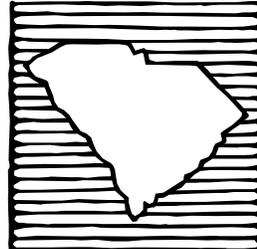


REGULATORY GUIDE B7

COMPLYING WITH TITLE B - MAMMOGRAPHY

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**South Carolina Department of Health
and Environmental Control**

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REGULATORY GUIDE B7 COMPLYING WITH TITLE B- MAMMOGRAPHY

Each medical 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 the medical facility in complying with Title B regulations.

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.

SHIELDING REQUIREMENTS

A shielding plan or radiation area survey, which is acceptable only if prior approval is given, is required for mammography units. Shielding plans must be submitted and approved by this Department prior to installation, or a written request must be made by a Class V, VII, or IX vendor to perform a post-install survey in lieu of a shielding plan.

Both shielding plans and requests for post installation radiation area surveys require the submission of a shielding review fee of \$62.50.

REGISTERING EQUIPMENT (See RHB 2.5)

All x-ray equipment is required to be registered with the Department within thirty (30) days of acquisition. See Regulatory Guide B1 for assistance in registering equipment. The registrant is also 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 procedures that may affect an approved shielding plan and any changes in the accepted operating procedures. In addition, 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.

FACILITY CERTIFICATION (See RHB 5.2)

Certification is a process that is administered by DHEC/FDA. DHEC issues an MQSA certificate upon notification by the ACR that a mammography facility has been accredited.

Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards.

Only DHEC/FDA-certified facilities can lawfully provide mammography services. The Centers for Medicare and Medicaid Services (CMS) will reimburse only for the mammography performed at a DHEC/FDA-certified facility.

EQUIPMENT (See RHB 5.8)

The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed an equipment evaluation or medical physicist's survey and that the application for accreditation of the unit has been submitted.

There are four cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), 3) if the unit is used for interventional mammography only or 4) the unit is an experimental one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. Note that under 1), 2) and 3) the unit still must have passed an equipment evaluation or survey and each such unit will be tested by the state inspector, during the annual inspection, regardless of its accreditation or ownership status.

In all cases the shielding must be approved prior to use and the unit must be registered with this department within thirty (30) days after installation of the unit.

TECHNOLOGISTS (See RHB 5.7.2)

In order to independently perform mammographic examinations, one must meet the following requirements:

1. Be certified by the South Carolina Radiation Quality Standards Association to perform general radiographic procedures. For more information, contact the SCRQSA at (877) 771-6141 or visit their website at www.scrqsa.org.
2. Have prior to April 28, 1999, qualified as a radiologic technologist under the interim MQSA regulations; OR completed 40 contact hours of specific training in mammography in the topics specified in the regulations, including performance of a minimum of 25 examinations under direct supervision.
3. Maintain mammography continuing education (15 CEU's/36 months).
4. Maintain continuing experience (200 examinations/24 months).
5. Requalification: Radiologic technologists failing to maintain the continuing requirements must requalify prior to independently performing mammographic examinations.
 - (a) Continuing Education: Must bring total up to 15 CEU's/36 months.

- (b) Continuing Experience: Perform a minimum of 25 mammography examinations under direct supervision.
- 6. Maintain a valid certificate to perform general radiographic procedures from the South Carolina Radiation Quality Standards

New Modalities

Must have 8 Hours of initial training in new modality

INTERPRETING PHYSICIANS (See RHB 5.7.1)

In order to independently interpret mammograms, one must qualify as an interpreting physician. To do this, one must have either qualified as an interpreting physician under the interim regulations prior to April 28, 1999, OR after April 28, 1999, have documented all of the following requirements:

1. Have a valid South Carolina State license to practice medicine.
2. Be Board Certified in Diagnostic Radiology by an FDA-approved body or have 3 months of formal training in mammography.
3. Have 60 category I CME credits in mammography with at least 15 obtained in the 3 years immediately prior to qualifying as an interpreting physician.
4. Have interpreted, under direct supervision, the mammographic examinations from 240 patients in the 6 months immediately prior to qualifying as an interpreting physician OR if the physician passed their certifying board in diagnostic radiology at the first allowable time the 6 month period could have been anytime in the last two years of the residency program.

After meeting all the initial requirements, all interpreting physicians must:

1. Maintain mammography continuing education (15 category I CME's/36 months).
2. Maintain continuing experience (960 examinations/24months).
3. Physicians failing to maintain the continuing requirements must requalify prior to performing independent mammographic interpretation.
 - (a) Continuing education: Must bring total up to 15 CME's/3 years.
 - (b) Continuing experience: Interpret 240 examinations under direct supervision or interpret a sufficient number, under direct supervision, to bring total to 960/24 months, whichever is less.
4. Maintain a valid South Carolina State license to practice medicine.

New Modalities

Must have 8 Hours of initial training in new modality

All interpreting physicians shall participate in quality assurance activities as described in 5.10.1.1.

Each mammographic facility shall designate one interpreting physician to be the lead interpreting physician, who is responsible for ensuring that the facility's quality assurance program meets the requirements of these regulations.

Each mammographic facility shall also designate at least one interpreting physician to be the reviewing interpreting physician(s), who is/are responsible for analyzing the medical outcomes audit. The reviewing interpreting physician may or may not be the lead interpreting physician.

Physicians in training may work at facilities as long as they are under the direct supervision of a qualified interpreting physician.

MEDICAL PHYSICIST (See RHB 5.7.3)

In order to independently conduct surveys of mammography facilities and provide oversight of a facility's quality assurance program, one must qualify as a medical physicist. Because the duties of the medical physicist encompass more than just the physics survey, FDA expects the facility to be able to call on the services of the medical physicist throughout the year. Therefore, the facility must be able to identify their qualified medical physicist at the time of the DHEC inspection.

To qualify under the initial qualifications of the final regulations, a medical physicist must document all of the following requirements:

1. Be registered as a Class IX vendor.
2. Have a master's degree or higher in a physical science with no less than 20 semester hours in physics.
3. Have 20 contact hours of specialized training in conducting mammography facility surveys.
4. Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units.

OR

To qualify under the alternative initial qualifications of the final regulations, a medical physicist must document all of the following requirements:

1. Be registered as a Class IX vendor.
2. Have qualified as a medical physicist under the interim regulations and maintained active status of any licensure, approval, or certification required under the interim regulations.
3. Prior to April 28, 1999 have:
 - (a) A bachelor's degree or higher in a physical science with no less than 10 semester hours in physics.
 - (b) Forty contact hours of documented specialized training in conducting surveys of mammography

facilities and,

(c) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

Having once met the initial qualifications, all medical physicists (whether they initially qualified under the interim or final regulations) must meet the continuing qualifications:

1. Continuing education (15 CEU's/36 months).
2. Continuing experience (2 facilities and 6 units/24 months).
3. Maintain Class IX registration.

Medical physicists failing to maintain the continuing requirements must requalify prior to independently conducting surveys of mammography facilities.

1. Continuing education: Must bring total up to 15 CEU's/3 years.
2. Continuing experience: Must bring total up to 2 facilities and 6 units/24 months under direct supervision.

New Modalities

Must have 8 Hours of initial training in new modality

EQUIPMENT EVALUATIONS (See RHB 5.13)

Whenever a new unit or processor is installed, disassembled and reassembled at the same or a new location, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.

This additional evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. For a new unit, an equipment evaluation is needed before the unit is used on patients unless the unit has already undergone a full survey. In this situation, the facility must follow the accreditation body procedures. Keep in mind that under MQSA, the facility has the ultimate responsibility for ensuring image quality and patient safety. If changes or repairs to the system are anticipated, contact the facility's accreditation body to inquire whether the change affects a major component and requires an evaluation.

The equipment evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist. These evaluations will be used to determine whether the new or changed equipment meets the requirements of applicable standards. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. A facility should maintain documentation that shows the date(s) on which a mammography equipment evaluation was performed, who performed the

evaluation, and that any identified problems were corrected before the equipment was used on patients. A facility must maintain this documentation until the next inspection that verifies compliance.

ANNUAL SURVEY (See RHB 4.12)

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in parts 5.11.5, 5.11.6 and the weekly phantom image quality test described in part 5.11.2.
2. The results of all tests conducted by the facility in accordance with part 5.11, as well as written documentation of any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.
3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.
4. The survey report shall be sent to the facility within 30 days of the date of the survey. Also the facility must submit a copy of this report and a copy of the corrective action records to this department within 10 days of completion of the corrective action.
5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

QUALITY CONTROL (See RHB 5.11)

Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be within $+0.03$ of the established operating level.
2. The mid-density shall be within ± 0.15 of the established operating level.
3. The density difference shall be within ± 0.15 of the established operating level.
4. The developer temperature control limits shall be plus or minus 1.0 degree F.

Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than ± 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA.
4. The density difference between the background of the phantom and an added test object, used to assess image

contrast, shall be measured and shall not vary by more than ± 0.05 from the established operating level.

Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

1. Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.
2. Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed

Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.
2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.
3. Compression device performance.
 - (a) A compression force of at least 111 newtons (25 pounds) shall be provided.
 - (b) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (45 pounds).

NON FILM BASED IMAGING SYSTEMS

Users of digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital system.

The manufacturer's current operating manual shall be available for Department review.

SELF-REFERRALS (See Appendix A)

Self-referrals cannot be accepted without prior approval of Appendix A (Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening) from Title B. Once approved, any changes, such as equipment replacement, a change in film or screens, or new personnel, must be reported to the Department within fifteen (15) days.

INSPECTIONS (See RHB 1.3)

The Department conducts annual inspections of mammography facilities. The Department will also conduct inspections if a valid complaint is received. If violations are reported on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Generally, the Department will call a facility about two weeks in advance of the inspection to schedule an inspection. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. **The Department does have the right to make unannounced inspections.**

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items such as records. Generally, an inspection requires use of the mammography equipment for about one hour. The facility can greatly assist the Department inspector by reviewing and completing the Inspection Confirmation information sheet which is sent to the facility once the inspection has been scheduled.

At the conclusion of the inspection, the inspector will conduct an exit interview to discuss any items of noncompliance, as well as any other pertinent observations. The inspector will mail the facility an inspection report documenting any violations, recommendations or comments. 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

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