

PART VII  
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RHB 7.1 Scope. This part establishes special requirements for analytical X-ray equipment. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

RHB 7.2 Electron Microscopes.

Electron microscopes shall be exempt from the other requirements of Part VII except that they:

7.2.1 Shall be registered with the Department; and

7.2.2 Shall be installed, shielded, and operated in such a manner that no one shall be exposed beyond the limits defined in Section 3.4.1 of these regulations.

RHB 7.3 Hand-Held Analytical X-ray Equipment.

Hand-held analytical x-ray equipment shall be exempt from the other requirements of Part VII except that they:

7.3.1 Shall be registered with the Department;

7.3.2 Shall only be operated by personnel who have completed documented training as outlined in RHB 7.9;

7.3.3 Shall have an interlock system that prevents the operation of the unit unless the x-ray exit port is in contact with or in close proximity to the item being irradiated;

7.3.4 Shall be operated in accordance with the manufacturer's specifications;

7.3.5 Shall have operating procedures in accordance with RHB 7.10.

RHB 7.4 General Requirements for all Analytical X-ray Equipment.

7.4.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.4.2 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION- X-RAY EQUIPMENT", or words having similar intent.

7.4.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.4.3.1 A label bearing the words "Caution - Radiation - This Equipment Produces Radiation When Energized" or words having a similar intent shall be placed near any switch which energizes an x-ray tube.

7.4.3.2 A sign bearing the words "Caution- High Intensity X-ray Beam", or words having a similar intent on the x-ray source housing, shall be placed in the area immediately adjacent to each tube head. The sign shall be so located that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

#### 7.4.4 Warning Lights.

7.4.4.1 An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized.

7.4.4.2 Warning lights shall have fail-safe characteristics.

#### 7.4.5 Safety Devices.

7.4.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:

7.4.5.1.1 Approved in advance by the radiation safety officer.

7.4.5.1.2 Specified in writing and posted near the x-ray tube housing.

7.4.5.1.3 Terminated as soon as possible.

7.4.5.1.4 Documented and the documentation maintained for inspection by the Department. This documentation shall contain: the nature of the alteration, and the signature and date of the individuals who made the alteration and who restored the unit to original condition.

7.4.5.2 Tests of all safety devices such as interlocks, shutters, and warning lights shall be conducted annually for all operable analytical x-ray equipment. Documentation of such tests shall be maintained for inspection by the Department.

7.4.5.3 The inspection and testing of safety devices shall not be a substitute for a radiation area survey.

7.4.5.4 Interlocks shall not be used to de-activate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.

7.4.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.4.6 Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface does not exceed 2.5 milliRoentgen per hour.

7.4.7 Generator Cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance from its surface to 0.25 milliRoentgen per hour.

7.4.8 Radiation in excess of the limits specified in RHB 7.4.6 and RHB 7.4.7 shall be eliminated prior to using the analytical x-ray equipment.

7.4.9 Repair or Modification of X-ray Tube System. Except as specified in 7.3.5.1, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

## RHB 7.5 Additional Requirements for Open Beam Configuration X-ray Equipment.

7.5.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configuration x-ray equipment. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

7.5.1.1 A description of the various safety devices that have been evaluated;

7.5.1.2 The reason each of these devices cannot be used;

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

7.5.1.4 The procedure for notifying proper persons in the event of an accident. This list shall include the names, addresses, and telephone numbers.

7.5.2 The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

7.5.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.5.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.5.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.5.4.2 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.5.5 Warning devices shall be labeled so that their purpose is easily identified.

7.5.6 Warning devices shall have fail-safe characteristics.

7.5.6.1 Where couplings exist, e.g., between the x-ray tube and the collimator of the diffractometer, etc., they shall prevent radiation from escaping the coupling.

7.5.6.2 Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place.

7.5.7 Operating Procedures. The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.5.7.1 Policies and procedures for personnel monitoring.

7.5.7.2 Policies and procedures for controlling access to radiation areas.

7.5.7.3 Policies and procedures for locking and securing the x-ray unit.

7.5.7.4 Policies and procedures for pregnant employees.

7.5.7.5 Policies and procedures for training new employees.

7.5.8 Operator training.

7.5.8.1 No person shall be permitted to operate, repair, modify, or maintain x-ray equipment unless such person has received instruction and demonstrated competence in:

7.5.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.5.8.1.2 Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.5.8.1.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures;

7.5.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques, if applicable;

7.5.8.1.5 Characteristics of ionizing radiation;

7.5.8.1.6 Methods of controlling radiation dose;

7.5.8.1.7 Units of radiation dose;

7.5.8.1.8 Personnel monitoring and the use of personnel monitoring equipment;

7.5.8.1.9 Symptoms of an acute localized exposure and;

7.5.8.1.10 Proper procedures for reporting an actual or suspected overexposure.

7.5.8.1.11 The regulations contained in this Part, and the applicable sections of Part III.

7.5.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.6 Additional Requirements for Enclosed Beam X-ray Equipment. To include stationary, mobile, and portable units.

7.6.1 The radiation source, sample, detector and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

7.6.2 The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a properly functioning interlock.

## RHB 7.7 Area Requirements for All Analytical X-ray Equipment.

7.7.1 Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation 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 RHB 3.4. These levels shall be met at any specified tube rating.

7.7.2 Surveys, Tests and Inspections. Radiation surveys, as required by RHB 1.4 of all analytical x-ray systems to show compliance with RHB 7.7.1 shall be performed and records kept and available for review:

7.7.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter.

7.7.2.2 Following any change in the initial arrangement, number, or type of local components in the system.

7.7.2.3 Following any change in operating parameters.

7.7.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system.

7.7.2.5 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed.

7.7.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition.

7.7.2.7 Whenever monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

7.7.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with 7.7.1 in some other manner. Upon approval by the Department, an area monitor or monitors may be used in place of an annual radiation survey. The area monitor shall be placed on the unit and changed on at least a quarterly basis. The results shall be documented and available for review. If an area monitor result shows a substantial increase over previous results, perform a documented investigation including a radiation area survey.

7.7.4 Tests and inspections of all safety devices shall be performed at least yearly to ensure their proper operation. The results shall be documented and available for review in accordance with RHB 1.10.2.4.

## RHB 7.8 Radiation Survey Instruments.

All provisions of RHB 1.4.4 apply.

## RHB 7.9 Minimum Personnel Radiation Safety Requirements For Radiation Safety Officers and Operators.

7.9.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

7.9.1.1 Has been instructed in the subjects outlined in RHB 7.9.2 of this Part;

7.9.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part IX, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

7.9.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

7.9.2 No person shall be permitted to operate, repair, modify, or maintain analytical x-ray equipment unless such person has received instruction and demonstrated competence in:

7.9.2.1 Identification of radiation hazards associated with the use of the equipment;

7.9.2.2 Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.9.2.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures as specified in RHB 7.10;

7.9.2.4 Characteristics of ionizing radiation;

7.9.2.5 Personnel and/or area monitoring and the use of personnel and/or area monitoring equipment, if applicable.

7.9.3 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

#### RHB 7.10 Operating Procedures

7.10.1 The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.10.1.1 Policies and procedures for personnel and/or area monitoring;

7.10.1.2 Policies and procedures for pregnant employees;

7.10.1.3 Policies and procedures for training new employees;

7.10.1.4 Methods and occasions for conducting radiation surveys;

7.10.1.5 Methods for controlling access to radiographic areas;

7.10.1.6 Methods for locking and securing X-ray machines, when not in use or in storage;

7.10.1.7 Maintenance of records.

7.10.2 A copy of operator training provided as required by RHB 7.9 and a copy of operating procedures as required by RHB 7.10 shall be provided to the Department upon request.

#### RHB 7.11 Personnel Monitoring.

7.11.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.11.2 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.11.2.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.11.2.2 Personnel maintaining analytical or research and development x-ray equipment if the maintenance procedures required the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.