

REQUEST FOR RECORDS DISPOSITION AUTHORITY <i>(See Instructions on reverse)</i>		LEAVE BLANK (NARA use only)	
TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		JOB NUMBER <i>71-088-06-1</i>	DATE RECEIVED <i>10-19-2005</i>
1. FROM (Agency or establishment) <i>Department of Health and Human Services</i>		NOTIFICATION TO AGENCY In accordance with the provisions of 44 U.S.C. 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
2. MAJOR SUBDIVISION Food and Drug Administration (FDA)			
3. MINOR SUBDIVISION Center for Device and Radiological Health (CDRH)			
4. NAME OF PERSON WITH WHOM TO CONFER Seung Ja Sinatra	5. TELEPHONE (301) 827-4274	DATE <i>7/27/06</i>	ARCHIVIST OF THE UNITED STATES <i>[Signature]</i>

6. AGENCY CERTIFICATION
I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal on the attached 3 page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO Manual for Guidance of Federal Agencies,

is not required;
 is attached; or
 has been requested.

DATE OCT 12 2005	SIGNATURE OF AGENCY REPRESENTATIVE <i>[Signature]</i> A. Prentice Barnes, Sr.	TITLE HHS Records Officer
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7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	<p>Unless specifically stated otherwise in the description or the retention, all items are media-neutral and apply to paper, electronic, microform, or other media in which records may exist.</p> <p>Mammography Program Records (see attached)</p> <p><i>[Signature]</i> Seung Ja Sinatra - FDA Records Officer</p> <p><i>[Signature]</i> Ann Wion - FDA Deputy Chief Counsel</p> <p><i>cc Agency, NR NWMW</i></p>		

Mammography Program Records

File Code Prefix = CDRH

Item No.	File Code	Records Description and Authorized Disposition	NARA Approved Citation
1	<u>5000</u>	<u>Mammography Program</u>	
1.1	5100	<u>Mammography Program Management Files.</u> Records include internal FDA policies and procedures regarding mammography facility accreditation denials and appeals, facility certification denials and appeals, and facility inspections and related regulatory procedures; accreditation bodies' (AB) applications including annual performance evaluations, reports of oversight visits, and accreditation fees; facility certificate extensions; Government entity audit records; applications by States to participate in the State-As-Certifiers (SAC) program; copies of Annual Reports to Congress and duplicate copies of Memorandum of Understanding (MOU). <u>Disposition: TEMPORARY.</u> Cutoff upon the final action or the incorporation into regulations. Destroy/delete 10 years after cutoff.	New
1.2	5200	<u>Mammography Program Reporting and Information System (MPRIS).</u> MPRIS is an integrated database management system that functions as a centralized repository of information regarding mammography facilities. Regulation of these facilities is mandated by the 1992 Mammography Quality Standards Act (MQSA) and the 1994 amendments, which established uniform national quality standards for mammography. It provides access to and tracks program activities, and produces reports based on predefined business rules. It is maintained by the Division of Mammography Quality and Radiation Programs (DMQRP), CDRH. The system contains confidential information and FOIA exemptions for public access apply.	
1.2.1	5210	<u>Input Records</u> Database records entered into MPRIS electronically via the inspector laptop software interface through an internal upload process. Records include findings, observations and notes related to the inspection process. <u>Disposition: TEMPORARY</u> Delete/Destroy upon successful upload and verification of data.	

1.2.2 5220 Accreditation, Certification, Inspections Records: MPRIS Database Records.
Records electronically entered without creating an input file include: Accreditation records entered by AB and FDA Headquarters personnel that include facility and unit accreditation information; Certification records electronically created by MPRIS in accordance with business rules; annual MQSA facility inspection records entered by FDA and State field inspectors, and facility inspection billing records.

Disposition: TEMPORARY.

Cutoff after the establishment is out of business or product is withdrawn or terminated. Delete 10 years after cutoff.

1.2.3 5230 ~~Inspector's Lap Top Inventory data: MPRIS Database Records.~~
~~Includes data on the inspector lap top inventory and system user accounts.~~

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Item 6a**

~~**Disposition: TEMPORARY.**~~

~~Destroy/delete inactive file 6 years after user account is terminated or password is altered, or when no longer needed for investigative or security purposes, whichever is later.~~

1.2.4 5240 Facility Score Card: MPRIS Output Records.
Includes statistical facility score cards on Web for external users to analyze trends in mammography facilities and industries.

Disposition: TEMPORARY.

Cutoff at end of calendar year. Delete 5 years after cutoff.

1.2.5 5250 Compliance Records: MPRIS Output Records.
Includes records on MQSA inspection observations and regulatory actions taken against MQSA facilities.

Disposition: TEMPORARY.

Cutoff upon the final action or the incorporation into regulations. Destroy/delete 10 years after cutoff.

1.2.6 5260 MPRIS Output Records: Reports. Status reports, ad-hoc reports and canned reports, generated as needed.

Examples include:

CMS weekly files are extracted for accreditation and certification data to be sent to Centers for Medicare and Medicaid Services (CMS). Apply disposition authorized for CMS;

FACTS (or its successor system) daily batch files are extracted for inspection data to be directly loaded onto FACTS (or its successor) maintained in ORA.
Apply disposition authorized under inspection records.

Disposition: TEMPORARY.

Delete/destroy when superseded or obsolete, or when no longer needed for administrative or reference purposes, whichever is sooner.

1.2.7 5270

~~**System Documentation.**~~

~~Includes systems operations manuals, user manuals, data dictionary, requirements documents, and other systems related materials.~~

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Item-11a**

~~**Disposition: TEMPORARY.**~~

~~Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or database, or upon the destruction of the output if the output is needed to protect legal rights, whichever is latest.~~

1.2.8 5280

~~**Backups.** Backups maintained for potential system restoration in the event of a system failure or other unintentional loss of data.~~

**GRS-24
Item-4a**

~~**Disposition: TEMPORARY.**~~

~~Delete/destroy incremental backups when superseded by a full backup, or when no longer needed for system restoration, whichever is later. Delete/destroy full backups when second subsequent back-up is verified as successful or when no longer needed for system restoration, whichever is later.~~

2

Electronic Mail and Word Processing System.

New

Electronic copies of records that are created on electronic mail and word processing systems and used solely to generate a recordkeeping copy of the records covered by the other items in this schedule. Also includes electronic copies of records created on electronic mail and word processing systems that are maintained for updating, revision, or dissemination.

2.1

Copies that have no further administrative value after the recordkeeping copy is made. Includes copies maintained by individuals in personal files, personal electronic mail directories, or other personal directories on hard disk or network drives, and copies on shared network drives that are used only to produce the recordkeeping copy.

Disposition: TEMPORARY: Destroy within 180 days after the recordkeeping copy has been produced.

2.2

Copies used for dissemination, revision, or updating that are maintained in addition to the recordkeeping copy.

Disposition: TEMPORARY: Destroy when dissemination,
revision, or updating is completed.