

Public Health Service, HHS

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inspect and copy any records relating to the activities covered by this part.

§ 73.17 Notification for theft, loss, or release.

(a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with § 73.21.

(b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.

(c) When reporting a theft or loss, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(2) An estimate of the quantity lost or stolen;

(3) An estimate of the time during which the theft or loss occurred; and

(4) The location (building, room) from which the theft or loss occurred.

(d) The entity shall immediately notify the HHS Secretary and State and local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers. The report must be made to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21.

(e) When reporting a release, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (*e.g.*, strain or other characterization information);

(2) An estimate of the quantity released;

(3) The time and duration of the release;

(4) The environment into which the release occurred (*e.g.*, in building or outside of building, waste system);

(5) The location (building, room) from which the release occurred;

(6) The number of individuals potentially exposed at the facility.

(7) Actions taken to respond to the release; and

(8) Hazards posed by the release.

(f) Within seven calendar days of theft, loss, or release, the entity must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316 in accordance with § 73.21.

§ 73.18 Administrative review.

An entity may obtain review of a decision denying or revoking a certificate of registration under § 73.7 and the affected entity or individual may obtain review of a decision denying or revoking approval under § 73.8 by requesting such review in writing within 30 calendar days after the adverse decision. The request for review must state the factual basis for the review, which will be carried out in accordance with 42 U.S.C. 262a(e)(7). Where the adverse decision is in whole or in part based upon notification by the Attorney General under 42 U.S.C. 262a (e)(3), the request for review will be forwarded to the Attorney General for the Attorney General's review and final notification to the HHS Secretary.

§ 73.19 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board (DAB) have been delegated authority to conduct hearings and to render decisions with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and

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documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The DAB of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

§ 73.20 Criminal penalties.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) provides specific criminal penalties for violation of provisions of this part. This is in addition to any other criminal penalties that would apply for violation of provisions of this part.

§ 73.21 Submissions and forms.

(a) CDC forms referred to in this part, including registration application packages, may be obtained on the Select Agent Program Web site at <http://www.cdc.gov>, or by requesting them in writing from the Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333. Forms (including any required attachments) must be submitted in accordance with the instructions on the form.

(b) Applications, requests, notifications, and other information required to be submitted to the HHS Secretary in writing, but not required to be on a form, unless otherwise specified, must be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at lrsat@cdc.gov.

(c) Information not required to be submitted to the HHS Secretary on a form may be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at lrsat@cdc.gov.

(d) If an application or request submitted to the HHS Secretary is incomplete or additional information is needed to allow the decision maker to make

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a determination, the HHS Secretary will notify the applicant or requester in writing of the deficiency and request additional information. If the applicant or requester fails to respond within 30 calendar days (or within such time period agreed upon by the applicant or requester and the HHS Secretary) the application or request will be deemed abandoned.

(e) You may request forms or other information from the USDA at the following address: APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 40, Riverdale, MD 20737-1231.

PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

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AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, Pub. L. 97-35, 95 Stat. 599-600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§ 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42