

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

5 U.S.C. 552a(k)(2). See 16 CFR 4.13(m). This exemption protects records compiled for law enforcement purposes and is intended to prevent unauthorized disclosure to a target of the complaint. The Commission reserves the right to afford, at its discretion, any individual with notification, access, and contesting procedures under the Commission's rules (16 CFR 4.13) with regard to information entered or otherwise submitted by that individual into the system.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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BILLING CODE 6750-01-P

## **GENERAL SERVICES ADMINISTRATION**

### **Notice of Intent to Prepare an EIS; MA**

The General Services Administration (GSA) intends to prepare an Environmental Impact Statement (EIS) on the following project:

#### **New Federal Courthouse, Springfield, Hampden County, Massachusetts**

The GSA will serve as lead agency and project sponsor in the preparation and filing of an EIS. The proposed action would involve the construction and operation of a new courthouse in Springfield, Massachusetts. Space and security constraints in the existing Federal Court facilities located in the Federal Building at 1550 Main Street, Springfield have caused the Court to seek relocation to a new building that would supply the required space, security, and facilities to accommodate the Court's current and projected caseload. This action is intended to provide approximately 140,000 occupiable square feet (13,000 square meters) of space for the various operations of the Federal Court and related agencies.

The EIS will evaluate a No-Action alternative and a Build alternative involving a preferred site on State Street between Elliot Street and Spring Street in Springfield, Massachusetts. It will also evaluate impacts on the affected environment, including, but not limited to, socioeconomic, hazardous materials, traffic/transportation, land use, urban design/neighborhood character, historic/cultural resources, noise, air quality, environmental justice, and cumulative impacts.

### **Public Scoping Meeting**

To ensure that all issues relating to the proposed project are identified and all potentially significant issues are addressed and satisfied in the EIS, public comments and suggestions are being solicited. To facilitate the receipt of comments, two public Scoping Meetings will be held in Springfield on Monday, November 15, 1999. The first will be held from 3 PM to 5 PM on the fifth floor of the Federal Building, 1550 Main Street, and the second will be from 6 PM to 8 PM on the second floor of the City Hall, 36 Court Street. Public comment concerning the scope of the EIS will be taken at these meetings.

#### **FOR FURTHER INFORMATION CONTACT:**

Kevin J. Richards, Asset Manager, U.S. General Service Administration, Portfolio Management Division (1 PT), 10 Causeway Street, 9th Floor, Boston, MA 02222-1077, Tel: (617) 565-5845, Fax: (617) 565-8650, E-mail: Kevin.Richards@gsa.gov.

Written comments may be mailed to the informational contact person no later than December 3, 1999.

Issued in Boston, Massachusetts on October 20, 1999.

**George Klueber,**

*Portfolio Manager, General Service Administration, Region 1.*

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## **GENERAL SERVICES ADMINISTRATION**

### **[GSA Bulletin FPMR H-78]**

#### **Utilization and Disposal**

**AGENCY:** Office of Governmentwide Policy, GSA.

**ACTION:** Notice of bulletin.

**SUMMARY:** The attached bulletin provides revised information for Federal agencies on the disposal of excess biomedical equipment and IT equipment with potential Y2K defects.

#### **FOR FURTHER INFORMATION CONTACT:**

Martha Caswell, Personal Property Management Policy Division, Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone (202) 501-3846; e-mail martha.caswell@gsa.gov.

#### **GSA Bulletin FPMR H-78 Utilization and Proposal**

**TO:** Heads of Federal agencies

**SUBJECT:** Disposal of Year 2000 (Y2K) Noncompliant Biomedical Equipment and Information Technology (IT) Equipment

1. *What is the purpose of this bulletin?* To provide revised information for Federal agencies on the disposal of excess biomedical and IT equipment with potential Y2K defects.

2. *When does this bulletin expire?*

This bulletin contains information of a continuing nature and will remain in effect until canceled or revised.

3. *What is the background?* The Y2K technology problem concerns computers, computer chips, and software that may not properly recognize or process dates after December 31, 1999. In addition, there are other specific dates that may be troublesome, such as February 29, 2000. This problem may affect the normal operation of biomedical equipment and information technology (IT) equipment. In biomedical equipment used in direct patient treatment, the monitoring of vital patient parameters, or used to support or sustain life, the Y2K problem may present a potential risk to public health and safety if not corrected. In those situations, biomedical device failure could injure the patient or compromise effective patient treatment. In response to this potential risk, GSA is providing guidance to Federal agencies on the disposal of such equipment when it becomes excess to their needs.

4. *What does this bulletin cover?* This bulletin applies to (1) all excess biomedical equipment, and (2) all excess IT equipment.

5. *Biomedical equipment.* a. *Where can I find information about the Y2K status and potential risks posed by biomedical equipment?* Federal agencies should consult the Food and Drug Administration's (FDA's) website at <http://www.fda.gov> for general Y2K information on biomedical equipment. Federal agencies can find more specific information provided by manufacturers of biomedical equipment in the Federal Y2K Biomedical Equipment Clearinghouse (Y2K Clearinghouse) located at <http://www.fda.gov/cdrh/yr2000/year2000/html>. Federal agencies can also access the Y2K Clearinghouse through the FDA website's Year 2000 link.

b. *How can I determine the Y2K status of the biomedical equipment?* Information provided by the original manufacturer is the best source for determining the Y2K status of the biomedical equipment under consideration.

c. *Where can I find manufacturer information?* Please consult the FDA Y2K Clearinghouse website or contact the manufacturer directly.

d. *How do I use Y2K information when disposing of excess biomedical*

equipment? Use the manufacturer's information, with the assistance of your biomedical engineers/technicians, to determine the Y2K status of equipment and label the biomedical equipment as:

- (1) Y2K compliant;
- (2) Y2K noncompliant; or
- (3) Y2K status unknown.

6. *How do I dispose of biomedical equipment that is Y2K compliant?* If Y2K compliant, identify excess biomedical equipment as "Y2K compliant" on the equipment itself and on the excess reporting document (SF 120). Dispose of such equipment through normal disposal procedures described in FPMR 101-43.3, 101-44.2, and 101-45.3. Federal agencies obtaining excess Y2K compliant biomedical equipment must reflect the "Y2K compliant" status on all inventory control documentation pertaining to such equipment.

7. *Y2K noncompliant biomedical equipment.* a. *What should I consider before I dispose of biomedical equipment that is not Y2K compliant?* Before you proceed with disposal, consider two questions: First, what is the potential risk posed by the equipment? And second, does the equipment meet the criterion for "extremely hazardous" property" as defined in paragraph 7.c.?

b. *How can I determine what types of Y2K noncompliant biomedical equipment pose the greatest potential risk?* Use the information found under "Computer-Controlled Potentially High-Risk Medical Devices" on the FDA website to help you identify biomedical equipment having the greatest potential for presenting a risk to patients if used with an uncorrected date problem.

**Note:** The FDA website is not all-inclusive. See paragraph 7.e. for the disposal of Y2K noncompliant biomedical equipment not mentioned on the "Computer-Controlled Potentially High-Risk Medical Devices" list.

c. *What is "extremely hazardous" biomedical equipment?* "Extremely hazardous," in this instance, is Y2K noncompliant biomedical equipment that is judged by the holding agency to pose a potential risk by endangering public health or safety, or the environment, if not rendered harmless (i.e., made Y2K compliant) before being used by other agencies or released outside the Government.

d. *How do I dispose of Y2K noncompliant biomedical equipment that I judge to be "extremely hazardous?"* If not made Y2K compliant, you must destroy Y2K noncompliant biomedical equipment that is extremely hazardous to render it innocuous, in accordance with FPMR

101-45.902-2(a)(2). Destruction means the rendering of biomedical equipment completely inoperable for its intended purpose. Actions such as cutting, tearing, crushing, breaking, burning, etc. will accomplish rendering inoperable.

e. *Do I need to be concerned about Y2K noncompliant biomedical equipment not mentioned under "Computer-Controlled Potentially High-Risk Medical Devices?"* Yes. Evaluate other Y2K noncompliant biomedical equipment for associated risks. Using the manufacturer's information, and with assistance from your biomedical engineers/technicians, assess whether or not the equipment, if used without a modification to address the date problem, will endanger public health or safety, or the environment (i.e., can be deemed "extremely hazardous"). If judged to be "extremely hazardous," dispose of in accordance with paragraph 7.d.

f. *What if I judge the Y2K noncompliant biomedical equipment, of any type, to be non-hazardous?* You must identify it as "Y2K noncompliant" on the equipment itself and on the excess reporting document (SF 120) and dispose of it through normal disposal procedures described in FPMR 102-43.3, 102-44.2 and 101-45.3. Federal agencies obtaining excess Y2K noncompliant biomedical equipment must reflect the "Y2K noncompliant" status on all inventory control documentation pertaining to such equipment.

8. *How do I dispose of biomedical equipment when the Y2K status is unknown?* You may not transfer excess biomedical equipment when the Y2K status cannot be determined. If the Y2K status cannot be determined, the holding agency must destroy the equipment in accordance with FPMR 101-45.902-2(a)(2).

9. *IT equipment.* a. *How do I define "IT" equipment?* "IT" is any equipment or interconnected system or subsystem of equipment that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information.

b. *Do I also report the status of IT equipment?* Yes, all IT equipment must also be identified by the holding agency as Y2K compliant, Y2K noncompliant, or Y2K status unknown. The Y2K status must be visible on the equipment and all excess reporting documents.

c. *What disposal procedures do I following for IT equipment?* IT equipment, of any status, will be disposed of through normal disposal

procedures as described in FPMR 101-43.3, 101-44.2 and 101-45.3.

10. *Whom should I contact for further information?* Martha Caswell, Personal Property Management Policy Division, Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone (202) 501-3846; e-mail martha.caswell@gsa.gov.

11. *Cancellation.* FPMR Bulletin H-76 dated August 4, 1999, is canceled.

Dated: October 21, 1999.

**G. Martin Wagner,**

*Associate Administrator for Governmentwide Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99N-1392]

#### Agency Information Collection Activities; Announcement of OMB Approval; State Enforcement Notification

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "State Enforcement Notification" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 24, 1999 (64 FR 46204), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0275. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.