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7. *Yersinia pestis*
Exemptions: vaccine strains as described in Title 9 CFR, 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens epsilon toxin*
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD_{50} for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

RECOMBINANT ORGANISMS/MOLECULES

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.

2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

OTHER RESTRICTIONS

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH ''Guidelines for Research Involving Recombinant DNA Molecules,'' if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

ADDITIONAL EXEMPTIONS

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the FEDERAL REGISTER for review and comment prior to inclusion in this Appendix.

[61 FR 55199, Oct. 24, 1996]

PART 73—SELECT AGENTS AND TOXINS

73.0 Applicability and related requirements.
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AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a)

SOURCE: 67 FR 76896, Dec. 13, 2002, unless otherwise noted.

§ 73.0 Applicability and related requirements.

(a) For those entities that on February 7, 2003, were conducting activities under a certificate of registration issued under § 72.6 of this chapter, or were lawfully possessing select agents and toxins, the provisions of part 73 and § 72.6 of this chapter are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§ 73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); § 73.9 (Responsible Official); § 73.10 (Safety); § 73.12 (emergency response); and §§ 73.15

through 73.21 (records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms).

(2) On and after February 7, 2003, the provisions of § 73.13 concerning training related to safety and emergency response are applicable; and on and after September 12, 2003, the remaining provisions of § 73.13, including those concerning training related to security, are applicable.

(3) On and after March 12, 2003, the provisions of § 73.14 (transfers) are applicable.

(4) On and after April 12, 2003, the provisions of § 73.8 regarding security risk assessments for the entity, the Responsible Official, and any individual who owns or controls the entity are applicable; and on and after June 12, 2003, the remainder of § 73.8 (including the provisions regarding individual risk assessments for other than the Responsible Official or any individual who owns or controls the entity) is applicable.

(5) On and after June 12, 2003, the provisions of § 73.11 regarding the development of a security plan are applicable, and on and after September 12, 2003, the remainder of the provisions of § 73.11, including the provisions regarding the implementation of a security plan, is applicable.

(6) On and after November 12, 2003, the provisions of § 73.7 (registration) are applicable.

(b) The following also applies to those entities that on February 7, 2003, already were conducting activities under a certificate of registration issued under § 72.6 of this chapter or already were lawfully possessing select agents and toxins:

(1) During the period from March 12, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under § 73.7 certifying compliance with the provisions referred to in paragraph (a)(1) of this section and the provisions in § 73.13 concerning training related to safety and emergency response.

(2) During the period from March 12, 2003, through April 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessment) to the Attorney General for the entity, the Responsible Official, and any individual who owns or controls the entity.

(3) During the period from April 12, 2003, through June 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessments) to the Attorney General for all individuals (other than the Responsible Official and any individual who owns or controls the entity) with access to select agents and toxins.

(4) Such an entity remains:

(i) Subject to the registration provisions of § 72.6 of this chapter until November 12, 2003, when superseded by § 73.7;

(ii) Subject to the security provisions of § 72.6 of this chapter regarding development of a security plan until June 12, 2003, when superseded by the requirement to develop a security plan under § 73.11;

(iii) Subject to the security provisions of § 72.6 of this chapter regarding implementation of a security plan until September 12, 2003, when superseded by the requirement to fully comply with § 73.11;

(iv) Subject to the training provisions of § 72.6 of this chapter related to security until September 12, 2003, when superseded by the training provisions of § 73.13 relating to security; and

(v) Subject to the transfer provisions of § 72.6 of this chapter until March 12, 2003, when superseded by § 73.14.

(c) For those entities that on February 7, 2003, were not already were conducting activities under a certificate of registration issued under § 72.6 of this chapter and were not already lawfully possessing select agents and toxins, the provisions of part 73 are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§ 73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); §§ 73.8

through 73.10 (Security risk assessments, Responsible Official, Safety); §§73.12 through 73.21 (emergency response, training, transfers, records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms) and must hold a valid permit under 9 CFR part 122 and/or 42 CFR part 71.54.

(2) The provisions of §73.11 are applicable on and after September 12, 2003.

(3) On and after November 12, 2003, the provisions of §73.7 (registration) are applicable.

(4) During the period from February 7, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under §73.7 certifying compliance with the provisions referred to in paragraph (b)(2) of this section.

§73.1 Definitions.

For purposes of this part:

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent *or toxin* provided that such analysis is directly related to protecting the public health or safety.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent or toxin means a biological agent or toxin included in §73.4.

Overlap select agent or toxin means a biological agent or toxin included in §73.5.

Proficiency testing means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Select agent or toxin or *select agent and toxin* without identification as HHS or overlap means all of those biological agents or toxins included in §§73.4 and 73.5 of this part.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means the United States of America, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

USDA means the United States Department of Agriculture.

USDA Secretary means the Department of Agriculture or his or her designee, unless otherwise specified.

Verification means the processes required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

§ 73.2 Purpose and scope.

(a) This part sets forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). The Act was designed to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The agents and toxins subject to requirements under this part are those that have the potential to pose a severe threat to public health and safety. They are further identified as either HHS select agents and toxins or overlap select agents and toxins. The term HHS select agents and toxins refers to those select agents and toxins subject to these regulations but not subject to USDA requirements at 9 CFR part 121. The overlap group consists of those select agents and toxins subject to requirements promulgated by the HHS Secretary under this part and also subject to corresponding requirements promulgated by USDA at 9 CFR part 121.

(b) This part does not set requirements for the exportation of select agents or toxins. The Department of Commerce has primary responsibility for regulating the exportation of microorganisms and toxins in Title 15 of the Code of Federal Regulations.

(c) This part does not set requirements for the transportation in commerce of select agents or toxins. The Department of Transportation has primary responsibility for regulating the transportation of such select agents and toxins as hazardous materials under 49 CFR parts 171 through 180.

§ 73.3 General prohibition.

An entity or individual may not possess or use in the United States, receive from outside the United States, or transfer within the United States, a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of this part. Registration, exclusions, and exemptions are automatically revoked when any event occurs that results in an entity or individual no longer being eligible.

§ 73.4 HHS select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are HHS select agents and toxins.

(a) Viruses:

(1) Crimean-Congo haemorrhagic fever virus.

(2) Ebola viruses.

(3) Cercopithecine herpesvirus 1 (Herpes B virus).

(4) Lassa fever virus.

(5) Marburg virus.

(6) Monkeypox virus.

(7) South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito).

(8) Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]).

(9) Variola major virus (Smallpox virus) and Variola minor virus (Alastrim).

(b) Bacteria:

(1) *Rickettsia prowazekii.*

(2) *Rickettsia rickettsii.*

(3) *Yersinia pestis.*

(c) Fungi: *Coccidioides posadasii.*

(d) Toxins:

(1) Abrin.

(2) Conotoxins.

(3) Diacetoxyscirpenol.

(4) Ricin.

(5) Saxitoxin.

(6) Tetrodotoxin.

(7) Shiga-like ribosome inactivating proteins.

(e) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include nonviable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) of this section does not include the vaccine strain of Junin virus (Candid #1).

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(5) The HHS Secretary may exclude from this section attenuated strains of HHS select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety. To apply for an exclusion an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing that the attenuated strain or toxin is eligible for exclusion. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at *http://www.cdc.gov*. Exclusions also will be referenced in this section when changes are made based on periodic reviews.

§ 73.5 Overlap select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are overlap select agents and toxins.

(a) Viruses:

(1) Eastern Equine Encephalitis virus.

(2) Nipah and Hendra Complex viruses.

(3) Rift Valley fever virus.

(4) Venezuelan Equine Encephalitis virus.

(b) Bacteria:

(1) *Bacillus anthracis.*

(2) *Brucella abortus.*

(3) *Brucella melitensis.*

(4) *Brucella suis.*

(5) *Burkholderia mallei* (formerly *Pseudomonas mallei*).

(6) *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*).

(7) Botulinum neurotoxin producing species of *Clostridium*.

(8) *Coxiella burnetii.*

(9) *Francisella tularensis.*

(c) Fungi: *Coccidioides immitis.*

(d) Toxins:

(1) Botulinum neurotoxins.

(2) *Clostridium perfringens* epsilon toxin.

(3) Shigatoxin.

(4) Staphylococcal enterotoxins.

(5) T–2 toxin.

(e) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include nonviable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) does not include the vaccine strain of Rift Valley fever virus (MP–12) or Venezuelan Equine encephalitis virus vaccine strain TC–83.

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 0.5 mg of Botulinum neurotoxins; 5 mg of Staphylococcal enterotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; or 1,000 mg of T–2 toxin.

(5) The HHS Secretary, after consultation with the USDA Secretary, may exclude from this section attenuated strains of overlap select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety and do not meet the criteria in 9 CFR part 121 for inclusion. To apply for an exclusion, an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary or the USDA Secretary in accordance with 9 CFR part 121, establishing that the attenuated strain is eligible for exclusion. In response to an application submitted to the HHS Secretary, the HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site at *http://www.cdc.gov*. Also, they will be referenced in this section when changes are made based on periodic reviews.

§ 73.6 Exemptions from requirements under this part.

(a) An entity is exempt from the provisions of this part, other than § 73.14 (transfer), provided that all of the following apply:

(1) The only activities conducted by the entity that are subject to this part concern select agents or toxins that are contained in specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing;

(2) Upon identification of a select agent or toxin as the result of diagnosis or verification, the entity immediately reports to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21 any of the following: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito);

(3) The entity reports as required under Federal, State, or local law, to appropriate authorities;

(4) After the diagnosis, verification, or proficiency testing, the entity either transfers the specimens or isolates containing a select agent or toxin from the specimens to a facility eligible for receiving them under this part, or destroys them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;

(5) The entity transfers or destroys those select agents or toxins used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after consultation with the HHS Secretary; and

(6) The entity transfers or destroys those select agents or toxins used for proficiency testing within 90 days after receipt; and

(7) The entity prepares a record of the identification and transfer or destruction on CDC Form 0.1318, submits the completed form to the HHS Secretary in accordance with §73.21 within seven days after identification, and maintains a copy of the record for a period of three years.

(b) Unless the HHS Secretary issues an order to an entity making specific provisions of this part applicable to protect the public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use is only for the approved purpose and meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq*).

(c) The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section and additional regulation under this part is not necessary to protect public health and safety. To apply for an exemption an applicant must submit to the HHS Secretary in accordance with §73.21 a completed CDC Form 0.1317 certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section, and that additional regulation under this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. The applicant must notify the HHS Secretary when an authorization for an investigation no longer exists. This exemption automatically ceases when such authorization is no longer in effect.

(d) The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days. To apply for an exemption or an extension of an exemption, an applicant must submit to the HHS Secretary in accordance with §73.21 a completed CDC Form 0.1317 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

(e) Upon request of the USDA Secretary, after the USDA Secretary has granted an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 based on a finding that there is an agricultural emergency, the HHS Secretary may temporarily exempt an entity from the applicability of the requirements of this part, in whole or in part, to provide for the timely participation of the entity in response to the agricultural emergency. With respect to the emergency, the exemption under this part may not exceed 30 days, except that upon the request of the USDA Secretary, the HHS Secretary may grant one extension of an additional 30 days.

§73.7 Registration.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has

been granted a certificate of registration by the HHS Secretary or the USDA Secretary.

(b) To apply for a certificate of registration an entity must:

(1) Obtain a registration application number from the HHS Secretary and then apply for approval under § 73.8 for the entity, the Responsible Official, and any individual who owns or controls the entity; and

(2) In accordance with § 73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes:

(i) Identification information (*e.g.*, name, address, contact numbers, identification number assigned by the Attorney General for compliance with § 73.8);

(ii) The name, source, and characterization information on select agents and toxins included in the registration, and quantities held at the time of the application;

(iii) The location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used;

(iv) Information addressing safety, security, emergency response plans, and training, including descriptions of any equivalent measures adopted pursuant to § 73.11(d);

(v) The name, position, and identification information regarding the Responsible Official, including the identification number assigned by the Attorney General for compliance with § 73.8;

(vi) A list of individuals who will need access to select agents and toxins;

(vii) A certification statement signed by the Responsible Official attesting to the accuracy of the information submitted; and

(viii) Any other information necessary for the determination.

(c) An application that covers any HHS select agents or toxins (regardless of whether it also covers overlap select agents or toxins) must be submitted to the HHS Secretary in accordance with § 73.21. An application that covers only overlap select agents or toxins may be submitted to either the HHS Secretary or the USDA Secretary.

(d) A certificate of registration will be valid only for the specific select agents and toxins, and the specified activities and locations that are consistent with the information provided by the entity upon which the certificate of registration or amendment was granted. The Responsible Official must promptly notify the HHS Secretary in writing in accordance with § 73.21, if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This includes modifications to the list of individuals approved under § 73.8, changes in area of work, or changes in protocols or objectives of studies. To apply for an amendment to a certificate of registration to add select agents or toxins or to change specified activities or locations, an entity must obtain the relevant portion of the registration application package and submit the information requested in the package to the agency that issued the certificate of registration. The package must be submitted to the appropriate address specified in the package.

(e) In response to an application to the HHS Secretary for a certificate of registration or amendment for select agents and toxins, the HHS Secretary will issue a certificate of registration or amendment if it is determined that the stated activities would be lawful (based on information submitted by the applicant or otherwise obtained by the HHS Secretary) and meet the requirements of this part. Otherwise, the application for a certificate of registration or amendment will be denied. The HHS Secretary will issue a certificate of registration or amendment for an overlap select agent or toxin only if the USDA Secretary concurs that the requirements for obtaining a certificate of registration or amendment under 9 CFR part 121 have been met. The determination of whether a certificate of registration or amendment will be granted may be contingent upon inspection or submission of additional information.

(f) A certificate of registration will cover activities at only one general

physical location (a building or a complex of buildings at a single mailing address).

(g) Unless terminated sooner in accordance with this paragraph, a certificate of registration will be valid for up to three years. To obtain a new certificate of registration an entity must submit a new application. (Note: To help ensure timely processing of an application for a certificate of registration or amendment, the applicant should submit the application at least eight weeks prior to the expiration date.)

(1) The HHS Secretary will terminate a certificate of registration based on a determination that the recipient no longer conducts activities covered by the certificate.

(2) Also, the HHS Secretary may terminate a certificate of registration based on a security risk assessment under § 73.8 or failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health or safety. Upon such termination, any select agent or toxin in the possession of the entity must be destroyed or transferred as directed by the HHS Secretary.

(h) An entity must provide notice in writing to the HHS Secretary in accordance with § 73.21 at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. This will allow the HHS Secretary to observe the destruction or take other action as appropriate.

§ 73.8 Security risk assessment.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless approved by the HHS Secretary or the USDA Secretary based on a security risk assessment by the Attorney General. This paragraph does not apply to Federal, State, or local governmental agencies, but does apply to the Responsible Official and others working for or otherwise acting on behalf of such agencies.

(b) An entity may not provide an individual access to a select agent or toxin and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or the USDA Secretary, based on a security risk assessment by the Attorney General.

(c) To obtain a security risk assessment under this section, an entity must submit to the Attorney General the information requested for the entity, the Responsible Official, any individual who owns or controls the entity, and any other individuals required to obtain approval under this section. The determinations regarding approval will be made by the agency that is responsible for making determinations regarding the corresponding certificate of registration. An entity will receive prompt notice of action taken in response to a request for approval for the entity, the Responsible Official, and individuals. An individual will receive prompt notice of a denial of approval.

(d) The Attorney General will conduct a security risk assessment on entities and individuals whose identifying information is properly submitted. Based on the security risk assessment, the Attorney General will notify the HHS Secretary if the Attorney General identifies any entity, individual who owns or controls the entity, or any other individual who is:

(1) A restricted person under 18 U.S.C. 175b; or

(2) Reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5);

(ii) Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(e) The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a restricted person under paragraph (d)(1). The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by

the Attorney General as meeting the criteria of paragraph (d)(2) unless determined by the HHS Secretary to be warranted in the interest of the public health and safety or national security. For individuals meeting the criteria of paragraph (d)(2) the HHS Secretary may provide a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of the public health and safety or national security.

(f) Unless a shorter period is granted under paragraph (e) of this section, an approval for an entity or individual under this section will be valid for five years unless terminated sooner. The HHS Secretary may terminate an approval for an entity or an individual based on a request from the entity or individual, a security risk assessment under this section, or a failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health and safety, or national security.

(g) The HHS Secretary will request the Attorney General to expedite the review process for an individual and will take action to expedite the HHS Secretary's review process for an individual upon a showing of good cause (*e.g.*, public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher). To apply for an expedited review, an entity must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing the need for such action. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

§ 73.9 Responsible Official.

(a) As a condition of conducting activities regulated under this part, an entity must identify and authorize an individual as the Responsible Official. The Responsible Official may identify one or more individuals, any of whom may serve as the Alternate Responsible Official when the Responsible Official is unavailable. The Responsible Official and all individuals identified to serve as the Alternate Responsible Official must meet all of the qualifications for a Responsible Official. The Responsible Official and all Alternate Responsible Officials must:

(1) Be approved under § 73.8;

(2) Be familiar with the requirements of this part; and

(3) Have authority and responsibility to ensure that the requirements of this part are met, on behalf of the entity.

(b) For purposes of this part, the Alternate Responsible Official acting in the absence of the Responsible Official may conduct all of those activities required under this part to be performed by the Responsible Official.

(c) The Responsible Official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing safety, security and emergency response plans in accordance with § 73.10—§ 73.12;

(2) Allowing only approved individuals to have access to select agents or toxins in accordance with § 73.8 and § 73.11;

(3) Providing appropriate training for safety, security and emergency response in accordance with § 73.13;

(4) Transferring select agents or toxins in accordance with § 73.14;

(5) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with § 73.13;

(6) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with § 73.15.

(7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with § 73.6.

§ 73.10 Safety.

(a) An entity subject to the provisions of this part, must develop and implement a safety plan. In developing a safety plan, an entity should consider:

(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories,'' including all appendices except Appendix F. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh,

Pennsylvania, 75250–7954 or call in the Washington, DC metropolitan area 202–512–1800 or outside that area call toll free 1–866–512–1800. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia. This publication is also available on the CDC Web site at *http://www.cdc.gov*.

(2) The specific requirements for handling toxins found in 29 CFR 1910.1450, ''Occupational Exposure to Hazardous Chemicals in Laboratories'' and/or 29 CFR 1910.1200, ''Hazard Communication,'' whichever applies and specific provisions for handling toxins found in Appendix I in the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories,''

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the ''NIH Guidelines for Research Involving Recombinant DNA Molecules,'' (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of funding. Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia, 30333. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E–79, Atlanta, Georgia. The ''NIH Guidelines for Research Involving Recombinant DNA Molecules,'' is also available on the CDC Web site at *http://www.cdc.gov*.

(b) The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan. The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.

(c) An entity may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

(d) [Reserved]

§ 73.11 Security.

(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.

(b) The plan must:

(1) Describe inventory control procedures, minimal education and experience criteria for those individuals with access to select agents or toxins, physical security, and cyber security;

(2) Contain provisions for routine cleaning, maintenance, and repairs; provisions for training personnel in security procedures; provisions for securing the area (*e.g.*, card access, key pads, locks) and protocols for changing access numbers or locks following staff changes;

(3) Describe procedures for loss or compromise of keys, passwords, combinations, etc.;

(4) Contain procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records;

(5) Contain provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons;

(6) Contain provisions for ensuring that all individuals with access, including workers and visitors, understand security requirements and are trained and equipped to follow established procedures;

(7) Establish procedures for reporting and removing unauthorized persons; and

(8) Establish procedures for securing the area when individuals approved under § 73.8 are not present (*e.g.*, card access system, key pads, locks), including protocols for changing access numbers or locks following staff changes.

(c) The security plan must be reviewed by the RO at least annually and after any incident.

(d) With respect to areas containing select agents and toxins, the entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(1) Allow unescorted access only to individuals who have been approved under § 73.8 and who are performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce);

(2) Allow individuals not approved under § 73.8 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (*e.g.*, card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under 73.8 does not share with any other person, his or her unique means (*e.g.*, keycards or passwords) of accessing the area or select agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

(i) Any loss or compromise of their keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of select agents or toxins; and

(v) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.

(e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.

(f) Upon termination of the use, a select agent or toxin must be

(1) Securely stored in accordance with the requirements of this section;

(2) Transferred to another registered facility in accordance with § 73.14; or

(3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

§ 73.12 Emergency response.

(a) An entity required to register under this part must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR 1910.120. Nothing in this section is to supersede or preempt the enforcement of the emergency response requirements imposed by the other statute or regulation.

(b) The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

(c) The emergency response plan must address the following:

(1) The hazards associated with the use of the select agents and toxins;

(2) Any hazards associated with response actions that could lead to a spread of a select agent or toxin;

(3) Planning and coordination with outside parties;

(4) Personnel roles, lines of authority, training, and communication;

(5) Emergency recognition and prevention;

(6) Safe distances and places of refuge;

(7) Site security and control;

(8) Evacuation routes and procedures;

(9) Decontamination;

(10) Emergency medical treatment and first aid;

(11) Emergency alerting and response procedures;

(12) Critique of response and follow-up;

(13) Personal protective and emergency equipment; and

(14) Special procedures needed to address the hazards of specific agents.

§ 73.13 Training.

(a) An entity required to register under this part and falls outside of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030(a) must provide information and training on safety and security for working with select agents and toxins to each individual approved for access under § 73.8 and each unapproved individual working in, or visiting, areas where select agents and toxins are handled or stored. The information and training must meet the requirements of this section and must ensure that all individuals who work in, or visit, the areas understand the hazards of select agents and toxins present in the area.

(b) The entity must provide information and training at the time of an individual's initial assignment to a work area where select agents or toxins are present and prior to assignments involving new exposure situations. The entity must provide refresher training annually.

(c) The Responsible Official must provide appropriate training in safety, containment, and security to all individuals with access to areas where select agents and toxins are handled or stored.

(d) In lieu of initial training for those individuals already involved in handling select agents or toxins, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.

(e) The entity must ensure that each individual with access to areas where select agents or toxins are handled or stored received and understood the training required by this section unless certified under paragraph (d) of this section. The entity must record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training.

§ 73.14 Transfers.

A select agent or toxin may not be transferred from one entity to another entity within the United States (regardless of whether the transfer is interstate or intrastate), or received by an entity in the United States from an entity outside the United States, unless:

(a) The sender:

(1) Has a certificate of registration that covers the transfer of the particular select agent or toxin to be transferred,

(2) Meets the exemption requirements under § 73.6 (a) for the particular select agent or toxin to be transferred, or

(3) Is transferring the select agent or toxin from outside the United States (and all import requirements are met);

(b) The recipient has a certificate of registration that includes the particular select agent or toxin to be transferred;

(c) Prior to the transfer, the recipient and sender completes CDC Form EA–101, and the recipient submits to the HHS Secretary in accordance with § 73.21 a completed CDC Form EA–101.

(d) CDC has authorized the transfer based on the finding that the recipient has a certificate of registration covering the transfer of the select agent or toxin;

(e) The sender complies with all applicable laws concerning packaging and shipping;

(f) The Responsible Official of the recipient provides a completed paper copy or facsimile transmission of CDC Form EA–101 to the sender and to the HHS Secretary within 2 business days

of receipt of the select agent or toxin; and

(g) The recipient immediately reports to the HHS Secretary if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package received containing select agents or toxins has been leaking or was otherwise damaged.

(h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA–101.

NOTE TO § 73.14: This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 73.15 Records.

The Responsible Official must maintain complete records relating to the activities covered by this Part. Such records include:

(a) An entity required to register under this part must maintain an up-to-date, accurate list of the individuals approved under § 73.8 for access to select agents and toxins.

(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

(1) The name, characteristics, and source data;

(2) The quantity held on the date of the first inventory (toxins only);

(3) The quantity acquired, the source, and date of acquisition;

(4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;

(5) The quantity used and date(s) of the use (toxins only);

(6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);

(7) The current quantity held (toxins only);

(8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and

(9) A written explanation of any discrepancies.

(c) The entity must maintain the following records:

(1) For access to the select agents or toxins:

(i) The name of each individual who has accessed any select agent or toxin;

(ii) The select agent or toxin used;

(iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;

(iv) The quantity removed (toxins only);

(v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and

(vi) The quantity returned (toxins only);

(2) For access to the area where select agents are used or stored:

(i) The name of each individual who has accessed the area;

(ii) The date and time the individual entered the area;

(iii) The date and time the individual left the area; and

(iv) For individuals not approved under § 73.8, the individual approved under § 73.8 who accompanied the unapproved individual into the area.

(d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.

(e) The entity must create a record concerning inspections conducted under § 73.10(b).

(f) Safety, security, and emergency response plans.

(g) Training records.

(h) Transfer documents (CDC Form EA–101) and permits.

(i) Safety and security incident reports.

(j) The entity must maintain all records created under this part for three years.

§ 73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to

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

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 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