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| SUBJECT:<br><br>Mammography Facility Inspections  |   | IMPLEMENTATION DATE  |
|   |   | COMPLETION DATE  |
| <b>DATA REPORTING</b>   |   |  |
| <b>PRODUCT CODES</b>  | <b>PROGRAM ASSIGNMENT CODES</b>               |  |
| Product Codes:<br>90I_ZH – screen/film<br>mammography system<br>90M_UE – full-field digital<br>mammography system<br>Establishment Type E | 85014<br>85014A<br>85014C<br>85014F<br>85S001 | Routine Inspections<br>Quality Assurance Audits<br>Compliance (Coord./Tech. Asst.)<br>Follow-up Inspections<br>State Inspections |

**Field Reporting**

**A. Mammography Program Reporting and Information System (MPRIS)**

Routine Inspections - Inspectors should record all data and observations during an inspection into the Field Inspection Support System (FISS) software, using the laptop computer provided by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) or a laptop provided by ORA. They should then upload the inspection (computer data) into MPRIS within five working days after the inspection. The inspector would usually print a report of the inspection observations from the computer and give this to the facility at the conclusion of the inspection. This report is titled "MQSA Facility Inspection Report," but may also be referred to as the "post-inspection report." The inspector should date and sign the report. In some instances, State inspectors will mail the report back to the facility, following review by his or her supervisor. Where serious violations are found (level 1, repeat level 1, and/or repeat level 2), FDA may do a follow-up inspection or send a Warning Letter to the facility. In cases where a Warning Letter is sent, a compliance inspection should be done within two to three months after the Warning Letter.

FDA field offices need to keep copies of the post-inspection and inspection detail reports in the corresponding FDA district file for the facility. Likewise, the States may print out the inspection reports for their records, though electronic storage as outlined in the State contracts is acceptable. In those cases where FDA inspectors inspect non-federal facilities, the State should be copied on the inspection report and other correspondence.

## B. FACTS Reporting

FDA MQSA inspectors should report all MQSA-related operations (inspections, audits of inspectors, coordination and technical assistance, training, etc.), into the Field Accomplishments and Compliance Tracking System (FACTS). Additional FACTS data entry is needed to ensure the FACTS inspection record is closed properly.

Inspections under the MQSA program will transfer into FACTS under Operation Code 12 – Domestic Inspection, PAC 85014 for annual inspections or PAC 85014F for follow-up inspections once they are uploaded from the Facility Inspection Support System (FISS).

**Note:** If the inspection revealed any adverse observations, the inspection will not transfer into FACTS until all noncompliances are resolved in MPRIS.

The MQSA inspections will have a FACTS status code of “In Progress” and will be located in the Personal In-Box of the inspector. MQSA inspectors should open the inspection in FACTS and complete the FACTS endorsement/cover sheet in accordance with the Investigations Operations Manual and/or their district’s policy. The inspector should electronically sign the FACTS cover sheet, set the inspection status code to “Awaiting Endorsement” (or “Completed” depending on your FACTS account privileges), and make any necessary adjustments to the hours initially reported in FISS for the completion of the inspection. The local supervisor of the MQSA inspector should endorse the inspection in FACTS to complete the FACTS record.

If the home district of the MQSA inspector is different than the home district of the mammography facility, the procedure you should follow is different. The MQSA inspector in this case should send notification to the Investigations Branch manager in the home district of the facility, informing him or her that the MQSA inspection has been completed and the status code has been set to “Awaiting Endorsement” (or “Completed” depending on your FACTS account privileges) in FACTS. MQSA inspectors should provide the FACTS Assignment ID to the Investigations Branch manager. The Investigations Branch Manager should search the district’s Organizational In-Box using the FACTS Assignment ID provided by the inspector to find the inspection. The inspection should be endorsed by the Investigations Branch Manager and closed in FACTS. Note: The MQSA inspector should send the inspection report and any other supporting documentation to the home district of the mammography facility for file.

**Special Instructions Concerning Audits.** MQSA auditors should audit FDA and State MQSA inspectors to ensure they are following FDA procedures and guidance for MQSA inspections. The majority of audit inspections are expected to be joint annual inspections (the auditor

accompanying the audited inspector). Districts should refer to the MQSA Auditors Guide for more information regarding audits.

**When an MQSA inspector uploads an audit inspection to MPRIS the audit inspection data will transfer into FACTS as an Operation Code 13 – Domestic Investigations, PAC 85014A. MQSA auditors SHOULD NOT create a record in FACTS for joint audits. The FACTS record of the audit will be automatically created by the transfer of the data from MPRIS to FACTS. This FACTS record will include the on-site inspection time entered into FISS by the MQSA inspector.**

Auditors can search for the FACTS documentation for the joint audit by selecting the “Navigate” function in their FACTS In-Box and then moving through the following selections: “Investigative Operations” and then “Investigations”. In the “Investigations Search” window the auditor should enter the home district of the facility as the “Accomplishing District” (regional employees may have to select their regional code). The auditor should also enter the date of the audit as the “Start Date” and PAC Code 85014A under “PAC”. Click “ExeQry” to execute the query. The up and down arrows should be used to move through the selected records until you come to the one you are looking for. You can update the record to include additional time spent by the auditor conducting paper audit reviews or other audit activities for the audit by clicking on the “Accomplishment Hours” function to bring up the “Accomplishment Hours” screen. You must click on the “Update” button to add any additional hours to the data visible on the screen.

**Note: When entering inspections, investigations, or other operations in FACTS for a specific mammography facility, the MQSA inspector should verify the information located under the “Firms” function. This includes entering the MQSA facility ID number in the “Cross Reference” function of the screen.**

**Mentored inspections:** When you are the mentor on a Mentored inspection your time will be transferred to FACTS as Operation Code 83-Training Given by FDA with a status code of “Completed.”

**Compliance, Coordination and Technical Assistance:** Inspectors and auditors should enter time spent providing technical assistance and compliance reviews under the MQSA program into FACTS under “Miscellaneous Accomplishments”, Operation Code 92- Coordination/Technical Assistance, and PAC 85014C.

**Training:** All hours spent in training activities should be reported into FACTS as Operation Code - 83 Training/Education Given or Operation Code 84 – Training Received, PAC 85014.

## C. SPECIAL

**Correspondence with Facilities** – You should send copies of Warning Letters to the State, the facility’s accreditation body, and Division of Compliance Management and Operations (HFC-210). You should provide copies of all correspondence of regulatory significance (e.g., minutes of meetings, follow-up letters to facility) to the appropriate state officials.

**New or Uncertified Facilities** – FDA field personnel and State agencies that receive information that a mammography facility is suspected of performing mammography while uncertified should send an electronic mail message to Division of Mammography Quality and Radiation Programs (DMQRP) as soon as possible (see compliance contacts in Attachment A), with a copy to the Regional Radiological Health Representative (RRHR).

**Compliance Information** - MPRIS Web has a section that is designed to track corrective actions for inspection observations. Each district designates personnel to update the compliance section of MPRIS Web which would normally include FDA MQSA auditors and inspectors as well as compliance personnel. For inspections where the facility is requested to respond (see Part V, A.1.a.), MPRIS Web should be updated. Districts should enter data regarding all correspondence with the facility, including Warning Letters and the receipt of facility response letters. This system should be updated no later than 15 business days after the letter is sent or received. See Attachment N for more information regarding MPRIS Web.

MPRIS Web users usually include MQSA auditors and inspectors, compliance officers, and compliance technicians. Only authorized users may update MPRIS Web. To get an account set up for a new user, districts should contact MPRIS Computer Support via telephone or e-mail or [computersupport@cdrh.fda.gov](mailto:computersupport@cdrh.fda.gov)).

## D. FACILITIES

All facilities that have been entered into the MPRIS database should also appear in the FACTS Firm File, with identifying Central Files Numbers (CFNs) or Firm Establishment Identifiers (FEIs). However, FACTS users should also enter the facility’s MQSA ID number into FACTS as a cross-reference.