

REGULATORY GUIDE B4

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



South Carolina Department of Health
and Environmental Control

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

Each 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.

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.

GENERAL REQUIREMENTS FOR INDUSTRIAL AND ANALYTICAL EQUIPMENT

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). The facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3. To receive a Facility Registration Approval, complete and return the FRA request form DHEC 0845 along with the application fee, including the following information:

- 1) Facility Name, Location Address, and Mailing Address
- 2) The name of the Radiation Safety Officer (RSO) who is responsible for radiation protection and the individual's qualifications to serve in this capacity
- 3) Manufacturer, model #, and type and make of x-ray equipment to be installed. For example:
 - i. Siemens Polydoros 80 Rad/Fluoro unit
 - ii. Belmont Model 071 Dental unit
- 4) The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved, then provide the information for all companies.
- 5) Operating policies and procedures. See below under "Operating Procedures"
- 6) A shielding plan, if required. Shielding review fees must accompany the shielding plan.
- 7) There is a \$62.50 non-refundable fee required for registration of new facilities.
- 8) The application fee must be submitted with the facility registration approval request. The \$62.50 should be sent in the form of a check or money order made out to SCDHEC.

- 9) After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

Registering Equipment (See RHB 2.5)

All x-ray equipment must be registered with the Department. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also required to report, in writing, any changes that affect his x-ray facility or the x-ray equipment. This includes change of location or mailing address, change of Radiation Safety Officer, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures.

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 that it is necessary.

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.

A Lost Badge Program must be established to include the following guidelines:

- a) Spare badges must be maintained in order to replace an individual's lost badge or to badge someone whose personal permanent badge is unavailable for whatever reason.
- b) A method for calculating exposure for the period in which a temporary badge is used must be established.
- c) Badged employees shall not work around x-ray equipment without a badge.

Each registrant must maintain records showing the radiation exposure for each person that is monitored. The records must be preserved indefinitely, or until the Department authorizes their disposal. The records may be maintained on microfilm or other archival media.

Prior Occupational Exposure

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the

worker had no prior occupational dose during the current year or states the nature and amount of any prior occupational dose during the current year. The registrant must also attempt to obtain the records of lifetime cumulative occupational radiation dose. The registrant must maintain these written statements until the Department authorizes their disposition.

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. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

Overexposures (See RHB 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, 24 hour, and/or twenty day written notification may be required. See RHB 3.24 concerning radiation levels and the requirements for reporting.

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 12 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 agrees 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. Documentation of these checks shall be maintained for Department review.

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 7.9.2 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

Training Plan (See RHB 7.9)

Each facility is required to ensure that all Radiation Safety Officers and x-ray operators are adequately instructed in safe operating procedures and competent in the safe use of the equipment. Each RSO and operator is also required to have instruction in specific areas. The Department will assess RSO and operator training by reviewing the training plan of each facility. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in the regulations. The training plan must document the following items:

- 1) The topics to be covered during the training period. According to regulations the following items must be addressed as a minimum:
 - 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.
- f) The operation, calibration, and limitations of radiation survey instruments. (If required by the employee's position) Proper survey techniques. (Open Beam Configuration)
- g) Units of radiation dose. (Open Beam Configuration)
- h) Methods of controlling radiation dose, such as time, distance, and shielding. (Open Beam Configuration)
- i) Symptoms of acute localized exposures. Proper procedures for reporting an actual or suspected exposure. (Open Beam Configuration)
- j) Applicable State regulations.

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

- 2) Records documenting the training that each operator has received and records documenting operator competence must be maintained. The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

Requirements for Operating Procedures (See RHB 7.9.3 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 cannot be operated in any manner except for that specified in the operating procedures. The procedures shall include but not be limited to:

- 1) **Personnel and/or area monitoring**
- 2) **Pregnant Employees**
- 3) **Training New Employees**
- 4) **Controlling Access to Radiation Areas (Open Beam Configuration)**
- 5) **Locking and securing the x-ray unit (Open Beam Configuration)**

Methods and Occasions for Conducting Radiation Surveys (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.

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.

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.

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 Plan starting on page 6 of this guide. (See RHB 7.9) 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 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) Unused ports on x-ray tube housings shall be secured in the closed position to prevent accidental opening. (See RHB 7.4.5.5)
- 5) All open beam configuration units must have a safety device to prevent entry into the primary beam path. An operator must be in immediate attendance at all times when the equipment is in operation. X-ray tube status and shutter status must be indicated. (See RHB 7.5.1)

INDUSTRIAL X-RAY EQUIPMENT REQUIREMENTS

Training Plan (See RHB 8.11)

Each facility is required to ensure that all Radiation Safety Officers and x-ray operators are adequately instructed in safe operating procedures and competent in the safe use of the equipment. Each RSO and operator is also required to have instruction in specific areas. The Department will assess RSO and operator training by reviewing the training plan of each facility. Therefore, each facility must establish a training plan to ensure instruction in the areas specified in the regulations. The training plan must document the following items:

- 1) The topics to be covered during the training period. According to regulations the following items must be addressed as a minimum:
 - 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;
 1. Time;
 2. Distance; and
 3. Shielding.
 - b) Radiation Detection Instrumentation to be Used including:
 - i. Use of radiation survey instruments including;
 1. Operation;
 2. Calibration; and

3. Limitations.
 - ii. Survey Techniques; and
 - 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 including:

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

- 4) Records documenting the training that each operator has received and records documenting operator competence must be maintained. The training records will be checked as part of the routine inspection by the Department. In addition, the Department may request at any time to review the training records of an employee.

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 cannot be operated in any manner except for that specified in the operating procedures. The procedures are required to include the following items:

- 1) **Methods and occasions for conducting radiation surveys.** (See page 11)
- 2) **Methods for controlling access to radiographic areas.**
- 3) **Methods for locking and securing the x-ray unit.**
- 4) **Personnel monitoring.** (See page 4)
- 5) **The proper handling of exposed personnel.**
- 6) **Minimizing exposure of individuals in the event of an accident.**
- 7) **The procedure for notifying proper persons in the event of an accident.** This must include the listing of names, addresses, and telephone numbers. (See page 5)
- 8) **Maintenance of records.** (See page 5)

Methods and Occasions for Conducting Area Surveys

Industrial x-ray units are subject to the following requirements:

- 1) 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 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. (See RHB 8.9)
- 2) 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)
- 3) 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)

Tests of Safety Devices (See RHB 8.12.1.2)

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.

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."

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 for additional requirements.)

- 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 Class IX 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 requires 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 for additional requirements.)
- 6) X-ray gauges. (See RHB 8.12.4 for requirements.)

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 severity of the violations warrants it. 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. The checklist also contains some questions that will be asked by the inspector. Generally, an inspection requires use of the x-ray equipment for about one hour per control. At the conclusion of the inspection, the inspector will conduct an exit interview to discuss items of non-compliance.

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 - Vendor Registration and Responsibilities
- B6 - 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

Visit our web site at: **<http://www.scdhec.net/health/radhth>**

CHECKLIST FOR DHEC INSPECTION

Please have available the following records for the DHEC inspector:

- _____ Personnel monitoring reports.
- _____ Records of previous occupational dose for employees.
- _____ Training plan.
- _____ Documentation of operator training.
- _____ Records from testing x-ray system performance, including calibration and service records, as well as in-house testing. Records from surveys, tests, and inspections.
- _____ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as quality control tech, etc. List the number of years experience taking x-rays that each operator has.
- _____ Operating procedures.
- _____ Utilization logs. (for field radiography)
- _____ 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"

Other questions the inspector will ask:

- 1) Who does servicing on the x-ray equipment?