DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 72

RIN 0920–AA02

Requirements for Facilities Transferring or Receiving Select Agents

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: CDC administers regulations that govern the transfer of certain biological agents and toxins (''select agents''). These regulations require entities that transfer or receive select agents to register with CDC and comply with biosafety standards contained in the Third Edition of the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories (''BMBL'').'' On October 28, 1999, CDC published a Notice of Proposed Rulemaking (''NPRM'') seeking both to revise the biosafety standards facilities must follow when handling select agents and to provide new biosecurity standards for such facilities. These new standards are contained in the Fourth Edition of BMBL, which the NPRM proposed to incorporate by reference, thereby replacing the Third Edition. No comments were received in response to this proposal. CDC is therefore amending its regulations to incorporate the Fourth Edition.

DATES: Effective date is January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Laboratory Registration/Select Agent Transfer (LR/SAT) Program, Office of Health and Safety, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., MS-A13, Atlanta, GA 30333; telephone (404) 639–4418; LR/SAT Program website at *http://www.cdc.gov/od/ohs/lrsat.htm.*

SUPPLEMENTARY INFORMATION:

Background

''The Antiterrorism and Effective Death Penalty Act of 1996,'' Pub. L. 104–132,(42 U.S.C. § 262 note) enacted on April 24, 1996, established new provisions to regulate the transfer of certain biological agents and toxins (i.e., select agents), and required HHS to issue rules to implement these provisions. The final rule was published in the **Federal Register** on October 24, 1996 (61 FR 551990–01) and became effective April 15, 1997. To comply with the final rule, commercial suppliers of select agents, as well as government agencies, universities, research institutions, and private companies that transfer these agents, must register with the Centers for Disease Control and Prevention (CDC). Prior to transferring or receiving a select agent listed in Appendix A of 42 CFR part 72, the facility must be equipped and capable of handling the covered agent at Biosafety Level (BSL) 2, 3, or 4, depending on the agent. The requirements for BSL 2, 3, or 4 operations are contained in the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (BMBL), and are currently incorporated by reference in the Third Edition. In May, 1999, the Fourth Edition of the BMBL was published. The Fourth Edition revises some of the biosafety standards contained in the Third Edition as a result of a number of events (e.g. emerging and re-emerging infectious diseases, laboratory associated infections and advances in facility design and construction). The Fourth Edition also contains biosecurity standards, which have not been included in previous editions of the BMBL. These biosecurity provisions are intended to assure that registered entities take measures to prevent unauthorized use of agents and/or use of agents by unqualified persons. These measures are also designed to protect against theft of these agents thereby decreasing the likelihood that the agents may be used for nefarious purposes.

On October 28, 1999, CDC published a Notice of Proposed Rulemaking (NPRM) seeking to replace the Third Edition of the BMBL with the recently published Fourth Edition (64 FR 58022). No comments were received in response to this proposed revision. This final rule therefore incorporates by reference the Fourth Edition.

Effective January 1, 2002, all facilities subject to 42 CFR section 72.6 are required to comply with the biosafety and biosecurity standards contained in the Fourth Edition. Facilities currently registered with CDC are therefore required to comply with the Fourth Edition as of January 1, 2002, but are not required to ''re-register'' until their registration expires as indicated on their current registration certificate.

To assist facilities seeking registration, CDC has developed a new application form that contains the Fourth Edition requirements. CDC will use this form when registering all facilities after publication of this Final Rule. Facilities that register using the new form may continue to operate in accordance with the Third Edition of the BMBL until January 1, 2002.

Because a large number of current registrations expire before January 1, 2002, facilities whose registration expires between the publication date of this final rule and January 1, 2002 must submit applications no later than October 1, 2001, in order to allow the Laboratory Registration/Select Agent Transfer Program office time to process the applications.

CDC will mail revised applications to all facilities that express an interest. The revised application is also available on the LR/SAT Program website at *http://www.cdc.gov/od/ohs/lrsat.htm.* Questions about this Final Rule and requests for application packages should be faxed to CDC, Office of Health and Safety (404–639–0880) or sent by e-mail (lrsat@cdc.gov). All applications for registration of facilities under this regulation should be mailed to: Centers for Disease Control and Prevention, Office of Health and Safety, Laboratory Registration/Select Agent Transfer Program, 1600 Clifton Road, MS A–13, Atlanta, Georgia 30333.

Analysis of Impacts

Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of the Office of Management and Budget (OMB), and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection entitled 'Importation of Etiological Agents and Packaging and Handling of Infectious Substances and Select Agents' and has assigned OMB control number 0920–0199. For further information on this information collection contact Anne O'Connor, CDC Assistant Reports Clearance Officer, Centers for Disease Control and Prevention, Office of Program Planning and Evaluation, 1600 Clifton Road, MS D–24, Atlanta, Georgia 30333, (404) 639–7090.

The Unfunded Mandates Reform Act of 1995, in sections 202 and 205, requires Federal agencies to prepare several analytic statements before proposing a rule that may result in expenditures of $100 million by State, local, and tribal governments, or by the private sector in any one year. CDC addressed these concerns in the NPRM published on October 28, 1999—Packaging and Handling of Infectious Substances and Select Agents (42 CFR part 72). Because a final rule resulting from this proposal would not result in

expenditures of this magnitude, such statements are not necessary.

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis of the potential impact of the proposed rule on small entities and permits agency heads to certify that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. CDC also addressed these concerns in the NPRM published on October 28, 1999—Packaging and Handling of Infectious Substances and Select Agents (42 CFR part 72). CDC requested comments on the economic burden from a number of small entities. It also requested recommendations on other possible less burdensome approaches. No comments were received.

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that this rule does not have implications for federalism.

Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

This rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulation Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order.

Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (*5 U.S.C. 801 et seq.*), the Department will report to Congress promulgation of this rule prior to its effective date. The report will state that the Department has concluded that this rule is not a ''major rule'' because it is not likely to result in an annual effect on the economy of $100 million or more.

List of Subjects in 42 CFR Part 72

Biologic, Incorporation by reference, Packaging and containers, Transportation.

Text of the Rule

For the reasons stated in the preamble, part 72 is amended as follows:

PART 72—[AMENDED]

1. The authority section for part 72 continues to read as follows:

Authority: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

2. Amend § 72.6 by revising paragraphs (a)(5) and (c)(1) to read as follows:

§ 72.6 Additional requirements for facilities transferring or receiving select agents.

(a) * * *

(5) The biosafety standards and requirements for BSL–2, 3, and 4 operations are contained in the CDC/NIH publication, ''Biosafety in Microbiological and Biomedical Laboratories,'' Fourth Edition, May 1999 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop A–13 Atlanta, Georgia, or at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. The manual is also available on the CDC web site at *www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm.*

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(c) * * *

(1) the Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories,'' Fourth Edition.

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Dated: August 16, 2001.

Jeffrey Koplan,

Director, Centers for Disease Control and Prevention.

Dated: August 29, 2001.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 356

[Docket No. MARAD–2001–10518]

RIN 2133–AB45

Eligibility of U.S.-Flag Vessels of 100 Feet or Greater in Registered Length To Obtain a Fishery Endorsement to the Vessel's Documentation

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Interim final rule and request for comments.

SUMMARY: The Maritime Administration (''MARAD,'' ''we,'' ''our,'' or ''us'') is publishing this interim final rule amending our regulations implementing the new U.S. citizenship requirements set forth in the American Fisheries Act of 1998 (''AFA''). MARAD's regulation,