

Attachment N

## MPRIS Web

MPRIS Web is the primary application for accessing and updating data in MPRIS relating to mammography facilities. While the FISS application, which is only used to enter data during inspections and is only installed on inspection laptops provided to inspectors, MPRIS Web has wider availability. In addition to MQSA inspectors, DMQRP has provided access to compliance officers, RRHRs, and others within the field with a need to access and update data regarding facility inspections.

**Home Page** (<https://192.168.163.14:4443/MPRISWeb/user/login.jsp>)

The MPRIS Web home page has two main columns titled Latest News and MPRIS Documents. Latest News includes recent emails sent to inspectors. MPRIS Documents are other inspector-related documents, such as updates on software releases for FISS and MPRIS Web and the MQSA inspection procedures.

### Search Tab

In the upper left-hand corner of the every screen in MPRIS Web is the Search tab (see Figure 1) which can be used to search for specific facilities or inspections. You should use the search by the Facility ID if you know the number and need to find information on a specific facility. The Advanced Search and Inspection Search allow for broader searches for facilities or inspections. For example, the Inspection Search tab can be used to find all inspections within the district in the last six months with a level 1 inspection observation. These searches also allow the data to be exported in either PDF or Excel formats.



Figure 1

**Facility Information**

If you select a specific facility using the search capability, you will pull up basic information including the expiration date of the facility’s certificate and the date of the last inspection (see Figure 2).

The screenshot shows a web interface for facility information. At the top, there are search fields for 'Facility ID' and 'AB ID'. Below these, a 'Search' button is visible. The main content area displays the following information:

- Facility ID:** [Empty field]
- AB ID:** [Empty field]
- Certification Status:** Certified
- Certificate Expiration:** 11/06/2008
- Accreditation Body:** [American College of Radiology]
- Accreditation Status:** Accredited
- Last Inspection Date:** 06/20/2008

Below the search area, there are tabs for 'Facility', 'Certification', 'Units', and 'Inspections'. The 'Facility' tab is currently selected. A 'View In Excel' button is located in the top right corner. Below the tabs, there is a section titled 'Facility Information' with a 'View In Excel' button. This section contains the following details:

- Facility ID:** [Empty field]
- Type:** Private Practice – Radiology
- Accreditation Contact:**
  - Name: [Empty field]
  - M.D. [Empty field]
  - Title: [Empty field]
  - Company: [Empty field]
- Inspection Contact:**
  - Name: [Empty field]
  - Title: Technologist
  - Company: [Empty field]

Figure 2

From the Facility Information screen, you can also access information on inspections by clicking on the Inspections tab which will pull up the Inspection History with a list of inspections (see Figure 3).

The screenshot shows the 'Inspection History' screen. At the top, there are tabs for 'Facility', 'Certification', 'Units', 'Inspections', 'Compliance Case', and 'Billing'. The 'Inspections' tab is currently selected. A 'View In Excel' button is located in the top right corner. Below the tabs, there is a table with the following data:

Inspection ID	Inspection Type	Inspection Date	Locked?	Unit Count	Inspector ID/Name	Inspection Status
0010	Annual Inspection	06/20/2008	N	1	[Empty field]	Open
0009	Annual Inspection	06/29/2007	N	1	[Empty field]	Closed
0008	Annual Inspection	06/27/2006	N	1	[Empty field]	Closed
0007	Annual Inspection	06/03/2005	N	1	[Empty field]	Closed
0006	Annual Inspection	06/11/2004	N	1	[Empty field]	Closed
0005	Annual Inspection	06/13/2003	N	1	[Empty field]	Closed

Figure 3

You can then click on any of the inspections in the left-hand column, which will put up Inspection Details including a list of the inspection observations (see Figure 4)

The screenshot shows the MPRIS Web interface with the 'Inspections' tab selected. The 'Inspection Details' section includes the following information:

- Inspection Status: Closed
- Inspection Type: Annual Inspection
- Inspection ID: [redacted]
- Unit Count: 1
- Inspector ID: [redacted]
- Inspector Name: [redacted]
- Inspection Date: 02/20/2008
- Next Response Due Date: 09/12/2008
- Final Response Adequate Date: 07/23/2008
- Inspection Closed Date: 07/23/2008
- Download Date: 02/07/2008
- First Upload Date: 02/20/2008
- Last Upload Date: 02/20/2008

The 'Noncompliances' section contains a table with three rows of data:

Level	Repeat	Status	Noncompliance Code	Noncompliance Description
1	N	Resolved	Proc. QC consec d	Processor QC records were missing at least 5 consecutive days for processor PROCESSOR 1, [redacted] or [redacted] room DARKROOM 1 at site [redacted] Hospital
1	N	Resolved	Proc. out of limits	Mammograms were processed in processor PROCESSOR 1, [redacted], room DARKROOM 1 at site [redacted] Hospital, when it was out of limits on at least 5 days
1	N	Resolved	Proc. QC miss.%	Processor QC records in the month of 08/2007 were missing for at least 30% of operating days, for processor PROCESSOR 1 [redacted] room [redacted]

Figure 4

**Updating MPRIS Web – Corrective Actions for Inspection Observations**

In the section entitled Compliance Information (section C of the Cover Page), it states that field personnel are responsible for updating MPRIS Web regarding corrective actions and correspondence for inspection observations (i.e., noncompliances). In Figure 4 above, one of the choices is Add Correspondence which provides districts with data on contacts to or from a facility (letters, phone calls, etc.). By clicking on Add Correspondence, users will pull up the screen shown in Figure 5 below.

**Add Correspondence**

An asterisk (\*) denotes a mandatory field

**Correspondence Details**

\*Sent Date: 05/22/2008  
 Received Date:  
 Reviewed Date:  
 \*Next Response Due Date: 07/12/2008

\*Initiator: FDA  
 \*Correspondence Type: Letter  
 \*Contact Person:

**Remarks**

Asked for most recent phantom QC chart

**Noncompliance List**

Noncompliance Code	Noncompliance Description	Level	*Related <input type="checkbox"/>	Resolved <input type="checkbox"/>
Ph. QC missing	Phantom QC records were missing for at least 4 weeks for unit 4, room Rm. 217	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ph. QC missing	Phantom QC records were missing for at least 4 weeks for unit 6, DMR+, room Rm 225	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Figure 5

For the typical inspection, the facility will send a letter to the district which provides sufficient documentation that the facility has corrected all of the noncompliances. In this case, the user:

- will enter the date of the letter under Sent Date
- choose “FAC” under Initiator of the letter (the facility)
- enter the Contact Person which may be the signer of the letter or the person indentified in the letter as the contact
- check off the Related and Resolved boxes at the top of these columns to indicate the letter relates to all of the noncompliances and that they have been corrected

You should select “Final Response” as the Correspondence Type. Since entering information into the Remarks block is mandatory, entering “Response adequate” should be sufficient.

For some inspections, FDA may need to contact the facility. In the example in Figure 5 above, the user has entered information on a letter the district sent requesting additional information. Since the related noncompliances aren’t resolved, the user has indicated that the noncompliances are related to the letter, but are still unresolved. The Correspondence Type choices include Letter, E-Mail, Fax, Telephone Call,

Warning Letter, Final Response, and Other. The Remarks field is mandatory so a short explanation of why additional contact was needed should be entered. For example, the user may enter correspondence data regarding a phone call to the facility and enter “Called facility since it failed to respond to the inspection observations”. Once the facility finally submits an adequate response to the district, this final communication should be entered as “Final Response”

### **Tracking resolution of noncompliances in MPRISweb**

DMQRP routinely monitors the resolution of inspection noncompliances by using the following MPRISweb reports:

- Noncompliance Response Pending Report
- Noncompliance Response Overdue Report

Noncompliances will show up in the pending report after upload and will show up in the overdue report after about seven weeks if no correspondence is entered for the inspection.

### **Time frames for closing out noncompliances**

Typically, the vast majority of inspections can be closed out after review of the initial response. In these cases, the only correspondence entered would be this initial response from the facility and the adequate response letter (see Attachment J of CP 7385.014).

In some cases, the facility fails to provide an adequate response or does not respond. In these cases, add additional correspondence information to MPRISweb regarding follow-up contacts to and from the facility. Where there are problems with the initial response, noncompliances may take longer than seven weeks to resolve. If correspondence data is entered, the next response due date is reset to prevent the inspection from showing up in the overdue report.

Based on our experience, only under unusual circumstances should noncompliances in MPRISweb remain unresolved more than 90 days after the inspection. While it is possible to reset the next response due date for inspections without entering additional correspondence information, we discourage that approach. If noncompliances cannot be resolved quickly, you should periodically enter correspondence data regarding contacts with the facility to indicate that you are actively working to resolve the noncompliances.

### **Inspections where further action is needed**

There may be situations where a facility is being considered for further action, such as a follow-up inspection or regulatory action. In these and similar cases, the situation has escalated to the point that the original noncompliances should be closed out. For these situations, you should:

1. enter correspondence data under Other
2. check on the Resolved block for the noncompliance(s)

3. enter an explanation in the Remarks section

Some examples for information in Remarks would be “Follow-up inspection planned for 6/5/2009,” “Recommendation for additional mammography review being prepared,” and “possible fraud at facility referred to OCI for investigation.”

### Locked inspections

When a facility has a new annual inspection and the previous inspection has unresolved noncompliances, the prior inspection will be locked against updates to these noncompliances. A locked inspection can only be unlocked by contacting MPRIS Computer Support at [computersupport@cdrh.fda.gov](mailto:computersupport@cdrh.fda.gov).

### Reports Tab

By clicking the Reports Tab, you can access a number of useful database reports. Below are some of the more useful reports to districts. These reports allow the user to view the report information online or export the information in either Acrobat PDF or Microsoft Excel formats.

- **Inspection History Report:** The Inspection History Report contains facility, inspector, inspection and noncompliance information for inspections of a specified facility or conducted by a specified inspector(s). In addition, users can view data for all inspections conducted in a state, region or nationwide, during the specified date range. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **Noncompliance Inspection Report:** This report lists all of the facilities issued a particular noncompliance.
- **Facility Count Report:** This report shows a count of certified facilities, grouped by certificate type and accreditation body.
- **Facility Expiration Warning Report:** This report provides a list of facilities with a certification expiration date that is 90 days, 120 days, 180 days or less from the date specified.
- **State Contract Scorecard Report:** This report provides data for negotiating annual inspection contracts with the States. Microsoft Excel is required to run this report.
- **State Inspection Contract Performance Monitor Report:** This report provides state contract information, number of facilities in each state, number of contract inspections completed contract year-to-date, and number of available facilities inspected contract year-to-date. Microsoft Excel is required to run this report.
- **Audit, Federal, and VHA Inspections Report:** This report lists all audit, federal, and VHA inspections. Microsoft Excel is required to run this report.
- **Elapsed Time between Inspections Report:** This report gives the elapsed time, in days, between the two most recent inspections for all facilities within the specified State or nationwide. CAUTION: This report can take a long time to run, especially for nationwide.
- **Facilities Not Inspected in the last Fourteen Months:** This report displays all new facilities that are overdue for inspection (exceeded 14 months since certification) but have never been

inspected, and or facilities that have had a previous inspection but not one in the 14 months since they became certified. By default, when selecting All Facilities, results are sorted first by region.

- **Inspection Summary Report:** This report provides the fiscal year to date numbers of certified facilities, inspections conducted, and inspectors by State and Region with inspection performance goals by State and a statistical summary of noncompliant facilities. Microsoft Excel is required to run this report.
- **Inspections by Selected Inspector(s) Report:** This report displays the inspection ID and date, facility name, city and state of all inspections conducted by the selected inspector(s) in a state, region or nationwide during the specified date range. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **VHA Facility Inspections Report:** This report gives a list of the Veterans Administration Hospital (VHA) facilities that were inspected during a specified date range.
- **Inspection History Report (FOIA):** The Inspection History Report (FOIA) contains facility, inspector, inspection and noncompliance information for inspections at a specified facility; inspections conducted by a specified inspector(s); or for all inspections conducted in a state, region or nationwide, during the specified date range. The data is produced in a pre-redacted format that can be released under the Freedom of Information Act. NOTE: This report can produce very large result sets and will take a long time to run if the search criteria are too large.
- **Level One and Level Two Status Report:** This report shows the current compliance status vis-à-vis correspondence with the FDA, for facilities who received level one or level two noncompliances within the date range specified.
- **Noncompliance Response Overdue Report:** This report consists of the facilities that have not responded to a noncompliance by the response due date. The report displays the facility ID and name, inspector ID, response due date, number of days overdue, level of noncompliance, and the noncompliance code.
- **Noncompliance Response Pending Report:** This report consists of the facilities that have not responded to a noncompliance. The report displays the facility ID and name, inspector ID, response due date, number of days overdue, level of noncompliance, and the noncompliance code.