DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4005]

Memorandum of Understanding Between the Food and Drug Administration and the State of Illinois, Emergency Management Agency, Bureau of Radiation Safety

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 Food and Drug Administration and the State of Illinois, through the Illinois Emergency Management Agency, to continue to conduct a State as certifiers program in Illinois under the Mammography Quality Standards Act as amended by the Mammography Quality Standards Reauthorization Act of 1998.

DATES: The agreement became effective August 18, 2004.

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: June 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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Control No. 225-04-4005

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE STATE OF ILLINOIS

EMERGENCY MANAGEMENT AGENCY
BUREAU OF RADIATION SAFETY

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 Illinois, through the Illinois Emergency Management Agency (Agency), to continue to conduct a State as certifiers (SAC) program in Illinois 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 Agency 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 Illinois.

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. 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 Illinois applied to participate in the Project and was approved by FDA on August 3, 1998. The State's participation in the Project was subsequently renewed, through an MOU, on November 3, 1999. The State of Illinois 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 Illinois to continue to serve in its capacity as a certifying State.

III. SUBSTANCE OF AGREEMENT:

1. FDA hereby reauthorizes the State of Illinois, through the Agency, 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 Agency'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 Illinois 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 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 Illinois 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 Illinois 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 Illinois 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 Illinois will, in accordance with 21 CFR 900.23, provide all information as specified by FDA as part of FDA's 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 Illinois 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 Illinois 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 Illinois, 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 Illinois with access to the FDA MQSA database (MPRIS).

IV. NAMES AND ADDRESSES OF PARTICIPATING AGENCIES:

State of Illinois:
Illinois Emergency Management Agency
110 East Adams Street
Springfield, IL 62701

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 Agency is:

Marilyn Haycraft
Mammography Certification Program
Division of Nuclear Safety
Illinois Emergency Management Agency
1035 Outer Park Drive
Springfield, Illinois 62704
Phone: (217) 785-9923
FAX: (217) 785-9946
E-mail address: Haycraft@iema.state.il.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
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 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 ILLINOIS

(Signature and date) 8/3/04
William C. Burke
Director
Illinois Emergency Management Agency
State of Illinois

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

(Signature and date) 8/18/04
Lynne L. Rice
Director
Office of Communication, Education, and Radiation Programs
Center for Devices and Radiological Health
Food and Drug Administration

[FR Doc. 05–13706 Filed 7–12–05; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers and Methods and Kits for Targeting

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 60/010,166, filed January 5, 1996, entitled ''Mesothelin, A Differentiation Antigen Present On Mesothelium, Mesotheliomas And Ovarian Cancers And Methods And Kits For Targeting'' [E–002–1996/0–US–01]; United States Patent No. 6,153,430, issued on November 28, 2000, entitled ''Nucleic Acid Encoding Mesothelin, A Differentiation Antigen Present On Mesothelium, Mesotheliomas And Ovarian Cancers'' [E–002–1996/0–US–02]; United States Patent Application No. 09/684,599, filed October 5, 2000, entitled ''Mesothelin, A Differentiation Antigen Present On Mesothelium, Mesotheliomas And Ovarian Cancers And Methods And Kits For Targeting'' (E–002–1996/0–US–03); United States Patent No. 6,083,502, issued on July 4, 2000, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–US–02]; PCT Application No. PCT/US97/00224, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–PCT–01]; Australian Patent No. 703769, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–AU–03]; Canadian Patent No. 2241604, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–CA–04]; Japanese Patent Application No. 9–525355, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–JP–06]; European Patent No. 0871492, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–EP–05]; Switzerland Patent Application No. 0871492, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–CH–07]; German Patent No. 69726404.1, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' (E–002–1996/1–DE–08); French Patent Application No. 0871492, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–FR–09]; Italian Patent No. 05503/BE/2004, January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–T–10]; Spanish Patent No. 0871492, filed January 3, 1997, entitled ''Mesothelium Antigen And Methods And Kits For Targeting It'' [E–002–1996/1–ES–11]; United Kingdom Patent No.