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SECTION B - ARS OCCUPATIONAL HEALTH MANAGEMENT FUNCTION

CHAPTER V - ARS CONTROLLED SUBSTANCES - ACQUISITION,

REGISTRATION, RECORDKEEPING, AND SECURITY

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ARC CONTROLLED SUBSTANCES - ACQUISITION, REGISTRATION,

RECORDKEEPING, AND SECURITY

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CHAPTER V - SECTION B

ARS CONTROLLED SUBSTANCES - ACQUISITION, REGISTRATION, RECORDKEEPING, AND SECURITY

A PURPOSE OF THE CHAPTER

State ARS policy and procedures covering the acquisition, registration, recordkeeping, and security of controlled substances found within ARS research operations. Public Law 91-513 (Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that every person who manufactures,

imports, distributes, dispenses, or administers any controlled substances, or conducts research or chemical analysis with controlled substances, shall obtain annually a Certificate of Registration from the DEA, Department of Justice. Accordingly, the provisions of this law apply to ARS scientists, veterinarians, chemists, and other employees engaged in dispensing narcotic and nonnarcotic controlled substances or conducting research or chemical analyses with controlled substances.

B APPLICABILITY

The contents of this chapter are applicable to all functions under the direction of the ARS Administrator whether accomplished by ARS personnel, cooperators, or contractors within ARS. Exceptions to the provisions of this MANUAL require Office of the Deputy Administrator, Administrative Management approval. Waivers must be documented and copies furnished to the next higher management level. In all instances, however, program coverage consistent with the intent of the pertinent provision will be provided.

No employee shall engage in any activity for which registration is required until a Controlled Substances Registration Certificate, Form DEA-223, is issued by the Director, DEA.

C ABBREVIATIONS

AAO - Area Administrative Officer

DEA - Drug Enforcement Administration (U.S. Department of Justice)

FD - Facilities Division

P.L. - Public Law

D AUTHORITIES

P.L. 91-513 Comprehensive Drug Abuse Prevention and Control Act of 1970.

E FORMS

Form AD-700. Procurement Request to be used by ARS officials when requesting action by acquisition personnel.

Form AD-744. Purchase Order/Invoice/Voucher which is the acquisition instrument to be used by a certified registrant in actual emergency situations.

The following DEA forms are required when applying for registration. These forms should be requisitioned directly from the DEA:

Form DEA-41. Registrant's Inventory of Drugs Surrendered which serves as a complete record of all stocks of controlled substances on hand and the effective date of registration.

Form DEA-106. Report of Theft or Loss of Controlled Substances to notify the cognizant DEA regional office in the event of loss or theft of any controlled substances.

Form DEA-222. U.S. Official Order Forms - Schedules I & II when requesting any controlled substances on Schedules I or II.

Form DEA-223. Controlled Substances Registration Certificate which provides authority to conduct research or chemical analyses with controlled substances.

Form DEA-224. New Application for Registration to dispense, or conduct instructional activities with, narcotic or nonnarcotic controlled substances listed in Schedules II through V.

Form DEA-224a. Renewal Application for Registration to dispense, or to conduct instructional activities with, narcotic or nonnarcotic controlled substances listed in Schedules II through V.

Form DEA-225. New Application for Registration to conduct research with narcotic controlled substances listed in Schedules I through V.

Form DEA-225a. Application for Registration to conduct research with narcotic controlled substances listed in Schedules I through V.

These forms can be obtained by contacting the nearest DEA office.

F POLICY

To comply with the law, ARS will require the registration of any employee or group of affiliated employees (Division, Branch, laboratory, etc.) at one general physical location where controlled substances are distributed, dispensed, or otherwise administered in the conduct of their program work.

G PROCEDURES

1 Application for Registration. Individual employees or groups of employees falling within the intent of P.L. 91-513 must apply for registration to:

Drug Enforcement Administration

Registration Section

P.O. Box 28083, Central Station

Washington, DC 20005

Employees of the U.S. Government having an official need for a registration certificate are exempt from payment of a fee for registration. All copies of the Forms DEA-224 or DEA-225 should be sent to the appropriate AAO, or Director FD, for approval and transmittal to DEA. The AAO or Director FD, will:

a Review applications for completeness.

b Determine whether individual registration is required or if one registration certificate will cover a group of affiliated employees at the same location. A number of employees at the same location may now hold registration certificates. AAO's and Director, FD, may wish to survey this possibility and determine whether a single certificate will adequately cover the official needs of a group of affiliated employees. If so, the individual registration should not be renewed after expiration (see paragraph G 2 below).

c Sign approved applications in the space provided for "Certifying Superior," forward two copies to the DEA, Washington, D.C., and return one copy to the applicant.

2 Renewal of Registration. Annual renewal applications, Form DEA-224a or -225a, as appropriate, will be mailed out automatically by DEA to all registrants 60 calendar days before the expiration date

shown on the certificate. If a renewal application is not received on time, the registrant should directly contact the DEA at the address in paragraph G 1.

G PROCEDURES (Continued)

3 Procurement of Controlled Substances. Except for actual emergencies, as described below, no local purchase actions are authorized. All requisitions for procurement of controlled substances must be submitted to the authorized acquisition official within the user's organization for purchase action. Both the AD-700 requisition and the covering purchase order must cite the DEA Registration Number shown on the registration certificate. Requisitions can only be signed by the individual to whom the certificate was granted.

a When requesting any controlled substances on Schedules I or II, the requisitioner must also enclose an order form, Form DEA-222, for completion and distribution by the purchasing office. This order form is serially numbered and issued by DEA with the name, address, registration number, authorized activity and schedules of the registrant, and DEA Controlled Substances Code Numbers which the registrant is authorized to handle.

Copies 1 and 2 must be attached to the original copy of the purchase order submitted to the vendor and copy 3 retained for office records.

b **Emergency Procedures.** Only in the case of an actual emergency situation may a controlled substance be acquired by over-the-counter purchase from local sources. In such emergencies, the purchase must be made by a certified registrant using an AD-744. The registration number must appear on the AD-744 and the registrant will be required to show proper identification to the supplier. For the

purpose of this regulation, the term "actual emergency" means a situation where the unforeseen shortage of a controlled substance would adversely affect the public health or be of serious consequence to a major research experiment. For example, an animal disease outbreak, or a laboratory experiment, which if interrupted would result in the loss of valuable research information would qualify for an emergency purchase of needed drugs.

4 Recordkeeping. Every registrant is required to make a complete record of all stocks of controlled substances on hand on the effective date of the registration. This inventory record must:

G PROCEDURES (Continued)

a Indicate the date on which the inventory was taken and whether taken at the close or opening of business day.

b Be signed by the person responsible for taking the inventory.

c Be maintained at the location appearing on the registration for at least 2 years.

In addition to the biennial inventory of stocks on hand, every registrant must keep a copy of all transactions affecting the laboratory, such as quantities received, dispensed, or disposed. For further

specific information on these transactions records, call the Registration Section of the DEA at (202) 724-1013. All drugs surrendered for DEA disposition shall be inventoried and submitted to DEA using Form DEA-41.

5 Security. All stocks of controlled substances will be kept in a locked storage cabinet, combination lock file cabinet, or safe. Keys to cabinets and safe combinations will be available only to holders of a certificate of registration. When that person leaves ARS or transfers to another location, the locks or safe combinations must be changed promptly. In the event of loss or theft of any controlled substances, the registrant will notify the regional office of DEA using Form DEA-106 for this purpose.

These security precautions apply both to registrants and to employees to whom a controlled substance has been dispensed. Accordingly, if the employee does not have similar security facilities, any controlled substances issued but not used during the working day must be returned to the controlled substances storage area of the registrant.

6 Interface with DEA. Generally, all questions regarding registration certificates, renewal applications, forms, and other matters relating to controlled substances should be directed to the Washington Office of DEA. However, any emergency situation needing an immediate answer may be referred to the appropriate regional office of DEA.