

Inspection Demonstration Program

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and Radiation Programs**

Mammography Quality Standards Act (MQSA)

- **MQSRA enacted October 1992**
- **Mandated annual inspections of all certified facilities**

Mammography Quality Standards Reauthorization Act (MQSRA)

- **MQSRA enacted October 1998**
- **New requirements & authorizations**
 - **Inspection Demonstration Program (IDP)**
**A test program under which inspections of
selected facilities may be conducted less
frequently than annually**

Inspection Demonstration Program Congressional Restrictions

- **Could not be implemented before 4/1/01**
- **Facilities must be substantially free of non-compliance**
- **Number of facilities shall provide a statistically significant sample**
- **Inspection frequency will reasonably assure compliance with standards**

FDA IDP Plan

- **Include States and facilities using established criteria**
- **Include study and control groups**
- **Conduct biennial inspections for study group**
- **Conduct annual inspections for control group**

State Participation Criteria

For a State to participate , the State shall:

- **Agree to participate in the inspection demonstration program**
- **Have no State laws/regulations/policy which require annual inspections of mammography facilities (units and records)**
- **Inspect participating facilities at the frequency designated by FDA**

State Participation Criteria

continued

- **Accept modifications in the State inspection contract based on the number of facilities to be inspected under the IDP**
- **Notify FDA of potential serious public health risks, of which they become aware, at any of the participating facilities**

Participants

- Arkansas
- **District of Columbia**
- Florida
- Mississippi
- **New York (city)**
- New York (state)
- Ohio
- Oklahoma
- Pennsylvania
- **Puerto Rico**
- South Dakota
- Washington
- Wisconsin
- Wyoming

Facility Participation Criteria

The facility must:

- **Have undergone at least two annual inspections under the final regulations**
- **Received no citations during the two most recent annual inspections under the final regulations**
- **Received no regulatory action (i.e., compliance action), nor have been considered for regulatory action by FDA**

Facility Participation Criteria

continued

- Anticipate providing mammography services throughout the inspection demonstration program**
- Maintain full accreditation/certification throughout the inspection demonstration program**
- Be selected by FDA to participate in the IDP**

Study Group Facilities

- (6) Arkansas
- (1) District of Columbia
- (23) Florida
- (6) Mississippi
- (12) New York (city)
- (23) New York (state)
- (24) Ohio
- (6) Oklahoma
- (22) Pennsylvania
- (7) Puerto Rico
- (2) South Dakota
- (10) Washington
- (12) Wisconsin
- (1) Wyoming

Status

- **Notification Sent to States, Accreditation Bodies, and Facilities**
- **Approximately 155 facilities in the study group**
 - **Next inspections beginning in May of 2003**
- **Approximately 155 facilities in the control group**
 - **Standard annual inspection schedule**
- **Implemented the program in May 2002**

Projections

- **Annual – Inspection of Control Group**
- **01/2003 – Procedure and Software Modifications**
- **03/2003 – Testing of Software Modifications**
- **05/2003 – Begin Testing of Study Group Facilities**
- **07/2004 – Complete Study Group Testing**
- **08/2004 – Begin Data Analysis**