appropriate words having a similar intent.

Analytical systems need to have an appropriate warning label located near the exposure switch or control: The label needs to have the words "CAUTION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or wording having similar intent.

Open beam analytical systems need to have an additional warning label located on or near the x-ray housing. The label needs to have the words "CAUTION - HIGH INTENSITY X-RAY BEAM" or wording having similar intent.

(5) Each x-ray source housing installed on or after August 1, 2011 will be equipped with an interlock that shuts off the radiation beam when the housing is opened. For each x-ray source housing installed prior to August 1, 2011 and not equipped with an interlock, administrative controls will be instituted to include that the power will be disconnected before any disassembly.

X-ray source housings of analytical systems installed on or after August 1, 2011 need to have an interlock that shuts the radiation off before a door or port is opened, and before the housing is disassembled.

X-ray source housings of analytical systems installed prior to August 1, 2011 and not equipped with an interlock shall have administrative procedures requiring the power be disconnected prior to any disassembly.

Rule 3701:1-68-04(C)(3) requires the interlocks to be checked every 6-months.

(6) Unused beam ports on x-ray source housings will be secured in the closed position, or mechanically blocked.

The source housing may have multiple ports. In this case, all unused ports need to be securely closed or blocked.

(7) All analytical systems other than open-beam analytical systems will be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from any external surface such that it is not capable of producing a dose in excess of 2.5 microsievert (0.25 millirem) in one hour.

Analytical systems other than open-beam analytical systems need to have a protective cabinet that limits leakage radiation at 5 centimeters from the surface on the cabinet unit to no more than 0.25 millirem in one hour.

(B) Handlers of analytical systems will comply with the following radiation safety obligations:

(1) The facility's individual responsible for radiation protection (IRRP) will document and implement operating procedures relative to radiation safety. The IRRP will be qualified in accordance with paragraph (H) of rule 3701:1-68-02 of the Administrative Code. The IRRP will assure and document that all operators of analytical systems have received appropriate training. No individual will be permitted to operate analytical systems in any manner other than that specified in the procedures unless such individual has obtained written approval of the IRRP.

The IRRP needs to provide written safe operating procedures regarding the use of analytical radiation-generating equipment and processes to follow to minimize and protect individuals from radiation exposure. The IRRP needs to implement the safe operating procedures by training operators and documenting that the operators received the training. This can be documented by signature receipt from trainee or a check list of the individuals trained signed by the IRRP.

(2) Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding will be recorded. This record will:

(a) Contain such information as date the alteration was made, type of alteration, length of time alteration remained in place, and signature of the individual who made the alteration and the individual who restored the safety device to the original condition; and

Any temporary alterations to safety devices need to be documented. This documentation will include the following:

- **Date of the alteration.**
- **Type of alteration.**
- **The length of time the alteration was in place.**
- **The name of the individual who made the alteration.**

- **The name of the individual who restored the safety device.**

(b) Be approved, and signed in advance for a specified period of time by the individual responsible for radiation protection, and posted near the x-ray source housing with the signatures of approval.

The IRRP needs to approve all alterations in advance and the approval needs to be posted near the x-ray source.

(3) Except as specified in paragraph (B)(2) of this rule, no operation involving removal of covers, shielding materials or x-ray source housings or modifications to shutters, collimators, or beam stops will be performed without ascertaining that the x-ray source is off and will remain off until safe conditions have been restored. The x-ray source power switch, in conjunction with appropriate interlocks, will be used for routine shutdown in preparation for repairs.

The radiation safety procedures need to address routine shutdown for repairs to ensure the x-ray unit is off and will remain off until safe conditions are restored.

(C) In addition to the radiation protection obligations in rule 3701:1-68-02 of the Administrative Code, handlers of analytical systems will comply with the following:

(1) The local components of an analytical system will be located, arranged, and include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Chapter 3701:1-38 of the Administrative Code. These levels will be met at any specified radiation source rating.

Local components - means parts of an analytical system and includes areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

All local components of an analytical system need to have shielding or access control such that no radiation levels surrounding the local components can result more than the dose limits provided in Ohio Administrative Code 3701:1-38.

Dose Limits:
Rule 3701:1-38-12(A) requires the licensee or registrant to limit the occupational dose to an adult, as follows:

1) An annual limit, which is the more limiting of:

● The total effective dose equivalent being equal to 0.05 sievert (five rem); or
● The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (fifty rem).

2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

● A lens dose equivalent of 0.15 sievert (fifteen rem), and
● A shallow-dose equivalent of 0.5 sievert (fifty rem) to the skin of the whole body or to the skin of any extremity.

Rule 3701:1-38-13(A)(1) requires total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert (0.1 rem) in a year.

Rule 3701:1-38-13(A)(2) requires the dose in any unrestricted area from external radiation sources not exceed 0.02 millisievert (0.002 rem) in any one hour.

Rule 3701:1-68-04(C)(2) requires a radiation area survey to be performed upon installation and annually to confirm compliance with the dose limits

(2) Radiation area surveys of all analytical systems will be performed and the results recorded to confirm compliance with paragraph (A) of rule 3701:1-38-14 the Administrative Code:

(a) Upon installation;

A radiation area survey needs to be performed, and results recorded upon installation to confirm compliance with the dose limits of Chapter 3701:1-38, as required by rule 3701:1-38-14(A).

Dose Limits:

Rule 3701:1-38-12(A) requires the licensee or registrant to limit the occupational dose to an adult, as follows:

1) An annual limit, which is the more limiting of:
- **The total effective dose equivalent being equal to 0.05 sievert (five rem); or**
- **The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 sievert (fifty rem).**

2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:
- **A lens dose equivalent of 0.15 sievert (fifteen rem), and**
- **A shallow-dose equivalent of 0.5 sievert (fifty rem) to the skin of the whole body or to the skin of any extremity.**

Rule 3701:1-38-13(A)(1) requires total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed one millisievert (0.1 rem) in a year.

Rule 3701:1-38-13(A)(2) requires the dose in any unrestricted area from external radiation sources not exceed 0.02 millisievert (0.002 rem) in any one hour.

(b) Following any change in the initial arrangement, number, or type of local components in the system;

A radiation area survey needs to be performed, and results recorded after any change in the arrangement, number or type of local components in the system to confirm compliance with the dose limits of Chapter 3701:1-38, as required by rule 3701:1-38-14(A). See rules 3701:1-38-12(A), 3701:1-38-13(A)(1) and 3701:1-38-13(A)(2) for dose limits.

Local components are parts of an analytical system and includes areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include

power supplies, transformers, amplifiers, readout devices, and control panels.

An example of a change in initial arrangement would be moving the unit to a different room within the facility.

An example of a change in the number of local components would be adding another shutter assembly.

An example of a change in the type of local component would be replacing the shutter assembly with another shutter type.

(c) Following any maintenance requiring the disassembly or removal of a local component in the system;

A radiation area survey needs to be performed, and results recorded after maintenance requiring disassembly or remove of a location component in the system to confirm compliance with the dose limits of Chapter 3701:1-38, as required by rule 3701:1-38-14(A). See rules 3701:1-38-12(A), 3701:1-38-13(A)(1) and 3701:1-38-13(A)(2) for dose limits.

(d) During the performance of maintenance and alignment procedures if the procedures obligate the presence of a primary beam when any local component in the system is disassembled or removed;

A radiation area survey needs to be performed, and results recorded during the performance of maintenance and alignment procedures requiring the presence of the primary beam when local components are disassembled or removed. See rules 3701:1-38-12(A), 3701:1-38-13(A)(1) and 3701:1-38-13(A)(2) for dose limits.

(e) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

A radiation area survey needs to be performed, and results recorded any time a visual inspection of the local components in the system reveals abnormal conditions to confirm compliance with the dose limits of Chapter 3701:1-38, as required by rule 3701:1-38-14(A). See rules 3701:1-38-12(A), 3701:1-38-13(A)(1) and 3701:1-38-13(A)(2) for dose limits.

(f) Whenever personnel monitoring reports show an unexplained increase over the previous monitoring period or the readings are approaching the limits specified in rules adopted pursuant to Chapter 3701:1-38 of the Administrative Code.

A radiation area survey needs to be performed, and results recorded if personnel monitoring reports show an unexplained increase over the previous monitoring period or the readings are approaching the dose limits in rule 3701:1-38. See rules 3701:1-38-12(A), 3701:1-38-13(A)(1) and 3701:1-38-13(A)(2) for dose limits.

(3) Analytical systems will be evaluated and the results recorded at least every six months by individuals qualified according to paragraph (H) of rule 3701:1-68-02 of the Administrative Code, unless the system has been locked out and tagged "DO NOT USE."

Analytical systems need to be evaluated, and the results recorded at least every six months. The individual needs to be qualified to operate the analytical system.

This evaluation does not need to be performed if the analytical system is locked out and tagged "Do Not Use".

(a) The evaluation will verify:

(i) Proper functioning of each interlock and warning light; and

The six-month evaluation of the analytical system needs to include a check for proper functioning of the interlocks and warning lights. The results of the six-month evaluation check will be recorded.

(ii) Each tag and label is legible and properly affixed in the appropriate location.

The six-month evaluation of the analytical system needs to include review to make sure the warning tags and labels are readable and affixed in the proper locations. The results of the six-month evaluation check will be recorded.

(b) If an interlock or light is not functioning properly, it will be immediately labeled as defective and repaired or replaced within seven calendar days.

If an interlock and warning light is not functioning properly, the interlock and/or warning light needs to be labeled as defective and needs to be repaired or replaced within seven calendar days if the system is being used. The results of the evaluation need to be recorded to include the date of evaluation (defect discovered) and the date the defective part was corrected.

(4) Finger or wrist radiation monitoring devices will be provided to and will be used by:

(a) Operators of open-beam analytical systems without provisions for engineering controls as provided in paragraph (A)(1) of this rule; and

All open-beam system operators need to be provided radiation monitoring devices unless the equipment is provided with an automatic shut-off control system that will prevent any part of a person's body from being exposed to the primary x-ray beam path.

(b) Personnel maintaining analytical systems if the maintenance procedures include the presence of an external radiation beam when any local component in the analytical system is disassembled or removed.

Maintenance staff need to be provided with a radiation monitoring device if the maintenance involves generating radiation from the analytical system.

(D) Handlers of gauging units will be exempt from the obligations of paragraphs (C)(2)(c) to (C)(2)(e) of this rule.

Gauging units do not need a radiation area survey for the following:

- **After maintenance requiring the disassemble or removal of a local component - rule 3701:1-68-04(C)(2)(c).**
- **During the performance of maintenance and alignment procedures - rule 3701:1-68-04(C)(2)(f).**
- **A visual inspection that reveals abnormal conditions - 3701:1-68 04(C)(2)(e).**

(E) Handlers of hand-held analytical systems will:

(1) Be exempt from the obligations of paragraphs (A)(1) and (A)(3) of this rule;

Hand held systems are exempt from the following:

- **(A)(1) Having an automatic shut-off feature.**
- **(A)(3) Having warning devices, or a system of warning devices, such as redundant lights with fail-safe characteristics.**

(2) Obligate the IRRP to document and implement safe operating procedures to include, but not be limited to:

(a) Using specific administrative controls to prevent unauthorized access or use of the system;

The IRRP needs to provide safe operating procedures to include administrative controls to prevent unauthorized access and use of the hand-held analytical systems, such as:

- **A procedure that informs all staff that only authorized operators are permitted to operate the hand-held analyzer.**
- **Administrative controls that only provides key access to authorize operators.**

(b) Assuring that the system remains in direct control of the authorized operator;

The IRRP needs to provide safe operating procedures that requires the operator to keep the hand-held analytical system within his/her control during use.

(c) Banning individuals from holding a sample in their hand during irradiation;

The IRRP needs to provide safe operating procedures that prohibits individuals from holding samples in their hands during radiation exposure.

(d) Operating of software, trigger locks and proximity sensors;

The IRRP needs to provide safe operating procedures that includes training to operate the software, trigger locks and proximity sensors of the hand-held analytical system.

(e) Using analyzer stands when the sample fits or when the part does not completely cover the beam port;

The IRRP needs to provide safe operating procedures that includes the use of analyzer stands when the sample fits and the part does not cover the beam port. Large parts do not require the use of an analyzer stand.

(f) Taking precautions during irradiation to prevent exposure of the operator or other individuals;

The IRRP needs to provide safe operating procedures that includes precautions during irradiation to prevent exposure of the operator or other individuals, such as:

- **Verbal warnings that the unit is about to be operated.**
- **Use of caution tape or cones to designate the restricted area.**

(g) Establishing and maintaining a restricted area of at least three feet opposite the side of the sample being exposed;

The IRRP needs to provide safe operating procedures that requires the operators to

establish and maintain a restricted area of at least three feet opposite the side of the sample during exposure.

(h) Having alternative engineering and administrative safety controls that effectively prevent personnel exposure to the primary beam; and

The IRRP needs to provide safe operating procedure that includes alternate engineering or administrative safety controls that prevents personnel from being exposed directly to radiation beam coming out of the analytical system, such as: 1) keeping hands out of the primary beam, 2) do not point primary beam toward any individual and 3) watch for others during exposure.

(i) Requiring operators to wear assigned ring badges on the hand closest to the primary beam.

The IRRP needs to provide safe operating procedures that requires the operators to wear a ring on the hand closest to the primary beam.