orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 6, 1999. Oral presentations from the public will be scheduled on August 27, 1999, between approximately 11 a.m. to 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 6, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 30, 1999

**Linda A. Suydam,**

*Senior Associate Commissioner*

[FR Doc. 99–20365 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### [FDA 225–98–6000]

## Memorandum of Understanding Between the Food and Drug Administration and States of Illinois

**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 FDA and the State of Illinois Department of Nuclear Safety. The purpose of the MOU is to authorize the State to implement a State certification program under the Mammography Quality Standards Act.

**DATES:** The agreement became effective August 3, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lireka P. Joseph, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 2094 Gaither Rd., Gaithersburg, MD 20850, 301–443–2845. **SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

BILLING CODE 4160–01–F

Control No. 225-98-6000

# MEMORANDUM OF UNDERSTANDING

# BETWEEN THE

# STATE OF ILLINOIS
# DEPARTMENT OF NUCLEAR SAFETY

# AND

# U.S. FOOD AND DRUG ADMINISTRATION
# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
# OFFICE OF HEALTH AND INDUSTRY PROGRAMS

## I. PURPOSE:

The purpose of this Memorandum of Understanding (MOU) is to authorize the State of Illinois, through the Department of Nuclear Safety (Department), to implement a State certification program in Illinois under the Mammography Quality Standards Act (MQSA). The MOU will authorize the Department to implement MQSA certification standards as approved by the United States Food and Drug Administration (FDA), and to issue certificates to mammography facilities to ensure safe, reliable, and accurate mammography in Illinois. FDA recognizes that the Radiation Protection Act of 1990 and Department emergency/proposed rules, to be filed and effective upon execution of this MOU, meet the requirements of the MQSA for approval by FDA of a State certification program in Illinois.

## II. BACKGROUND:

The MQSA (Pub. L. 102-539) was enacted on October 27, 1992, to establish national quality standards for mammography. Pursuant to MQSA, the authority to approve accreditation bodies and to certify facilities was delegated by the Secretary of Health and Human Services (Secretary) to the FDA.

Subsection (q) of the MQSA authorized the Secretary to authorize State programs to carry out certain MQSA certification program requirements. Section 24.5 of the Radiation Protection Act of 1990 authorizes the Department to enter agreements and promulgate rules as necessary to implement such a State program in Illinois.

FDA has developed a States as Certifiers Demonstration Project (Project) to allow a limited trial of State Programs under Subsection (q) of the Act. The State of Illinois has applied and been approved by the FDA to participate in the Project. The Project is for one year, but may be renewed by mutual agreement. FDA anticipates that the Demonstration Project will lead to a national States as Certifiers program which will be

open to all states that apply and are approved by FDA.

## III. AUTHORITY:

FDA has been delegated authority by the Secretary to authorize, under Subsection (q) of the MQSA, State MQSA certification programs. Pursuant to Section 24.5 of the Radiation Protection Act of 1990, the Department is authorized to enter into agreements to carry out the State Certification program requirements provided for in the MQSA.

## IV. TERMS:

1. FDA, under the Project, hereby authorizes the State of Illinois, through the Department, to implement a program to carry out the certification requirements of subsections (b), (c), (d), (g)(1), (h), (i), and (j) of the MQSA (including the requirements under regulations promulgated pursuant to such subsections). The Department shall implement the program in accordance with its application dated February 9, 1998 and its response to the FDA review letter of April 7, 1998, submitted with the Department's letter of April 20, 1998.

2. FDA shall continue to carry out subsections (e) and (f), may take action under subsections (h), (i), and (j), and shall conduct oversight functions under subsections (g)(2) and (g)(3) of the MQSA.

3. The State of Illinois will provide the FDA with the results of all MQSA inspections conducted by the State during the Project. Based on this information, the FDA will bill and charge each inspected mammography facility a fee of $509 to cover the FDA's costs for the annual inspection. This fee may be subject to change.

4. Under the MQSA, all certified mammography facilities except governmental entities are subject to the payment of inspection fees. During the period of time the State of Illinois is participating in the Project, facilities that qualify as government entities will not be required to pay the FDA inspection fee but will be required to recertify their government entity status using the form provided when billed by FDA

   During the period of time Illinois is participating in the Project, the Department will directly bill and charge all facilities certified by the Department to perform mammography under MQSA an annual certification fee of $750.

## V. NAME AND ADDRESSES OF PARTICIPATING AGENCIES:

| FDA: | State of Illinois |
|---|---|
| Office of Health and Industry Programs<br>1350 Piccard Drive<br>Rockville, MD 20850 | Department of Nuclear Safety<br>1035 Outer Park Drive<br>Springfield, IL 62704 |

## VI. LIAISON OFFICERS:

For matters and notices related to this MOU, the contact person for FDA is:

Al Van De Griek
Division of Mammography Quality and Radiation Programs
Food and Drug Administration, HFZ-240
1350 Piccard Drive
Rockville, Maryland 20850
(301) 594-0866

The contact person for the Department is:

Paul Brown, Chief
Illinois Department of Nuclear Safety
Division of Electronic Products
1035 Outer Park Drive
Springfield, Illinois 62704
(217) 785-9978

Either party may, from time to time, designate in writing different contact persons or addresses.

## VII. PERIOD OF AGREEMENT:

After acceptance by both parties, this MOU will be become effective on the effective date of 32 Illinois Administrative Code 370 (Quality Standards and Certification Requirements for Facilities Performing Mammography) and continue until the completion of the Project or upon termination in writing by either party with a 30-day prior notice (such notice shall be sent to the addresses listed in Section VI). This MOU may be modified by mutual written consent at any time.

NOW THEREFORE, the parties hereto mutually agree to the terms and conditions set forth above.

FDA:

8/3/98
(Signature and date)
Lireka P. Joseph, Dr.P.H.
Director
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration

State of Illinois:

8/3/98
(Signature and date)
Thomas W. Ortciger
Director
Department of Nuclear Safety
State of Illinois

Dated: August 2, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99–20358 Filed 8–6–99; 8:45 am]

**BILLING CODE 4160–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99N–2359]**

## Medical Devices; Global Harmonization Task Force: Summary Technical File Documents for Premarket Documentation of Conformity With Requirements for Medical Devices; Recommendations on the Role of Standards in the Assessment of Medical Devices; and a Recommendation on Medical Device Classification; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of three documents entitled ''Summary Technical File for Premarket Documentation of Conformity With Requirements for Medical Devices;'' ''Recommendation: Role of Standards in the Assessment of Medical Devices;'' and ''Recommendation on Medical Devices Classification.'' Study group 1 of the Global Harmonization Task Force (GHTF) has prepared these documents on premarket regulation of medical devices. These documents are intended to provide information only and represent harmonized proposals and recommendations that may be used by governments developing or updating their premarket regulation schemes for medical devices. Elements of the approach set forth in these documents may not be consistent with current U. S. regulatory requirements. FDA is requesting comments on these documents.

**DATES:** Written comments by September 30, 1999. After the close of the comment period, written comments may be submitted at any time to Kimber C. Richter (address below).

**ADDRESSES:** Submit written comments on the documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web (WWW), submit written requests for single copies on a 3.5″ diskette of the document listed above to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these documents.

**FOR FURTHER INFORMATION CONTACT:** Kimber C. Richter, Office of Device Evaluation (HFZ–400), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France, by senior regulatory officials to evaluate international harmonization. At this time it was decided to form GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world. The most recent GHTF meeting was held in June and July 1999, in Bethesda, MD, in the United States.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by study group 1.

Study group 1 was formed in January 1993, and was originally tasked with identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of their efforts, this group has developed three draft documents that are described briefly in the following paragraphs.

(1) ''Summary Technical File for Premarket Documentation of Conformity With Requirements for Medical Devices'' (GHTF.SG1.NO11R7). Study group 1 suggests that this document should be used with the document