

repair medical devices (hereafter termed “third-party entity or entities”), including radiation-emitting devices subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Comments on the service, maintenance, refurbishment, and alteration of medical devices, by third-party entities as well as challenges third-party entities face in maintaining or restoring devices to their original or current specifications will inform FDA when we hold a public meeting later in 2016 to further engage this segment of the device industry and healthcare community.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful response to the document on “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.”

FDA has considered the requests and is extending the comment period for the document on “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers” for 30 days, until June 3, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying future workshop on these important issues.

Dated: April 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-09443 Filed 4-22-16; 8:45 am]

**BILLING CODE 4164-01-P**

## OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

### 32 CFR Part 1704

#### Mandatory Declassification Review Program

**AGENCY:** Office of the Director of National Intelligence.

**ACTION:** Proposed rule.

**SUMMARY:** The Office of the Director of National Intelligence (ODNI) is publishing this proposed rule pursuant to Executive Order 13526, relating to classified national security information. It provides procedures for members of

the public to request from ODNI a Mandatory Declassification Review (MDR) of information classified under the provisions of Executive Order 13526 or predecessor orders such that the agency may retrieve it with reasonable effort. This rule also informs requesters where to send requests for an MDR.

**DATES:** Submit comments on or before May 25, 2016.

**ADDRESSES:** You may submit comments by any of the following methods: By mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511, by facsimile at (703) 874-8910, or by email at [dni-FOIA@dni.gov](mailto:dni-FOIA@dni.gov).

**FOR FURTHER INFORMATION CONTACT:** Jennifer L. Hudson, 703-874-8085.

**SUPPLEMENTARY INFORMATION:** It is the policy of the ODNI to act in matters relating to national security information in accordance with Executive Order 13526 and directives issued thereunder by the Information Security Oversight Office (ISOO). The purpose of this rule is to assist in implementing specific sections of Executive Order 13526 concerning the Mandatory Declassification Review (MDR).

#### Regulatory Impact

This proposed rule is not a significant regulatory action for the purposes of Executive Order 12866. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, we certify that this proposed rule will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies.

#### List of Subjects in 32 CFR Part 1704

Declassification, Information, Intelligence, National security information.

■ For the reasons set forth in the preamble, ODNI proposes to add 32 CFR part 1704 to read as follows:

#### PART 1704—MANDATORY DECLASSIFICATION REVIEW PROGRAM

Sec.

1704.1 Authority and purpose.

1704.2 Definitions.

1704.3 Contact information.

1704.4 MDR program feedback.

1704.5 Guidance.

1704.6 Exceptions.

1704.7 Requirements.

1704.8 Fees.

1704.9 Determination by originator or interested party.

1704.10 Appeals.

**Authority:** 50 U.S.C. 3001; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp. p. 298.

#### § 1704.1 Authority and purpose.

(a) *Authority.* This part is issued under the authority of 32 CFR 2001.33; Section 3.5 of Executive Order 13526 (or successor Orders); the National Security Act of 1947, as amended (50 U.S.C. 3001 *et seq.*).

(b) *Purpose.* This part prescribes procedures, subject to limitations set forth below, for requesters to request a mandatory declassification review of information classified under Executive Order 13526 or predecessor or successor orders. Section 3.5 of Executive Order 13526 and these regulations are not intended to and do not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers, employees, or agents, or any other person.

#### § 1704.2 Definitions.

For purposes of this part:

*Control* means the authority of the agency that originates information, or its successor in function, to regulate access to the information. (32 CFR 2001.92)

*Day* means U.S. Federal Government working day, which excludes Saturdays, Sundays, and federal holidays. Three (3) days may be added to any time limit imposed on a requester by this part if responding by U.S. domestic mail; ten (10) days may be added if responding by international mail.

*D/IMD* means the Director of the Information Management Division and the leader of any successor organization, who serves as the ODNI's manager of the information review and release program.

*Federal agency* means any *Executive agency*, as defined in 5 U.S.C. 105; any *Military department*, as defined in 5 U.S.C. 102; and any other entity within the executive branch that comes into the possession of classified information.

*Information* means any knowledge that can be communicated or documentary material, regardless of its physical form that is owned by, produced by or for, or under the control of the U.S. Government; it does not include information originated by the incumbent President, White House Staff, appointed committees, commissions or boards, or any entities within the Executive Office that solely advise and assist the incumbent President.

*Interested party* means any official in the executive, military, congressional, or judicial branches of government, or U.S. Government contractor who, in the sole discretion of the ODNI, has a subject

matter or other interest in the documents or information at issue.

*NARA* means the National Archives and Records Administration.

*ODNI* means the Office of the Director of National Intelligence.

*Order* means Executive Order 13526, "Classified National Security Information" (December 29, 2009) or successor Orders.

*Originating element* means the element that created the information at issue.

*Presidential libraries* means the libraries or collection authorities established under the Presidential Libraries Act (44 U.S.C. 2112) and similar institutions or authorities as may be established in the future.

*Referral* means coordination with or transfer of action to an interested party.

*Requester* means any person or organization submitting an MDR request.

#### **§ 1704.3 Contact information.**

For general information on the regulation in this part or to submit a request for a Mandatory Declassification Review (MDR), please direct your communication by mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511; by facsimile to (703) 874-8910; or by email to [DNI-FOIA@dni.gov](mailto:DNI-FOIA@dni.gov). For general information on the ODNI MDR program or status information on pending MDR cases, call (703) 874-8500.

#### **§ 1704.4 Suggestions or comments.**

The ODNI welcomes suggestions for improving the administration of our MDR program in accordance with Executive Order 13526. Suggestions should identify the specific purpose and the items for consideration. The ODNI

will respond to all communications and take such actions as determined feasible and appropriate.

#### **§ 1704.5 Guidance.**

Address all communications to the point of contact as specified in § 1704.3. Clearly describe, list, or label said communication as an MDR Request.

#### **§ 1704.6 Exceptions.**

MDR requests will not be accepted from a foreign government entity or any representative thereof. MDR requests will not be accepted for documents required to be submitted for pre-publication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information contained within an operational file exempted from search and review, publication, and disclosure under the FOIA. If the ODNI has reviewed the requested information for declassification within the past two years, the ODNI will not conduct another review, but the D/IMD will notify the requester of this fact and the prior review decision. Requests will not be accepted from requesters who have outstanding fees for MDR or Freedom of Information Act (FOIA) requests with the ODNI or another federal agency.

#### **§ 1704.7 Requirements.**

An MDR request shall describe the document or material containing the information with sufficient specificity to enable the ODNI to locate it with a reasonable amount of effort.

#### **§ 1704.8 Fees.**

(a) *In general.* Any search, review, and reproduction fees will be charged in

accordance with the provisions below relating to schedule, limitations, and category of requester. Applicable fees will be due even if a subsequent search locates no responsive records.

(b) *Agency discretion to waive fees.* Records will be furnished without charge or at a reduced rate when ODNI determines:

(1) As a matter of administrative discretion, the interest of the United States Government would be served, or

(2) It is in the public interest to provide responsive records because the disclosure is likely to contribute significantly to the public understanding of the operations or activities of the United States Government and is not primarily in the commercial interest of the requester.

(c) *Agreement to pay fees.* If you request an MDR, it shall be considered a firm commitment by you to pay all applicable fees chargeable under this regulation, up to and including the amount of \$25.00. When making a request, you may specify a willingness to pay a greater or lesser amount.

(d) *Advance payment.* The ODNI may require an advance payment of up to 100 percent of the estimated fees when projected fees exceed \$250.00, not including charges associated with the first 100 pages of production and two hours of search (when applicable), or when the requester previously failed to pay fees in a timely fashion, for fees of any amount. ODNI will hold in abeyance for 45 days those requests where advance payment has been requested.

(e) *Schedule of fees—(1) In general.* The schedule of fees for services performed in responding to requests for records is as follows:

#### **Personnel Search and Review**

Clerical/Technical .....	Quarter Hour .....	\$ 5.00
Professional/Supervisory .....	Quarter Hour .....	10.00
Manager/Senior Professional .....	Quarter Hour .....	18.00

#### **Computer Search and Production**

Search (on-line) .....	Flat Rate .....	10.00
Search (off-line) .....	Flat Rate .....	30.00
Other activity .....	Per minute .....	10.00
Tapes (mainframe cassette) .....	Each .....	9.00
Tapes (mainframe cartridge) .....	Each .....	9.00
Tapes (mainframe reel) .....	Each .....	20.00
Tapes (PC 9mm) .....	Each .....	25.00
Diskette (3.5") .....	Each .....	4.00
CD (bulk recorded) .....	Each .....	10.00
CD (recordable) .....	Each .....	20.00
Telecommunications .....	Per minute .....	.50
Paper (mainframe printer) .....	Per page .....	.10
Paper (PC b&w laser printer) .....	Per page .....	.10
Paper (PC color printer) .....	Per page .....	1.00

## Paper Production

Photocopy (standard or legal) .....	Per page .....	.10
Pre-printed (if available) .....	Per 100 pages .....	5.00
Published (if available) .....	Per item .....	NTIS

(2) *Application of schedule.* Personnel search time includes time expended in manual paper records searches, indices searches, review of computer search results for relevance, and personal computer system searches. In any event where the actual cost to ODNI of a particular item is less than the above schedule (e.g., a large production run of a document resulting in a cost less than \$5.00 per hundred pages), then the actual lesser cost will be charged.

(3) *Other services.* For all other types of output, production, or reproduction (e.g., photographs, maps, or published reports), ODNI will charge actual cost or amounts authorized by statute. Determinations of actual cost shall include the commercial cost of the media, the personnel time expended in making the item to be released, and an allocated cost of the equipment used in making the item, or, if the production is effected by a commercial service, then that charge shall be deemed the actual cost for purposes of this regulation.

(f) *Limitations on collection of fees—*  
(1) *In general.* No fees will be charged if the cost of collecting the fee is equal to or greater than the fee itself. That cost includes the administrative costs to ODNI of billing, receiving, recording, and processing the fee for deposit to the Treasury Department and, as of the date of these regulations, is deemed to be \$10.00.

(g) *Associated requests.* If it appears a requester or a group of requesters acting in concert have requested portions of an apparently unitary request for the purpose of avoiding the assessment of fees, ODNI may aggregate any such requests and charge accordingly. Requests from multiple requesters will not be aggregated without clear evidence. ODNI will not aggregate multiple unrelated requests.

#### **§ 1704.9 Determination by originator or interested party.**

(a) *In general.* The originating element(s) of the classified information (document) is always an interested party to any mandatory declassification review; other interested parties may become involved through a referral by the D/IMD when it is determined that some or all of the information is also within their official cognizance.

(b) *Required determinations.* These parties shall respond in writing to the D/IMD with a finding as to the classified

status of the information, including the category of protected information as set forth in section 1.4 of the Order, and if older than ten years, the basis for the extension of classification time under sections 1.5 and 3.3 of the Order. These parties shall also indicate whether withholding is otherwise authorized and warranted in accordance with sections 3.5(c) and 6.2(d) of the Order.

(c) *Time.* Responses to the requester shall be provided on a first-in/first-out basis, taking into account the business requirements of the originating element(s) and other interested parties, and, in accordance with Executive Order 13526, ODNI will respond to requesters within one year of receipt of requests.

(d) *Deciding official.* The IMD FOIA Branch Chief, in consultation with the D/IMD and the Classification Management Branch Chief, will ordinarily be the deciding official on initial reviews of MDR requests to the ODNI.

#### **§ 1704.10 Appeals.**

(a) *Administrative.* Appeals of initial decisions must be received in writing by the D/IMD within 60 days of the date of mailing of the ODNI's decision. The appeal must identify with specificity the documents or information to be considered on appeal and it may but need not provide a factual or legal basis for the appeal.

(1) *Exceptions.* No appeal shall be accepted from a foreign government entity or any representative thereof. Appeals will not be accepted for documents required to be submitted for pre-publication review or other administrative process pursuant to an approved nondisclosure agreement; for information that is the subject of pending litigation; nor for any document or material containing information contained within an operational file exempted from search and review, publication, and disclosure under the FOIA. No appeals shall be accepted if the requester has outstanding fees for information services at ODNI or another Federal agency. In addition, no appeal shall be accepted if the information in question has been the subject of a declassification review within the previous two years.

(2) *Receipt, recording, and tasking.* The D/IMD will record each appeal

received under this part and acknowledge receipt to the requester.

(3) *Appellate authority.* The ODNI Chief Management Officer (CMO), after consultation with all interested parties or ODNI component organization as well as with the Office of General Counsel, will make a final determination on the appeal within 60 days.

(b) *Final appeal.* The D/IMD will prepare and communicate the ODNI administrative appeal decision to the requester, NARA, Presidential Library and referring agency, as appropriate. Correspondence will include a notice, if applicable, that a further appeal of ODNI's final decision may be made to the Interagency Security Classification Appeals Panel (ISCAP) established pursuant to section 5.3 of Executive Order 13526. Action by that Panel will be the subject of rules to be promulgated by the Information Security Oversight Office.

Dated: April 12, 2016.

**Mark W. Ewing,**

*Chief Management Officer.*

[FR Doc. 2016-09251 Filed 4-22-16; 8:45 am]

**BILLING CODE 9500-01-P**

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 174 and 180**

**[EPA-HQ-OPP-2015-0032; FRL-9944-86]**

### **Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of filing of petitions and request for comment.

**SUMMARY:** This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

**DATES:** Comments must be received on or before May 25, 2016.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the