REGULATORY GUIDE B7

COMPLYING WITH TITLE B - MAMMOGRAPHY

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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 new 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 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.

SHIELDING REQUIREMENTS

(See RHB 4.4)
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 to and accepted by this Department prior to installation, or a written request must be made prior to installation 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 accepted shielding plan. 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 accepted 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)

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

1. Be certified and maintain a valid certificate issued 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.

B. After meeting all the initial requirements, all radiologic technologists must:

1. Maintain mammography continuing education (15 CEU's/36 months).

2. Maintain continuing experience (200 examinations/24 months).

3. 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. At the end of the 6 month grace period, the technologist must have performed 200 examinations.

4. Maintain a valid certificate to perform general radiographic procedures from the South Carolina Radiation Quality Standards

C. New Modalities - Must have 8 Hours of initial training in each new modality, i.e. Full Field Digital Mammography (FFDM), Digital Breast Tomosynthesis (DBT) systems, etc.

INTERPRETING PHYSICIANS

(See RHB 5.7.1)

A. 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.

B. 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.

   Continuing education: Must bring total up to 15 CME's/3 years.

   (a) 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. At the end of the 6 month grace period, the physician must have interpreted at least 960 examinations.

4. Maintain a valid South Carolina State license to practice medicine.

C. New Modalities - Must have 8 Hours of initial training in each new modality, i.e. Full Field Digital Mammography (FFDM), Digital Breast Tomosynthesis (DBT) systems, etc.

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.

A. 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 l 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.

B. 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.

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

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

C. New Modalities - Must have 8 Hours of initial training in each new modality, i.e. Full Field Digital Mammography (FFDM), Digital Breast Tomosynthesis (DBT) systems, etc.

QUALITY ASSURANCE REQUIREMENTS (EQUIP - ENHANCING QUALITY USING THE INSPECTION PROGRAM)
(See RHB 5.10)
Since the quality of mammograms is one of the most important determinants of the accuracy of mammography, the production of high quality clinical images by certified mammography facilities is one of the primary goals of the Mammography Quality Standards Act (MQSA).

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 (LIP), who is responsible for ensuring that the facility's quality assurance program meets the requirements of these regulations.

All interpreting physicians (IP) for the facility are required to follow the facility procedures for corrective

action when the images that they are asked to interpret are of poor quality. The facility must have a mechanism for the IP to provide feedback to the RT's or other designated facility personnel when images are of poor quality. The facility must have a mechanism to document corrective action taken and the effectiveness of the corrective action.

Facilities must have a system in place to ensure that images continue to comply with the clinical image quality standards established by the facility's accreditation body. The facility must perform regular reviews of image quality attributes of a sample of mammograms performed by each active RT and of mammograms accepted for interpretation by each active IP. During each annual inspection, inspectors will ask for documentation that the facility performed a clinical image review at least once since the last inspection.

The LIP is responsible for providing oversight of the QA and QC records, including a review of the frequency of performance of all required tests, and review of any corrective actions when needed. The LIP must be either available to answer questions on the day of the inspection, sign an attestation provided to the facility, or sign a written facility procedure regarding QA/QC oversight which includes the elements above and is presented during the inspection.

In addition, all interpreting physicians for the facility are required to participate in the facility's medical outcomes audit program. 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 RECORDS AND MAMMOGRAPHY REPORTS

(See RHB 5.96)

Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

1. The name of the patient and an additional patient identifier
2. Date of examination
3. The name of the interpreting physician who interpreted the mammogram
4. Overall final assessment of findings

The overall final assessment of findings must be classified in one of the following categories:

1. **Negative**
2. **Benign**
3. **Probably Benign**
4. **Suspicious**
5. **Highly suggestive of malignancy**
6. **Incomplete: Need additional imaging evaluation**

While the final assessment findings must not vary from these categories and must be stated as written above, limited flexibility is allowed for further description as long as it doesn't change the meaning of the

category. The following are considered equivalent to the wording listed above and are acceptable final overall assessments:

1. **Negative**
   Negative Mammogram
2. **Benign**
   Benign Finding
   Benign Findings
   Benign Abnormality
   Benign Abnormalities
   Benign Mammogram
3. **Probably Benign**
   Probably Benign Finding
   Probably Benign Findings
   Probably Benign Abnormality
   Probably Benign Abnormalities
   Probably Benign-Short Interval Follow-up Suggested
   Probably Benign Finding-Short Interval Follow-up Suggested
   Probably Benign Mammogram
4. **Suspicious**
   Suspicious Finding
   Suspicious Findings
   Suspicious Abnormality
   Suspicious Abnormalities
   Suspicious for Malignancy
   Suspicious Abnormality-Biopsy Should Be Considered
   Suspicious Finding-Biopsy Should Be Considered
   Suspicious Mammogram
5. **Highly Suggestive of Malignancy**
   Highly Suggestive of Malignancy
   Highly Suggestive of Malignance - Appropriate Action should be Taken
6. **Incomplete: Need Additional Imaging Evaluation**
   Incomplete: Needs Additional Imaging Evaluation
   Incomplete: Additional Imaging Evaluation Needed
   Incomplete: Need Additional Imaging Evaluation -Comparison with Prior Studies
   Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison
   Incomplete: Need prior mammograms for comparison
   Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example as this is the only incomplete BIRADS assessment category)
   Incomplete Mammogram: Need Additional Imaging Evaluation

Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy", the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible. Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

When the patient has a referring health care provider or the patient has named a health care provider, the facility shall provide a written report of the mammography examination to that health care provider as soon as possible, but no later than 30 days after the date of the examination. If the assessment is "Suspicious" or "Highly suggestive of malignancy", the facility must make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

Each facility that performs mammograms shall maintain mammography films and reports in a permanent record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility. Upon request by, or on behalf of, the patient, the facility shall permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient or to the patient directly. Any fee charged to the patient for providing films and/or reports shall not exceed the documented costs associated with this service.

MAMMOGRAPHY MEDICAL OUTCOMES AUDIT

(See RHB 5.21)

Each facility shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammography assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity and accuracy of the interpretation of mammograms.

Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become know to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

The facility's first audit analysis shall be initiated no later than twelve months after the date the facility becomes certified. This audit analysis shall be completed within an additional twelve months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses shall be conducted at least once every twelve months.

Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every twelve months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. The individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility results, as a whole. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

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 5.12)

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 he 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 1.7)

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.

If the MQSA (Mammography Quality Standards Act) report results in a Level 1, repeat Level 1 or repeat Level 2 finding, a written Corrective Action Plan shall be provided to the Department within 15 calendar days of the date of citation. If the MQSA report results in a Level 2 or repeat Level 3 finding, a written Corrective Action Plan shall be provided to the Department within 30 calendar days of the date of citation.

The facility must notify the Department, in writing, by the appropriate 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 and accepted the required 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
B11 - Complying with Title B - Therapy Facilities

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