* * * * *

[FR Doc. 03–27263 Filed 10–31–03; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Possession, Use, and Transfer of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule and request for comments.

SUMMARY: We are amending an interim final rule published on December 13, 2002, that established requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins. The requirements were established to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities under a certificate of registration issued under 42 CFR 72.6, or already were lawfully possessing select agents and toxins, required entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment. We are now amending the applicability requirements to allow for the issuance of provisional registration certificates for all entities, and provisional grants of access for all individuals, from whom, prior to November 12, 2003, the Attorney General has received all of the information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73. This action is necessary to ensure that both ongoing and new research and educational efforts important to the national defense are not disrupted.

DATES: This interim final rule is effective as of November 3, 2003. Written comments must be submitted on or before January 2, 2004.

ADDRESSES: Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Rd., E–79, Atlanta, GA 30333. Comments may be e-mailed to: *SAPcomments@CDC.GOV.*

FOR FURTHER INFORMATION CONTACT: Mark Hemphill, Chief of Policy, Select Agent Program, Centers For Disease Control and Prevention, 1600 Clifton Rd., MS E–79, Atlanta Ga. 30333. (404) 498–2255.

SUPPLEMENTARY INFORMATION: The December 2002 interim final rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107–188 (referred to below as the Act). The Act bolstered the authority of the Secretary of the United States Department of Health and Human Services (referred to below as HHS) to protect the American public against the misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland (such as the recent terrorist acts involving anthrax) or other criminal acts. The Act gave to the Secretary broad discretion in establishing and enforcing the new regulations to ensure that select agents and toxins would remain available for research, education, and other legitimate purposes.

In a document published in the **Federal Register** on December 13, 2002 (67 FR 76886), we promulgated an interim final rule to establish requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of certain biological agents and toxins (referred to below as select agents and toxins). This includes requirements concerning registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. The December 2002 interim final rule is set forth at 42 CFR part 73.

In general, the entities regulated under the December 2002 interim final rule are academic institutions and biomedical centers; commercial manufacturing (the pharmaceutical industry) or distribution facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; and research facilities.

The Act also gives the United States Department of Agriculture (referred to below as USDA) the authority and responsibility for regulating activities regarding select agents and toxins to protect animal and plant health and animal and plant products. The Act gives the Secretary of HHS the authority and responsibility for regulating activities regarding select agents and toxins to protect the public health and safety. Some of the select agents and toxins regulated under the HHS December 2002 interim final rule are also regulated by USDA under 9 CFR part 121. The select agents and toxins subject to regulation by both agencies are identified as ''overlap'' select agents and toxins and those regulated solely by HHS are identified as HHS select agents and toxins. The Act provides for interagency coordination between the two departments regarding overlap select agents and toxins.

The December 2002 interim final rule established a phase-in period for certain requirements to allow entities to comply without causing disruption or termination of research or educational projects. The phase-in for entities that on February 7, 2003, were already conducting activities under a certificate of registration issued under 42 CFR 72.6, or already were lawfully possessing select agents and toxins, required that entities applying for registration with the select agent program, and individuals requiring access to select agents and toxins, to undergo a security risk assessment by the Attorney General before November 12, 2003. The regulations also provided that an entity that on February 7, 2003, was not already conducting activities under a certificate of registration issued under 42 CFR 72.6, or was not already lawfully possessing select agents and toxins, would be eligible for registration to possess, use, or transfer select agents and toxins as soon as the entity met all of the applicable requirements of Part 73, including the requirement for the Attorney General to conduct a security risk assessment.

The Attorney General has assigned the responsibility to conduct the security risk assessments required by the Act to the Federal Bureau of Investigation (FBI). The Criminal Justice Information Services (CJIS) Division is the component of the FBI responsible for implementing this program. The CJIS Division continues to receive complete application packages, which consist of completed FBI Information Forms (FD–961) and usable fingerprint cards, and has finalized over 5,000 security risk

assessments.[1] The CJIS Division had diverted personnel from other key programs in order to finalize as many security risk assessments as possible without compromising its other missions. It is important to note that the time needed to process a security risk assessment varies in relation to the complexity of each application. Some individuals may be processed in as little as two weeks once processing begins, while other individuals can take several months. At its current processing rate, the CJIS Division expects to be able to finalize by the November 12, 2003, deadline the security risk assessments of almost all of the completed applications that were pending as of October 1, 2003.

However, in addition to the complete application packages, the CJIS Division also has received incomplete packages. The CJIS Division has sent more than 2,450 letters informing Responsible Officials of the incomplete applications of their personnel. In light of its present capacity and processing times, the CJIS Division has projected that even if immediately completed, these outstanding applications could not be processed by the November 12, 2003 regulatory deadline.

We believe that the continued operation of these facilities is vital to the public interest. We also believe that those entities and individuals that have submitted all of the required information and forms by November 12, 2003, have made a good faith effort to comply with these regulations. We are therefore amending the applicability requirements to allow for the issuance of provisional registration certificates for entities, and provisional grants of access for individuals, from whom, prior to November 12, 2003, the Attorney General has received all of the information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73. This action is necessary to ensure that, as required by the Act, ongoing research and educational efforts important to the national defense are not disrupted. We are also amending the applicability requirements to allow for the issuance of provisional registration certificates for entities not currently in possession of select agents or toxins from whom, prior to November 12, 2003, the Attorney General has received all the information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73 and the Secretary, HHS, determines such action is in the interest of the public health and national security. An entity's provisional registration will stay in effect until the Secretary either grants the entity a certificate of registration or revokes the entity's provisional registration. An individual's provisional grant of access will remain in effect until the Secretary either grants access or revokes the individual's provisional grant of access. This action is necessary to ensure that new research, educational, and national security preparedness efforts are not impeded.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Authority for Interim Final Rule

We are amending the December 2002 interim final rule to insure that the provisions of the Part 73 are consistent with the original intent of the Act. Consequently, the Act also requires this amendment to be published as an interim final rule (42 U.S.C. 262a, note). Further, pursuant to 5 U.S.C. 553, we find that notice and public procedure are impracticable, unnecessary, and contrary to the public interest and that we have good cause to dispense with notice and comment on this amendment. The amendment will prevent disruption or termination of ongoing research and educational projects by hundreds of entities and thousands of individuals needing access to select agents and toxins.

Immediate action is necessary to prevent the imposition of an unnecessary burden on the regulated community; and to ensure the appropriate availability of biological toxins for research, education, and other legitimate purposes. Under these circumstances, the Secretary has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

Paperwork Reduction Act

This interim final rule does not contain any new provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Executive Order 12866

This interim final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Unfunded Mandates

The Unfunded Mandates Reform Act at 2 U.S.C. 1532 requires that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This interim final rule is not expected to result in any one-year expenditure that would exceed $100 million.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

List of Subjects in 42 CFR Part 73

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

Dated: October 30, 2003.

Tommy G. Thompson,

Secretary.

■ For the reasons stated in the preamble, 42 CFR part 73 is amended as follows:

■ 1. The authority citation for Part 73 continues to read as follows:

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).

§ 73.0 [Amended]

■ 2. Amend § 73.0 by adding paragraphs (b)(5), through (b)(8) and paragraphs (c)(5) through (c)(8) to read as follows:

[1] To avoid delays related to incomplete applications, individuals and entities should submit their FD–961 forms and fingerprint cards to the CJIS Division in one package. However, this does not apply to applicants who are submitting follow-up information or fingerprint cards for an existing incomplete application.

§ 73.0 Applicability and related requirements.

* * * * *

(b) * * *

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this Part.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

(c) * * *

(5) A provisional registration certificate may be issued to an entity if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this Part; and

(iii) The HHS Secretary finds that circumstances warrant such action in the interest of the public health and safety or national security.

(6) A provisional registration certificate will be effective until the Secretary either issues a certificate of registration or suspends or revokes the provisional registration.

(7) A provisional grant of access may be issued to an individual identified by an entity as having a legitimate need to have access to a select agent or toxin from whom, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual.

(8) A provisional grant of access will be effective until the Secretary either grants the individual access or denies access to a select agent or toxin.

[FR Doc. 03–27659 Filed 10–31–03; 8:45 am]

BILLING CODE 4160–17–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket Nos. 02–34, 00–248, and 96–111, FCC 03–128]

Satellite Licensing Procedures

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts a procedure that will give operators the flexibility to operate satellites in their fleets at any one of their orbit locations assigned to their fleet without individual prior Commission approval. The Commission also relaxes a licensing requirement for receive-only earth stations accessing certain foreign-licensed satellites. These actions are necessary to provide U.S.-licensed and non-U.S.-licensed satellite operators authorized to provide service to the United States more flexibility to meet their customers' needs.

DATES: This final rule contains information collection requirements that have not been approved by OMB. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date of these amendments.

FOR FURTHER INFORMATION CONTACT: Steven Spaeth, Attorney Advisor, Satellite Division, International Bureau, telephone (202) 418–1539 or via the Internet at *steven.spaeth@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order, IB Docket Nos. 02–34, 00–248, and 96–111, FCC 03–128, adopted June 4, 2003, and released June 20, 2003. The complete text of this Second Report and Order is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554, and also may be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893, facsimile (202) 863–2898 or via e-mail *qualexint@lol.com*. It is also available on the Commission's Web site at *http://www.fcc.gov.*

Paperwork Reduction Act Analysis: The actions taken in the *Second Report and Order* have been analyzed with respect to the Paperwork Reduction Act of 1995 (PRA), Public Law No. 104–13, and found to impose new reporting requirements or burdens on the public. Implementation of these new or modified reporting and recordkeeping requirements will be subject to approval by the Office of Management and Budget (OMB) as prescribed by the PRA.

Summary of Report and Order: In this document, the Commission adopts a streamlined procedure for certain modifications of space station licenses, which it refers to as ''Fleet Management'' modifications. A space station operator may modify its license without prior authorization, but upon 30 days prior notice to the Commission and any potentially affected licensed spectrum user, provided that the operator meets the following requirements: (1) The space station licensee will relocate a Geostationary Satellite Orbit (GSO) space station to another orbit location that is assigned to that licensee; (2) the relocated space station licensee will operate with the same technical parameters as the space station initially assigned to that location, or within the original satellite's authorized and/or coordinated parameters; (3) the space station licensee certifies that it will comply with all the conditions of its original license and all applicable rules after the relocation; (4) the space station licensee certifies that it will comply with all applicable coordination agreements at the newly occupied orbital location; (5) the space station licensee certifies that it has completed any necessary coordination of its space station at the new location with other potentially affected space station operators; (6) the space station licensee certifies that it will limit operations of the space station to Tracking, Telemetry, and Control (TT&C) functions during the relocation and satellite drift transition period; and (7) the space station licensee certifies that the relocation of the space station does not result in a lapse of service for any current customer. The Commission also adopts rules to allow earth station operators that need to modify their licenses to repoint their antennas in response to a satellite Fleet Management modification to do so on a streamlined basis. Finally, the Commission extends its Fleet Management modification rules to non-U.S.-licensed satellites.

In addition, the Commission relaxes a licensing requirement for certain receive-only earth stations. Historically, receive-only earth stations receiving from non-U.S.-licensed satellites were required to be licensed. Under the rule revisions adopted here, receive-only