REGULATORY GUIDE B4

COMPLYING WITH TITLE B - FACILITIES UTILIZING ANALYTICAL OR INDUSTRIAL X-RAY EQUIPMENT

March 2017

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REGULATORY GUIDE B4
COMPLYING WITH TITLE B - FACILITIES UTILIZING ANALYTICAL OR INDUSTRIAL X-RAY EQUIPMENT

Each industrial facility that is registered with the Department is required to comply with Regulations 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist facilities using industrial and analytical x-ray equipment in complying with Title B regulations.

GENERAL REQUIREMENTS FOR INDUSTRIAL AND ANALYTICAL EQUIPMENT

A. Analytical Vs. Industrial X-Ray Equipment

The regulations are different for analytical and industrial units. It is important to identify your equipment type. X-ray equipment located at industrial settings usually falls into two types - industrial or analytical. Industrial x-ray equipment is defined as equipment that is used to look at the macroscopic structure of a material, while analytical x-ray equipment is defined as equipment used to look at the microscopic or elemental composition of a material. Examples of industrial x-ray units include: cabinet x-ray units, shielded room radiography, field radiography, irradiators, and x-ray gauges. Industrial units are typically used to look for voids in manufactured material, or the presence of metallic items in a material. Examples of analytical x-ray units include diffraction units, x-ray fluorescence units, and electron microscopes. Analytical units are typically used to look for a particular element, such as iron or lead, in a material. Analytical units may be located in an industrial setting, just as industrial units may be located in an academic setting. The designations of industrial and analytical are for the type of analysis the unit does, not the location of the unit. You may contact this Department with any questions in determining a unit type. Throughout this regulatory guide, the regulations are specified as applying to industrial or analytical units.

B. Facility Registration Approval

(See RHB 2.4)

Prior to installing an x-ray machine, a facility must apply to the Department for a Facility Registration Approval (FRA). To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the non-refundable application fee, of $62.50.

A FACILITY SHALL NOT INSTALL OR CAUSE TO BE INSTALLED AN X-RAY PRODUCING MACHINE UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

If a facility moves to a new location, a letter must be submitted to the Department stating the new location address and any updated facility contact information. Facility Registration Approval is not transferable to a new owner or any additional locations. A new Facility Registration Approval and processing fees are required for the acquisition of an existing facility.

Please note that certain types of equipment require a shielding plan prior to installation in accordance to RHB 4.4. See Regulatory Guide B6 or contact the Department for assistance.

C. Registering Equipment

(See RHB 2.5)

All x-ray equipment is required to be registered with the Department within thirty (30) days of installation. See Regulatory Guide B1 for assistance in registering equipment. Upon registration of equipment (a control), the Department shall issue the facility a registration sticker to be placed on each control. The registration stickers shall be placed on the control panel in a clearly visible location.

D. Report Of Change

(See RHB 2.5.3)

The registrant is required to report, in writing, any changes that affect the x-ray facility or x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating conditions that may affect an approved shielding plan and any changes in the ownership of the facility.

E. Personnel Monitoring

(See RHB 3.12)

Personnel monitoring is required in the following situations:

a) When an employee is likely to receive greater than 10% of their occupational dose limit for the year.
b) When an employee under 18 years of age, or a declared pregnant woman, is likely to receive greater than 10% of their applicable dose limit.
c) Finger or wrist dosimetric devices are required of analytical operators using open-beam configuration systems without a safety device, and personnel maintaining analytical equipment if the maintenance procedures requires the presence of a primary beam when any component is disassembled or removed.
d) Personnel monitoring is required for all operators of industrial x-ray equipment. For shielded room radiography, personnel monitoring devices are also required for workers who make "set-ups" and maintenance personnel. During field radiography, a pocket dosimeter or pocket chamber must also be worn.
e) When an individual enters a high radiation area.
f) When the Department deems it necessary.

Personnel monitoring badges must be returned for processing within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to manufacturer specifications. The Registrant must document explanations of any late, absent, or unused badges and maintain these records for Departmental review.

When a protective lead apron is worn by the operator and a personnel monitoring device is used, the monitoring device must be worn at the collar outside of the apron.

The personnel monitoring devices used to determine compliance with occupational dose limits must be processed by a vendor which possesses current personnel dosimetry accreditation from the National

Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology (NIST). The accreditation must be for the type of radiation for which the individual wearing the device is monitored.

Each registrant must maintain records showing the radiation exposure for each person that is required to be monitored. Adjustments to the dose of permanent record must be determined by the Radiation Safety Officer.

Personnel monitoring records must be retained indefinitely or until the Department authorizes their disposal, even if the service is discontinued.

F. Prior Occupational Exposure

(See RHB 3.20)

Each registrant has the responsibility to determine the occupation radiation dose received within the current year for any new individual who enters the facility's restricted or controlled area. This may be done through signed written statements or previous personnel monitoring reports for the individual. The registrant must maintain these records for 5 years after the termination of the registration.

G. Occupational Exposure at Multiple Facilities

(See RHB 3.4.4)

If an employee is likely to receive a dose in excess of 50% of the annual allowable dose, the exposure that an employee receives at any facility must be recorded by each facility at which the employee works. Each facility must ensure that the total dose received by the employee at both locations does not exceed the occupational limits.

H. Overexposures

(See RHB 3.24 and 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The registrant is also required to report any radiation levels in an unrestricted area that are in excess of 10 times any limit in the regulations. The time frame for reporting overexposure depends on the exposure that an individual receives. Immediate or 24 hours, and/or 30 days written notification may be required. See RHB 3.24 concerning radiation levels and the requirements for reporting.

I. Radiation Survey Instruments

(See RHB 1.4.4)

All radiation survey instruments used in surveys and tests must be properly calibrated. The calibration must be performed at intervals not to exceed 24 months and after each instrument servicing. The calibration should be traceable to within 20 percent of the national standard and performed at two or more widely separated points, other than zero. Records of these calibrations must be maintained for inspection. The instrument must have a minimum operation range consistent with the radiation field being measured. Instrument calibration records must be maintained at the facility for review by the Department.

The survey instrument manufacturer's instructions must be available to operators. Operators must adhere to and demonstrate competency in these instructions. Documentation must be maintained that the

operators have read and agree to adhere to these instructions.

The operator shall check each survey instrument for proper operation with a dedicated check source each day of use to ensure the instrument is operating properly.

J. Records

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

- Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)
- Records showing model and serial numbers of all tubes and controls. (RHB 1.10.2.1)
- Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. (RHB 1.10.2.4)
- Copies of all correspondence with the Department. (RHB 1.10.2.5)
- Records of prior occupational dose for employees. (RHB 3.20)
- Records of personnel monitoring results. (RHB 3.22)
- Records of alterations of safety devices - analytical. (RHB 7.4.5.1.4)
- Records of testing of safety devices - analytical. (RHB 7.7.4)
- Records of surveys, tests, and inspections. (RHB 7.7.2 or 8.9.1)
- Calibration records for survey instruments. (RHB 1.4.4)
- Records of personnel instruction and competency testing. (RHB 7.9.3 or 8.7.2.4)
- Utilization logs for field radiography. (RHB 8.12.3.1)
- Records from pocket dosimeters for field radiographers. (RHB 8.12.3.8.4)

ANALYTICAL X-RAY EQUIPMENT REQUIREMENTS

A. Training Requirements

Each facility is required to ensure that all Radiation Safety Officers and x-ray operators are adequately instructed in the facility's written operating procedures, basic radiation concepts, and competent in the safe use of the equipment. The Department will assess RSO and operator training during onsite visits. Therefore, each facility must be able to present the inspector with the written training resources and the documented competence for each RSO and operator.

1) All operators must be trained in the following (See RHB 7.9):

   a) Identification of radiation hazards associated with the use of the equipment;

   b) 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;

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

   d) Characteristics of ionizing radiation;

   e) Personnel and/or area monitoring and the use of personnel and/or area monitoring devices if applicable;

2) Additional training requirements for Open Beam Configuration (See RHB 7.5.8):

   a) The operation, calibration, and limitations of radiation survey instruments and proper survey techniques, if applicable;

   b) Units of radiation dose;

   c) Methods of controlling radiation dose, such as time, distance, and shielding;

   d) Symptoms of acute localized exposures;

   e) Proper procedures for reporting an actual or suspected exposure;

   f) Applicable State regulations contained in Part VII and Part III.

3) All RSOs must be trained as an operator **in addition to** the following (See RHB 7.9.1):

   a) The regulations contained in Part VII, Part X, and the applicable sections of Part III;

   b) The use of related handling tools and survey instruments that will be used by the RSO.

These topics are the minimum required subjects that must be covered in operator and RSO training for analytical units. Each facility must assess the type of equipment at their facility, and tailor their training program appropriately.

B. <u>Requirements for Operating Procedures</u>

(See RHB 7.10 and RHB 7.5.7)

Facilities using analytical x-ray units are required to have written operating procedures. The operating procedures must be available to all workers using the unit. The equipment must be operated in

accordance to the operating procedures. The procedures must include but not be limited to:

1) Personnel and/or area monitoring;

2) Pregnant employees;

3) Training new employees;

4) Methods for controlling access to radiation areas;

5) Methods for locking and securing the x-ray unit;

6) Methods and occasions for conducting radiation surveys;

7) Maintenance of records.

C. <u>Requirements for Conducting Radiation Surveys</u>

(See RHB 7.7.2)

Analytical x-ray units must have the surveys performed in the following situations:

1) Upon installation of the equipment and at least every twelve months after that;

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

3) Following any change in operating parameters;

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

5) During the performance of maintenance and alignment procedures if the procedures required the presence of a primary x-ray beam, when any local component in the system is disassembled or removed;

6) Any time a visual inspection of the unit reveals an abnormal condition;

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

Records of these surveys must be maintained for review by this Department.

Upon Departmental approval, an area monitor or monitors may be used in place of an annual radiation survey. The monitor shall be placed on the unit and changed at least quarterly. The results shall be documented and available for review. If a result is found to be substantially higher than previous results, a documented investigation including an area survey shall be performed immediately.

D. Tests of Safety Devices

(See RHB 7.7.4)

Tests of safety devices such as interlocks, shutters, and warning lights are required to be conducted on an annual basis. Records of these tests are required to be maintained for inspection by this Department.

E. Posting and Labeling

(See RHB 7.4.2 and 7.4.3)

All facilities must post a "Notice to Employees" in a location where it can be reviewed by all workers. A copy of this form is available on the DHEC website.

All analytical units must meet the following posting and labeling requirements:

1) Each area or room containing an analytical x-ray unit must be conspicuously posted with a sign or signs bearing the standard radiation symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having similar intent.

2) A label bearing the words "Caution - Radiation - This equipment produces radiation when energized" or words having a similar intent must be placed near any switch which energizes a tube.

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

F. Additional Analytical Equipment Requirements

1) **Electron microscopes:** Electron microscopes are required to be registered with the Department. The only requirement for electron microscopes is that they be installed, shielded, and operated in such a manner that radiation dose limits are not exceeded. They are exempt from all other requirements. (See RHB 7.2)

2) **Hand-held analytical x-ray equipment**: All operators must have documented training that includes the items listed under Training Requirements (see RHB 7.9) starting on page 6 of this guide to include the facility's written operating procedures (see RHB 7.10). Hand- held analytical x-ray units must be interlocked so they cannot be used unless they are touching or in close proximity to the sample being irradiated. The equipment must be operated according to manufacturer's specifications. Hand-held analytical x-ray units are exempt from all other requirements. (See RHB 7.3)

3) Warning lights labeled with the words "X-RAY ON" are required for all analytical units. They must be located near any switch that energizes an x-ray tube. They must also be illuminated only when the tube is energized, and be fail-safe. (See RHB 7.4.4)

4) All open beam configuration units must have a safety device to prevent entry into the primary beam path or a safety device that causes the beam to shut off upon entry into the primary beam. An operator must be in immediate attendance at all times when the equipment is in operation. However, the

equipment must be secured to prevent unauthorized operation when not in use. The x-ray tube status and shutter status must be indicated and located near the radiation source housing. (See RHB 7.5)

INDUSTRIAL X-RAY EQUIPMENT REQUIREMENTS

A. Training Requirements

(See RHB 8.7 and RHB 8.11)

Each facility is required to ensure that all Radiation Safety Officers and x-ray operators are adequately instructed in the facility's written operating procedures, basic radiation concepts, and competent in the safe use of the equipment. The Department will assess RSO and operator training during onsite visits. Therefore, each facility must be able to present the inspector with the written training resources and the documented competence for each RSO and operator.

1) All operators must be trained in the following:
   a) Fundamentals of radiation safety including:
      i. Characteristics of ionizing radiation;
      ii. Units of radiation dose; (rem or sievert)
      iii. Hazards of exposure to radiation;
      iv. Levels of radiation from sources of radiation;
      v. Methods of controlling radiation dose – time, distance, and shielding;

   b) Radiation detection instrumentation to be used including:
      i. Use of radiation survey instruments including – operation, calibration and limitations;
      ii. Survey techniques;
      iii. Use of personnel monitoring equipment:
         1. Film badges or other approved dosimeters; and
         2. Pocket dosimeters or pocket chambers, if applicable.

   c) Operation and control of x-ray machines.

   d) The requirements of pertinent state regulations.

   e) The registrant's written operating and emergency procedures

2) All RSOs must be trained as an operator **in addition to** the following (See RHB 8.7.1):

   a) The regulations contained in Part VIII, Part X, and the applicable sections of Part III;

   b) The use of related handling tools and survey instruments that will be used by the RSO.

These topics are the minimum required subjects that must be covered in operator and RSO training for industrial units. Each facility must assess the type of equipment at their facility, and tailor their training program appropriately.

B. Requirements for Operating and Emergency Procedures

(See RHB 8.8)

Facilities using industrial x-ray units are required to have written operating and emergency procedures. The operating procedures must be available to all workers using the unit. The equipment must be operated in accordance to the operating procedures. The procedures shall include but not be limited to:

1) The handling and use of the x-ray machine;

2) Methods and occasions for conducting radiation surveys;

3) Methods for controlling access to radiographic areas;

4) Methods for locking and securing the x-ray unit when not in use or in storage;

5) Personnel monitoring;

6) The proper handling of exposed personnel;

7) Minimizing exposure of individuals in the event of an accident;

8) The procedure for notifying proper persons in the event of an accident. This must include the listing of names, addresses, and telephone numbers;

6) Maintenance of records.

C. Requirements for Conducting Area Surveys

1) Cabinet x-ray units cannot be operated until a radiation survey has been performed. The unit and the area adjacent to the unit must be surveyed at least annually after the unit has been put into use. Surveys must also be performed after any repair, modification, or maintenance on the system. (See RHB 8.12.1)

2) Industrial units used in shielded room radiography and field radiography must be surveyed prior to each entry into the radiation exposure area to ensure that the unit is off. The survey must be performed with an instrument capable of measuring radiation of the energies and dose rates to be encountered. (See RHB 8.12.2.2 and RHB 8.12.3.7.1)

D. Tests of Safety Devices

(See RHB 8.9)

All industrial x-ray units must be checked for obvious defects at the beginning of each day of equipment use. At least yearly, components associated with radiation safety, such as interlocks, shutters, or alarm systems, must be inspected for proper functioning. If any component is determined to be damaged, the unit shall not be used until it is repaired. Records of these tests are required to be maintained for Departmental inspection.

E. Posting and Labeling

(See RHB 8.12.1.10)

All facilities must post a "Notice to Employees" in a location where it can be reviewed by all workers. A copy of this form is available on the DHEC website.

Industrial units must meet the following posting and labeling requirements:

1) A label which reads, "CAUTION - RADIATION - This equipment produces radiation when energized," shall be located near or adjacent to each switch that controls the production of x-rays.

2) Cabinet x-ray units must meet these requirements:

   a) Indicators of x-ray production must be legibly labeled "X-RAY ON."

   b) Each port of entry into a cabinet x-ray system must have a clearly legible and visible label bearing the statement: "CAUTION - DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED -- X-RAY HAZARD."

F. Additional Requirements for Industrial X-Ray Equipment

1) Each x-ray machine must be provided with a locking device to prevent unauthorized or accidental production of radiation. The device must be kept locked at all times except when under the direct supervision of a radiographer, radiographer's assistant, radiation safety officer, or an operator. (See RHB 8.2)

2) **Cabinet x-ray units:** Cabinet x-ray units must have a permanent floor, or be permanently attached to a support system. It must not be possible to insert any body part into the primary beam. The door of the cabinet must have at least two safety interlocks. (See RHB 8.12.1)

3) **Baggage checkers:** Baggage checkers must ensure operator presence at the control area in a position which allows surveillance of the ports and doors during x-ray generation. (See RHB 8.12.1.11)

4) **Shielded room radiography:** Shielding plans must be submitted and approved by the Department prior to use of the equipment. A radiation area survey must be performed by a qualified vendor, registered with the Department, within 30 days of installation. This survey must be submitted to this Department for review. See regulatory guide B6 for assistance. (See RHB 8.12.2)

5) **Field radiography:** Field operations require the use of a utilization log that includes a description (or make and model number) of the x-ray unit, the identity of the radiographer, the plant or site where it is used, and the dates each radiation machine is used and the number of exposures made. (See RHB 8.12.3)

2) **X-ray gauges:** A yellow or amber warning light labeled with “High Voltage On” must be located on the control panel or adjacent to the source housing. This light will only illuminate when power is applied to the x-ray tube. (See RHB 8.12.4)

Certified Cabinet X-Ray Units

(See RHB 8.12.1.12)

Certified cabinet x-ray units, to include baggage checkers, are exempt from the requirements of Part VIII if the registrant can provide documentation regarding the certified status of the unit. This documentation should be in the form of a tag or label permanently affixed to or inscribed on the unit.

Certified cabinet x-ray units are subject to the following requirements:

1) Operators must receive a copy and instruction in the operating procedures for the unit. Records that demonstrate compliance with this requirement must be maintained for Departmental review;

2) Interlock testing must be conducted and documented at least every six months. Records must be maintained for 5 years, until the next Departmental inspection, or until your facility no longer possesses the equipment;

3) An annual evaluation of radiation dose limits to determine compliance with Part III and 21 CFR 1020.40, Cabinet X-ray Systems. Records must be maintained for 5 years, until the next Departmental inspection, or until your facility no longer possesses the equipment;

4) The cabinet x-ray systems must be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification may be made to the system unless prior Departmental approval has been granted.

For more information on 21 CFR 1020.40:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.40

INSPECTIONS

The Department conducts routine periodic inspections of x-ray facilities. The Department will also conduct inspections if a complaint is received or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the Department deems it necessary. Inspections by the Department are mandatory, but every attempt will be made to accommodate facility schedules. **The Department does have the right to make unannounced inspections.**

The inspection consists of checking/verifying the operation of the x-ray equipment and reviewing records as outlined in the attached checklist. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. Generally, an inspection requires use of the x-ray equipment for a short time per control. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance as well as any other items the inspector deems relevant.

The inspector may leave an inspection report at the conclusion of the inspection or send a written report to the facility within approximately two weeks of the inspection. Any violations and/or recommendations will be included in this report. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate the corrective action that will be taken to correct any violations. The Department will respond, in writing, to the twenty day notification as needed.

All corrections must be made within sixty (60) days of receipt of the inspection report. The facility must notify the Department, in writing, by this date that corrections have been made. Corrective action must be described for each violation. The facility has the option of accepting Departmental recommendations. Each violation and recommendation must be addressed individually. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state so in their response. After the Department has received the sixty day notification and accepted the corrective action, a Completed Corrective Action letter will be sent to the facility.

QUESTIONS

If you have questions, please feel free to call or write:

SC Department of Health and Environmental Control
Bureau of Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

REGULATORY GUIDES

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B - Facilities Utilizing Analytical or Industrial X-ray Equipment
B5 – Complying with Title B - Vendors
B6 – X-Ray Facility Shielding Plans
B7 - Complying with Title B - Mammography
B8 - Complying with Title B - Bone Densitometers
B9 - Complying with Title B - Veterinary Facilities
B10 - Complying with Title B - Hospitals
B11 - Complying with Title B - Therapy Facilities

Visit our web site at: http://www.scdhec.gov/Health/FHPF/HealthFacilityRegulationsLicensing/X-RayFacilitiesRadioactiveMaterials/X-RayFacilities/

CHECKLIST FOR DHEC INSPECTION

Analytical/Industrial Facility

Please have available the following records for the DHEC inspector:

_____ Personnel monitoring reports.

_____ Records of previous occupational dose for employees.

_____ Training plan (including material used for training).

_____ Documentation of operator training.

_____ Records from testing x-ray system performance, including calibration and service records, as well as in-house testing. Records from radiation area surveys, tests, and inspections.

_____ A list of all operators of the x-ray equipment including routine operators as well as back-up/part time operators. This list should include the title of each operator (e.g., quality control tech, engineer, matallurgist, chemist, etc.).

_____ Operating and emergency procedures.

_____ Utilization logs (Field Radiography).

_____ Survey instrument calibration records.

Please be familiar with, and be prepared to show the DHEC inspector the following items:

_____ Posted radiation area signs.

_____ Posted "Notice to Employees"

_____ Survey instrument

_____ Survey instrument check source