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Date Posted: 03/30/2018

CHAPTER 74 MANAGING LABORATORY STOCKPILES AND SPECIAL PROGRAMS

7401 MANUFACTURING AND DISPOSING OF CONTROLLED SUBSTANCES FOR TRAINING OR FOR RESEARCH PURPOSES

The Laboratory Director (LD):

A. Authorizes laboratory personnel to manufacture controlled substances for any lawful purpose as authorized in Title 21 of the *Code of Federal Regulations*, Section 1301.24.

B. Ensures transfer of manufactured controlled substances into a stockpile (see 7403), or disposal (see 7401.3).

C. Ensures disposal of hazardous waste generated from such manufacture (see Laboratory Operations Manual (LOM) Chapter 78).

NOTE: Exhibit 1/7401 lists acronyms used in this subchapter.

7401.1 Requesting Approval to Manufacture Controlled Substances.

A. The LD approves requests to manufacture a controlled substance. This approval may not be delegated, and the Research Coordinator (RC) must obtain approval prior to the manufacture.

B. The RC requests approval to manufacture a controlled substance by a memorandum to the LD directed through the chemist's chain of command. The memorandum must include:

1. Purpose for the manufacture (e.g., reference material, training, etc.).
2. Person(s) manufacturing the substance(s).
3. Controlled substance(s) to be manufactured.
4. Approximate amount of the controlled substance(s) to be manufactured.
5. Estimated amount of (solvents, reagents, etc.) required for the manufacture.
6. Estimated amount of hazardous waste to be generated.
7. If intended for a stockpile, name of the stockpile and the person to whom the substance will be transferred.

C. The memorandum must include an area for the manufacturer and a witness to record specifics of the manufacture (see 7401.2A) REDACTED.

7401.2 Recording the Manufacture of Controlled Substances.

A. The RC records the manufacture on the request memorandum that documents:

1. Amount of controlled substance(s) manufactured.
2. Amount of hazardous waste generated.
3. Signatures of the witnesses of the manufacture.

B. At least two DEA employees witness the manufacture of a controlled substance, one of which must be the manufacturer.

7401.3 Disposing or Transferring Manufactured Controlled Substances.

A. The RC ensures the material will be transferred into a reference collection REDACTED.

B. The RC coordinates the transfer of the materials to a stockpile/collection (see 7403.1) REDACTED.

1. For manufactured substance transfer to a stockpile (see 7403), the manufacturing chemist will:
   a. Transfer the material to the stockpile/collection coordinator on a DEA-12.
   b. Provide a copy of the request to manufacture memorandum and a copy of the DEA-12 to the stockpile/collection coordinator and to the RC.
2. REDACTED:
   a. REDACTED.
   b. REDACTED.

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7401.4 Maintaining Records on the Manufacture of Controlled Substances.

A. The RC creates a file for each request memorandum that documents the manufacture REDACTED of controlled substances.

B. Each file includes the following:

1. Request memorandum documenting the manufacture and the LD's written approval.
2. DEA-12s documenting the transfer of controlled substances or hazardous waste.
3. REDACTED.
4. REDACTED.

C. REDACTED, the RC maintains the file for two years.

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7403 CREATING LABORATORY STOCKPILES AND OTHER NON-EVIDENTIARY ITEMS

NOTE: Exhibit 1/7403 lists acronyms used in this subchapter.

7403.1 Authorizing Laboratory Stockpiles.

A. SF DAA authorizes LDs to maintain stockpiles/collections of controlled substances in the following programs (see 7306.D):

1. Reference Materials, including controlled and non-controlled substances (see 7404.4).
2. Training Materials (see 7404.5).
3. REDACTED.

B. SF DAA authorizes the SFL1 LD to also maintain collections of controlled substances in the following stockpiles:

1. REDACTED.
2. Research Reference Collections (see 7404.7).
3. REDACTED.

C. SF DAA authorizes the LD in a regional laboratory to maintain a research collection containing controlled substance(s), if associated with approved special studies.

D. REDACTED.

E. The SF DAA approves the retention of evidence for historical purposes (see 7404.73).

F. LDs designate PCs and alternate coordinators to manage laboratory stockpiles, and to ensure compliance with the policies stated in 7403, 7404, REDACTED.

7403.2 Creating Laboratory Stockpiles.

A. The PC and DC may retain evidence. Follows PRO-7403.2A, Converting Evidence to Laboratory Program Stockpiles.

B. PCs track the material, received in a stockpile in accordance with 7404 and REDACTED.

NOTE: Additional program-specific requirements are listed in 7404 and REDACTED.

C. Based upon program needs, the PC reviews DEA-48s and LIMS records to determine exhibits suitable for inclusion in program stockpiles.

D. The PC requests retention of evidentiary materials from the LD. The request memorandum must specify:

1. The IA case number, IA exhibit number, LIMS case number, and lab exhibit number of the exhibit to be retained.

2. The amount to be retained.
3. The retention purpose or name of the stockpile where the material will be incorporated.

E. REDACTED.

REDACTED.

F. If the materials are in a different laboratory, the LD in the requesting laboratory requests the material from the custodial laboratory. Once approved, the custodial laboratory provides the materials. Follow PRO-7403.2F, Providing Stockpile Materials to Another Laboratory.

7404 MAINTAINING LABORATORY STOCKPILES AND OTHER NON-EVIDENTIARY ITEMS

A. PCs track stockpile items in a logbook. The logbook must contain the following:

1. IA case number and laboratory exhibit number.
2. Date transferred into the stockpile.
3. Program identifier (see 7403.2K).
4. Description of the material.
5. Original weight of material.
6. Current balance of material (weight or count).
7. Dates and amounts of transactions affecting the current weight.

EXCEPTION 1: Items 1 and 2 above do not apply to Reference Materials.

REDACTED.

REDACTED.

B. PCs maintain individual files for each stockpile item. The files must contain the following:

1. REDACTED.
2. Records of requests for materials (memoranda/teletypes).
3. DEA-12s used to distribute materials.
4. REDACTED.

EXCEPTION 1: Items 1 and 2 above do not apply to Reference Materials.

REDACTED.

C. PCs ensure that the amount of materials on-hand in a stockpile is accurately documented in the logbook.

D. If a laboratory needs to exceed the maximum storage limit for a particular stockpile item, the LD requests an exemption from SF DAA. The PC will maintain exemption documentation in the individual file if SF DAA grants an exemption.

NOTE: Exhibit 1/7404 lists acronyms used in this subchapter.

7404.1 Storing Stockpiles.

A. PCs maintain stockpile materials in a locked container within the in-process or main vault.

B. The LD limits access to the locked containers containing stockpile material to the coordinator, alternate coordinator, and a laboratory manager.

REDACTED.

NOTE: Information regarding quantity and composition of reference materials will be shared within the laboratory, and with other DEA laboratories.

7404.2 Recording Transactions Involving Stockpile Materials.

A. PCs transfer stockpile materials using a DEA-12.

EXCEPTION: 7404.2A does not apply to working amounts of reference materials.

B. The PC and receiver sign the DEA-12.

C. The PC files the DEA-12 in the individual file for that stockpile item.

REDACTED.

D. The PC records transactions of stockpile materials in the logbook to indicate the date of the transaction, the quantity removed/added, and the amount of drug remaining. Also, if transferred, the logbook must specify the recipient and reason for the transfer.

7404.3 Accounting for Stockpile Materials/Items.

A. The LD conducts an inventory of each stockpile in January of each year.

B. Unless it coincides with the annual inventory in January, the LD also ensures the completion of an inventory of the stockpile within 30 calendar days if a person with access to the stockpile transfers to another office, leaves the agency, or otherwise no longer requires access.

C. A supervisor and one other individual (without access to the stockpile) inventories the stockpiles and reconciles the items against the logbook and other program records. Follows PRO-7404.3C, Conducting an Inventory of Stockpile Items.

D. The supervisor determines the weight of material in each stockpile item during the inventory.

REDACTED.

NOTE: Proficiency samples (see 7403.12) and training samples (see 7403.13) will be accounted for in the evidence inventory (see 7304).

E. The supervisor conducting the inventory immediately investigates inventory discrepancies and reports discrepancies that cannot be immediately resolved to the LD.

F. LDs report discrepancies that cannot be immediately resolved to the Office of Professional Responsibility (OPR) and SF.

G. LDs report stockpile inventory completion to SF within 30 days of completing the inventory.

H. Upon completion of an inventory of research material stockpile or reference material stockpile, the LD also reports the following:

1. Quantity of each drug consumed since the last inventory.
2. Amount of each drug remaining.
3. Identity of drugs added, consumed or disposed of since the last inventory.

REDACTED.

7404.4 Handling Reference Materials.

A. The Reference Materials Coordinator (RMC) oversees the creation and management of reference materials, in accordance with ADM.

B. Reference material stockpiles may contain a maximum of:

1. REDACTED per drug type/drug salt form, if controlled.
2. REDACTED per drug type/drug salt form, if not controlled.

C. SFL1 RMC responds to requests for and distributes material from the Reference Material Stockpile. Follows PRO-7404.4D, Providing Reference Materials to Forensic Laboratories.

D. The SFL1 reference material stockpile may contain a maximum of:

1. REDACTED per drug type/drug salt form, if controlled.
2. REDACTED per drug type/drug salt form, if not controlled.

7404.5 Handling Training Materials.

A. The laboratory's training officer (TO) oversees the creation and management of training materials, in accordance with 7403 and 7404.

B. The TO uses training materials to:

1. Create training samples (see 7403.1A and 7404.9),
2. Conduct other types of training (e.g., field test training), or
3. Create proficiency samples (see 7403.1A and 7404.8).

C. Training stockpiles will contain a maximum of REDACTED per drug type/drug salt form.

EXCEPTION: This limit does not apply to the Office of Forensic Sciences Forensic Science Instruction Section (SFT).

D. The TO records sub-stockpile items, if created separately from the source material.

NOTE: Sub-stockpiles may be created by dilution with an adulterant or diluent.

E. The TO coordinates providing materials to SFT upon request. (See PRO-7403.2F, Providing Stockpile Materials to Another Laboratory.)

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7404.7 Managing Material in Research Reference Collections.

A. The LD maintains a Research Reference Collection of controlled substances and other materials needed to accomplish the research mission of the laboratory.

NOTE: The Research Reference Collection will not generally contain materials that meet criteria for inclusion in the Reference Materials stockpile (see 7403.1A1, 7404.4, and ADM).

B. Examples of materials properly included in Research Reference Collections are:

1. Precursors that are themselves controlled, that are needed for the synthesis of controlled substances for research.
2. Mixtures, impure materials, or crude natural products.

C. Research Reference Collection Stockpiles may contain a maximum of:

1. REDACTED per drug type/drug salt form, if controlled.
2. REDACTED per drug type/drug salt form, if not controlled.

D. Research chemists at SFL1 perform the duties assigned to the PC in 7403 and 7404. The RC in other laboratories performs the duties assigned to the PC in 7403 and 7404.

E. The research chemist or RC stores the collection and primary records (see 7403.2D, 7404.A, and 7404.B) relevant to the collection in a portion of the laboratory in-process vault accessible only to laboratory managers, research chemists, and/or the laboratory's RC.

F. SFL1 tracks and inventories the Research Reference Collections through a database. The RC in other laboratories tracks the collections in a logbook and individual files (see 7404.A and 7404.B).

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7404.73 Retaining Evidence of Historical Interest.

A. If any evidence (including drug material, paraphernalia, and drug manufacturing equipment) is of historical interest, of value for training purposes, or is otherwise useful to the laboratory, the SFL1 LD submits a written request to the SF DAA.

B. The SFL1 LD ensures that drug material is transferred to and retained in the laboratory in an existing research reference collection.

C. If the evidence is not drug material, the SFL1 LD first offers the item to the DEA museum before offering the item to another unit in DEA, or offers it to another federal agency for either training or display.

D. The removed items or drug material may not be transferred to any individual for personal use.

E. Before the item/material is transferred, the LD ensures that SF authorized the retention of the item/material.

F. If the retention requires a transfer between DEA laboratories:

1. The sending laboratory will create a RES container and transfer the item/material, in accordance with 7305.26. Once transferred, the container will be marked permanently offsite.

NOTE: A LIMS RES container code is used to identify items to be used in Research and Special Studies.

2. The receiving laboratory receives the item directly into the approved collection (see 7403.2). Once received, the PC signs and returns the DEA-12 to the sending laboratory.

7404.8 Managing Proficiency Samples.

A. The Proficiency Testing Program (PTP) Coordinator will oversee the creation and management of Internal Proficiency Testing Program (IPTP) and PTP samples, in accordance with ADM.

B. If the material for the proficiency sample is removed from evidence, the PTP Coordinator:

1. Obtains written approval from the LD (see 7403.1).
2. REDACTED.
3. Receives the evidence containers from evidence staff in LIMS.
4. With a witness, removes the materials from the evidence container(s).
5. Creates the IPTP/PTP samples, in accordance with ADM.
6. Creates the records, in accordance with ADM.
7. Transfers the samples to the evidence staff on a DEA-12.
8. Returns the original evidence containers to the evidence staff in LIMS.

C. Evidence staff creates a LIMS record for the samples, in accordance with ADM and LOM 7302.

D. REDACTED.

REDACTED.

REDACTED.

7404.9 Managing Training Samples.

7404.91 Training Samples Sent by the Forensic Sciences Instruction Section.

Section Chief (SC) for SFT:

A. Maintains responsibility for providing transitionary training exhibits to new Forensic Chemist graduates reporting to their assigned laboratory.

B. Delegates a member of the SFT staff to prepare DEA-7s for each training exhibit and maintains records for the transfer. Follow PRO-7404.91B, Providing Transitionary Training Exhibits from SFT.

C. REDACTED.

7404.92 Training Samples Created in the Laboratory.

A. The Associate Laboratory Director (ALD) determines the need for creation of samples for analyst training.

B. The TO creates training samples from the Training Materials Stockpile, and seals them in an evidence container.

C. Once sealed in a container, TO submits samples to the evidence staff with chain of custody documentation (e.g., DEA-7, DEA-12, etc.) for creation in LIMS.

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