DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4006]

Memorandum of Understanding Between the State of Iowa, Department of Public Health, Bureau of Radiological Health, and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the State of Iowa, through the Iowa Department of Public Health, Bureau of Radiological Health (the Department), and FDA. The purpose is to authorize the state of Iowa, through the Department, to continue to conduct a State as certifiers program in Iowa under the Mammography Quality Standards Act as amended by the Mammography Quality Standards Reauthorization Act of 1998.

DATES: The agreement became effective August 26, 2004.

FOR FURTHER INFORMATION CONTACT: Joanne Choy, Division of Mammography Quality and Radiation Programs (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: June 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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Control No. 225-04-4006

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE STATE OF IOWA

DEPARTMENT OF PUBLIC HEALTH
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 Iowa, through the Iowa Department of Public Health, Bureau of Radiological Health (Department), to continue to conduct a State as certifiers (SAC) program in Iowa 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 the Department 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 Iowa.

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 authority under subsection 354(q) to FDA. FDA developed a States as Certifiers Demonstration Project (Project) to allow a limited trial of State Programs under subsection 354(q) of the MQSA. The State of Iowa applied to participate in the Project and was approved by FDA on July 8, 1998. The State's participation in the Project was subsequently renewed, through an MOU, on July 30, 1999. The State of Iowa requested FDA's approval to continue to serve as a certifying state agency after the completion of the Demonstration Project. FDA has approved the State's request and authorizes, through this MOU, the State of Iowa to continue to serve in its capacity as a certifying State.

III. SUBSTANCE OF AGREEMENT:

1. FDA hereby reauthorizes the State of Iowa, through the Department, 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 reauthorization applies to facilities within the Department's jurisdiction.

2. FDA shall continue to 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 Iowa 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 qualified MQSA-qualified inspector;
   - 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 so 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 1st, the beginning of FDA's fiscal year, the State of Iowa 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 Iowa 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 costs for support of the inspection. 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 Iowa shall electronically update and maintain facility noncompliance information via the MPRIS facility compliance tracking data application (FaNTMS) to reflect status and resolution of inspectional findings. Quarters will begin in October and continue through September of the following year.

9. The State of Iowa 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 Iowa will provide FDA with updates and revisions to its policies and procedures previously approved by FDA, as appropriate.

11. In the event FDA determines, through its oversight activities under 21 CFR 900.23, or through other means, that the State of Iowa 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 Iowa, 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 Iowa with access to the FDA MQSA database (MPRIS).

IV. NAMES AND ADDRESSES OF PARTICIPATING AGENCIES:

State of Iowa:
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street
Suite D
Des Moines, IA 50309-4611

FDA:
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 the Department is:

Donald A. Flater, Chief
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309-4611
Phone: (515) 281-3478
dflater@idph.state.ia.us

B. The contact person for FDA is:

Joanne Choy
Food and Drug Administration, HFZ-240
Division of Mammography Quality and Radiation Programs
1350 Piccard Drive
Rockville, MD 20850
Phone: (301) 827-2963
jkc@cdrh.fda.gov

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

VI. **PERIOD OF AGREEMENT**:

This MOU will become effective on the date or as of the acceptance by both parties and will continue until termination in writing by either party with a 30-day prior notice (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 IOWA

8/26/04

(Signature and date)

Mary Mincer Hansen
Director
Iowa Department of Public Health
State of Iowa

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

8/18/04

(Signature and date)

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

[FR Doc. 05–13634 Filed 7–11–05; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21003]

Collection of Information Under Review by Office of Management and Budget (OMB): 1625–0040

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard has forwarded one Information Collection Request—1625–0040, Continuous Discharge Book, Merchant Mariner Application, Physical Examination Report, Sea Service Report, Chemical Testing and Entry Level Physical Report—abstracted below, to the Office of Information and Regulatory Affairs of the Office of Management and Budget for review and comment. Our ICR describes the information we seek to collect from the public. Review and comment by OIRA ensures that we impose only paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before August 11, 2005.

ADDRESSES: To make sure that your comments and related material do not reach the docket [USCG–2005–21003] or Office of Information and Regulatory Affiars (OIRA) more than once, please submit them by only one of the following means:

(1)(a) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(b) By mail to OIRA, 725 17th St., NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(2)(a) By delivery to room PL–401 at the address given in paragraph (1)(a) above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(b) By delivery to OIRA, at the address given in paragraph (1)(b) above, to the attention of the Desk Officer for the Coast Guard.

(3) By fax to (a) the Facility at (202) 493–2298 and (b) OIRA at (202) 395–6566, or e-mail to OIRA at *oira-docket@omb.eop.gov* attention: Desk Officer for the Coast Guard.

(4)(a) Electronically through the Web Site for the Docket Management System at *http://dms.dot.gov*.

(b) OIRA does not have a Web site on which you can post your comments.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov.*

Copies of the complete Information Collection Request (ICR) are available through this docket on the Internet at *http://dms.dot.gov*, and also from Commandant (CG–611), U.S. Coast Guard Headquarters, room 6106 (Attn: Ms. Barbara Davis), 2100 Second Street, SW., Washington, DC 20593–0001. The telephone number is (202) 267–2326.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Davis, Office of Information Management, telephone (202) 267–2326 or fax (202) 267–4814, for questions on these documents; or Ms. Andrea M. Jenkins, Program Manager, Docket