

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[FDA 225-05-6002]

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**Memorandum of Understanding Between the U.S. Food and Drug Administration and the State of South Carolina, Department of Health and Environmental Control, Bureau of Radiological Health**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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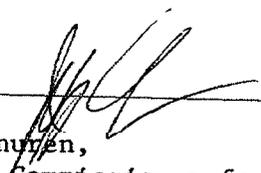
**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the State of South Carolina, Department of Health and Environmental Control, Bureau of Radiological Health. The purpose is to authorize the State of South Carolina, through the South Carolina Department of Health and Environmental Control (DHEC), to conduct a State as certifiers program in South Carolina under the Mammography Quality Standards Act (MQSA) as amended by the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA).

**DATES:** The agreement became effective April 29, 2005.

**FOR FURTHER INFORMATION CONTACT:** Joanne Choy, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration 1350 Piccard Dr., Rockville, MD 20850, 301-827-2963.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

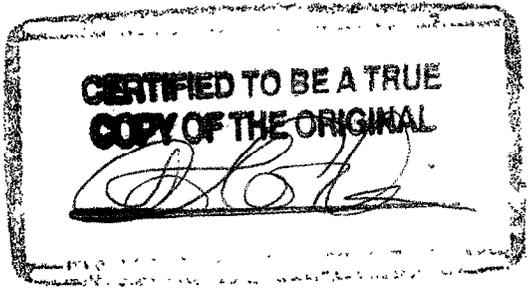
Dated: 6/27/05  
June 27, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[INSERT MOU]

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S



MEMORANDUM OF UNDERSTANDING

BETWEEN

THE STATE OF SOUTH CAROLINA

SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL  
BUREAU OF RADIOLOGICAL HEALTH  
AND

U.S. FOOD AND DRUG ADMINISTRATION  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
OFFICE OF COMMUNICATION, EDUCATION, AND RADIATION PROGRAMS

I. **PURPOSE:**

The purpose of this Memorandum of Understanding (MOU) is to authorize the State of South Carolina, through the South Carolina Department of Health and Environmental Control (DHEC), to conduct a State as certifiers (SAC) program in South Carolina under the Mammography Quality Standards Act (MQSA) (42U.S.C.263b) as amended by the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA). Through this MOU, the United States Food and Drug Administration (FDA) authorizes DHEC to enforce MQSA certification standards as approved by the FDA, to issue certificates to mammography facilities, to perform inspection of mammography facilities, and to take enforcement action against facilities that violate MQSA to ensure safe, reliable, and accurate mammography in South Carolina.

II. **BACKGROUND:**

The MQSA (Pub. L. 102-539) was enacted on October 27, 1992, to establish national quality standards for mammography. Subsection 354(q) of the MQSA gives the Secretary of Health and Human Services (Secretary) the power to authorize State programs to carry out certain MQSA certification program requirements. The Secretary has delegated his authority under subsection 354(q) to FDA. The State of South Carolina requested FDA's approval to serve as a certifying state agency on October 23, 2001. FDA has approved the State's request and authorizes, through this MOU, the State of South Carolina to serve in its capacity as a certifying State.

III. **SUBSTANCE OF AGREEMENT:**

1. FDA hereby authorizes the State of South Carolina, through the DHEC, to carry out the certification requirements of subsections 354(b), (c), (d), (g)(1), (h), (i), and (j) of the MQSA (including the requirements under regulations

promulgated pursuant to such subsections). This authorization applies to facilities within the DHEC's jurisdiction.

2. FDA shall carry out subsections 354(e) and (f), may take action under subsections 354(h), (i), and (j), and shall conduct oversight functions under subsections 354(g)(2) and (g)(3) of the MQSA.
3. The State of South Carolina shall, in addition, comply with the standards for certification agencies at 21CFR 900.22 and 900.25(b) including but not limited to, the requirements for establishing processes for the following activities:
  - certification and inspection of mammography facilities by MQSA-qualified inspectors;
  - appropriate criteria and processes for the suspension and revocation of certificates;
  - prompt investigation of and appropriate enforcement action for facilities performing mammography without certificates, as well as other violations of MQSA;
  - appeals by facilities regarding inspectional findings, enforcement actions, and adverse certification decisions or adverse accreditation decisions after exhausting appeals to their accreditation body;
  - additional mammography review of facilities when the State believes that mammography quality at a facility has been compromised and may present a serious risk to human health;
  - patient and physician notification by the facility when additional mammography review shows that the quality of mammography performed was so inconsistent with established quality standards as to present a significant risk to human health;
  - timely and accurate electronic transmission of inspection, certification, and compliance data in a format and timeframe determined by FDA;
  - authorization by FDA of changes the State proposes to make to any standard that FDA previously has accepted under 21 CFR 900.21.
4. By October 1<sup>st</sup>, the beginning of FDA's fiscal year, the State of South Carolina shall provide to FDA its plan for inspecting all of the facilities under its jurisdiction during the coming year. At the beginning of each quarter, the State shall provide an update to FDA describing any changes in its annual plan that occurred in the last quarter or are planned for the coming quarter. (Quarters will be calculated on a fiscal rather than calendar year basis, beginning in October and continuing through September of the following year).
5. The State of South Carolina will electronically transmit the dates of inspections and the results of all MQSA facility inspections conducted by the State within 5 business days after conducting the inspection by uploading

these data to the MQSA Mammography Program Reporting and Information System (MPRIS) facility inspection data application (FISS).

6. The FDA will bill and charge each inspected mammography facility a fee, in accordance with 42 USC 263b(r)(1), of \$509 to cover the FDA's cost for support of the inspections. This fee may be subject to change by FDA. The types of services that will be provided by the FDA are as follows:
  - Training and qualifying inspectors.
  - Billing facilities for the FDA portion of the fees due for annual inspections.
  - Collecting the FDA portion of the facility payments.
  - Developing instrument calibration procedures and calibrating instruments used in the inspections.
  - Supplying, repairing, and replacing inspection equipment.
  - Designing, programming, and maintaining inspection data systems.
  - Administering attributable support to facility inspections.
7. Facilities that qualify as governmental entities (GE) will not be subject to the payment of FDA inspection fees.
8. By the end of each quarter, the State of South Carolina shall electronically update and maintain facility noncompliance information via the MPRIS facility compliance tracking data application (FaNTMS) to reflect the status and resolution of inspectional findings. Quarters will begin in October and continue through September of the following year.
9. The State of South Carolina will, in accordance with 21 CFR 900.23, provide all information as specified by FDA as part of FDA's oversight responsibilities, including keeping FDA's SAC liaison informed of compliance actions as they occur and through resolution (e.g., AMR, PPN, Injunctions, Cease and Desist Order, Suspension, or Revocation).
10. The State of South Carolina will timely provide FDA with updates concerning revisions made to the State's policies and procedures for carrying out its MQSA certification, inspection, and enforcement responsibilities.
11. In the event FDA determines, through its oversight activities under 21 CFR 900.23, or through other means, that the State of South Carolina is no longer in substantial compliance with its certification program responsibilities, FDA may take action in accordance with 21 CFR 900.24.
12. FDA will provide to the State of South Carolina, under 21 CFR 900.25(a), the opportunity to appeal final actions taken by FDA regarding its approval or withdrawal of approval of the certification body.

13. FDA will provide the State of South Carolina with access to the FDA MQSA database (MPRIS).

**IV. NAMES AND ADDRESSES OF PARTICIPATING AGENCIES:**

State of South Carolina:  
SC DHEC  
Bureau of Radiological Health  
2600 Bull Street  
Columbia, SC 29201

FDA:  
Center for Devices and Radiological Health  
Office of Communication, Education, and Radiation Programs  
1350 Piccard Drive  
Rockville, MD 20850

**V. LIAISON OFFICERS:**

For matters and notices related to this MOU:

**A. The contact person for SC DHEC is:**

Aaron A. Gantt, Director  
SC DHEC, Bureau of Radiological Health  
2600 Bull Street  
Columbia, SC 29201  
Phone: 803-545-4420  
FAX: 803-545-4412  
E-mail address: ganttaa@dhec.sc.gov

**B. The contact person for FDA is:**

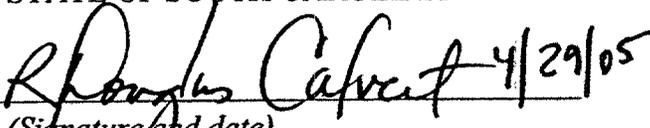
Joanne Choy  
Food and Drug Administration, HFZ-240  
Center for Devices and Radiological Health  
Division of Mammography Quality and Radiation Programs  
1350 Piccard Drive  
Rockville, MD 20850  
Phone: (301) 827-2963  
FAX: (301) 594-3306  
E-mail address: jkc@cdrh.fda.gov

Either party may designate in writing different contact persons or addresses.

VI. PERIOD OF AGREEMENT:

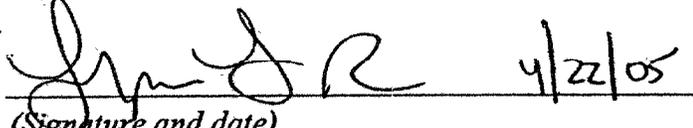
This MOU will become effective as of the date of acceptance by both parties and will continue in effect until termination in writing by either party with a 30-day prior notice period (such notice shall be sent to the addresses listed in Section V.) This MOU may be modified by mutual written consent at any time. The MOU will be formally reviewed by the FDA every seven years, and updated or modified as appropriate.

APPROVED AND ACCEPTED FOR THE  
STATE OF SOUTH CAROLINA

 4/29/05  
*(Signature and date)*

Doug Calvert  
Chief of Staff  
SC Department of Health and  
Environmental Control

APPROVED AND ACCEPTED FOR THE  
FOOD AND DRUG ADMINISTRATION

 4/22/05  
*(Signature and date)*

Lynne L. Rice  
Director  
Office of Communication, Education, and Radiation  
Programs  
Center for Devices and Radiological Health  
Food and Drug Administration