ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[FRL–6464–8]

EPA Standards for the Management of Cement Kiln Dust; Request for Comments

AGENCY: Environmental Protection Agency.

ACTION: Extension of period for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is today announcing an extension of the public comment period for its Proposed Rule on Standards for the Management of Cement Kiln Dust to February 17, 2000.

DATES: The comment period of the Proposed Rule on Standards for the Management of Cement Kiln Dust is extended and will close on February 17, 2000.

ADDRESSES: Those persons wishing to submit public comments must send an original and two copies of their comments referencing EPA docket number F–1999–CKDP–FFFFF to: RCRA Docket Information Center (5305W), U.S. Environmental Protection Agency Headquarters (EPA,HQ), 401 M Street, SW, Washington, DC, 20460. Hand deliveries of comments, including courier, postal and non-postal express deliveries, should be made to the Arlington, VA address below.

Comments may also be submitted electronically through the Internet to: rcra-docket@epa.gov. Comments in electronic format should also identify the docket number F–1999–CKDP–FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Commenters should not submit electronically any confidential business information (CBI). An original and two copies of CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, SW, Washington, DC 20460.

Public comments and supporting materials are available for viewing in the RCRA Docket Information Center (RIC), located at Crystal Gateway I Building, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling (703) 603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15 per page. The Proposed Rule is also available electronically. See the **SUPPLEMENTARY INFORMATION** section below for information on electronic access.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at (800) 424–9346 or TDD (hearing impaired) (800) 553–7672. In the Washington, DC metropolitan area, call (703) 412–9810 or TDD (703) 412–3323. For more detailed information on specific aspects of today's action, contact Bill Schoenborn, U.S. Environmental Protection Agency (5306W), 401 M Street, SW, Washington, DC 20460, at (703) 308–8483, or e-mail: *schoenborn.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

Customer Service

In developing the Proposed Rule, we tried to address the concerns of all our stakeholders. Your comments will help us improve this regulatory action. We invite you to provide different views on options we propose, new approaches we have not considered, new data, how this regulatory action may affect you, or other relevant information. We welcome your views on all aspects of this action, but we request comments in particular on the items discussed in the Proposed Rule. Your comments will be most effective if you follow the suggestions below:

- Explain your views as clearly as possible and why you feel that way.
- Provide solid technical and cost data to support your views.
- If you estimate potential costs, explain how you arrived at the estimate.
- Tell us which parts you support, as well as those you disagree with.
- Provide specific examples to illustrate your concerns.
- Offer specific alternatives.
- Refer your comments to specific sections of the report.
- Make sure to submit your comments by the deadline in this notice.
- Be sure to include the name, date, and docket number with your comments.

Copies of the full proposal, titled *Standards for the Management of Cement Kiln Dust; Proposed Rule* (EPA publication number EPA 530–Z–99–007), are available for inspection and copying at the EPA Headquarters library, at the RCRA Docket (RIC) office identified in **ADDRESSES** above, at all EPA Regional Office libraries, and in electronic format at the following EPA Web site: http://www.epa.gov/osw/special.htm. Printed copies of the proposal and related documents, can also be obtained by calling the RCRA/Superfund Hotline at (800) 424–9346 or (703) 412–9810.

Background

Cement kiln dust (CKD) is one of six ''special wastes'' (also known as *Bevill wastes*) that were temporarily exempt from hazardous waste regulation under Resource Conservation Recovery Act, until information could be gathered and assessed and the most appropriate regulatory approach could be determined. In 1993, EPA issued a detailed and comprehensive study of CKD in a Report to Congress that explored a broad spectrum of issues related to the adverse effects on human health and the environment from the disposal of CKD. Following extensive evaluation and public comment, on January 31, 1995, EPA concluded that additional control of CKD is warranted to protect human health, and to prevent environmental damage associated with current disposal practices, including off-site uses, for this waste (see 60 FR 7366, February 7, 1995). The Agency issued a proposed rule titled *Standards for the Management of Cement Kiln Dust; Proposed Rule* on August 20, 1999. In the Proposed Rule, EPA established a 90-day public comment period, which is scheduled to close on November 18, 1999. Subsequently, the Agency received requests from stakeholders to extend the comment period another 90 days. EPA supports the requests for an extension, and the comment period will now extend until February 17, 2000.

Dated: September 29, 1999.

Elizabeth Cotsworth,

Director, Office of Solid Waste.

[FR Doc. 99–28214 Filed 10–27–99; 8:45 am]

BILLING CODE 6560–50–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 72

RIN 0920–AA02

Packaging and Handling of Infectious Substances and Select Agents

AGENCY: Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention proposes to

amend the regulations concerning the interstate shipment of infectious substances in order to clarify and expand the existing requirements for proper packaging and handling of these agents. One purpose of the proposed rule is to ensure that all biological materials that are known or suspected of containing an infectious substance are packaged for interstate shipment to minimize the potential for leakage of contents that could contaminate the environment or come into direct physical contact with persons handling such packages during transit. A second purpose is to insure receipt of certain infectious substances. This new regulation will harmonize CDC regulations with other Federal agencies' regulations and with international regulations.

It also updates the requirements for facilities transferring or receiving select agents, incorporating by reference the 4th edition of the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories.

DATE: Written comments must be received on or before December 27, 1999. Written comments on the proposed information collection requirements should also be submitted on or before December 27, 1999.

ADDRESSES: Mail written comments to the following address: Nashandra Hayes, Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop—FO5, Atlanta, Georgia 30333.

Mail written comments on the proposed information collection requirements to: Wendy Taylor, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW, rm. 10235, Washington, DC 20503, Att.: Desk Officer for CDC.

FOR FURTHER INFORMATION CONTACT: Dr. Jonathan Y. Richmond or Dr. Richard Knudsen, Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop F05, Atlanta, Georgia 30333; telephone (404) 639–2453 or 639–3235, respectively.

SUPPLEMENTARY INFORMATION:

Revised Proposed Notice of Rulemaking

Replaces NPRM at 55 FR 7678, March 2, 1990.

I. Background

Under 42 U.S.C. 264, the Department of Health and Human Services is authorized to promulgate regulations to prevent the introduction, transmission and spread of communicable diseases from foreign countries and between the states. Authority was given to CDC in 1971 to regulate the interstate shipment of infectious substances. The current regulations are at 42 CFR part 72. The regulations provide requirements for minimum packaging and labeling for biological products and diagnostic specimens, and include a list of infectious agents for which special tracking is required. These regulations were last updated in 1980.

A Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** on March 2, 1990 (55 FR 7678), to update the existing packaging requirements for infectious substances. Impetus for that NPRM came from postal workers and members of Congress who expressed concerns about the potential risk of exposure to infectious agents for people who handle improperly packaged or damaged packages of biomedical material during transit. Persons shipping these materials also stated that some definitions in the 1980 regulation were unclear. There had also been changes in the list of infectious agents that required notification of receipt.

Comments on the 1990 NPRM focused on two major issues. Numerous parties, including United States Postal Service workers, submitted comments regarding the transport of clinical specimens for diagnostic studies. Several parties encouraged CDC to harmonize the proposed regulation with the international shipping regulations.

Several government agencies and industry groups, in addition to CDC, regulate the packaging, labeling and shipment of infectious materials within the United States and internationally.

- The Department of Transportation (DOT) Hazardous Materials regulations, at 49 CFR parts 171–180, regulate the interstate transportation by surface or air of infectious substances, medical waste, chemical and radioactive materials. That regulation does not apply to the transport of clinical or diagnostic specimens, unless specifically known to contain an infectious substance (49 CFR 173.134).
- The United States Postal Service (USPS) regulates the shipment, by U.S. mail, of etiologic agents, infectious substances, clinical specimens, biological products, and sharps (e.g., contaminated needles and other sharp medical materials) and unsterilized containers (39 CFR and Domestic Mail Manual C023, Etiologic Agent Preparations, Clinical Specimens, and Biological Products; and International Mail Manual 135 Mailable Dangerous Goods).
- The Department of Labor, Occupational Safety and Health Administration (OSHA), at 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens, regulates the worker safety aspects of the handling, packaging and transport of human blood and body fluids, unfixed tissues, organs and cell cultures, and other fluids from humans and animals infected or possibly infected with bloodborne pathogens.
- The Department of Commerce (DOC) maintains a list of controlled items, including certain microorganisms that cannot be exported from the U.S. (15 CFR parts 768–799). The DOC recommends that shippers follow the CDC regulation for packaging when a shipment is allowed to a foreign country.
- The United Nations Committee of Experts on the Transport of Dangerous Goods makes recommendations on the international transport of infectious substances and clinical specimens. These recommendations are included in the International Civil Aeronautics Organization (ICAO) technical instructions, which have been adopted by the International Air Transport Association (IATA).

—ICAO publishes Technical Instructions for the Safe Transport of Dangerous Goods by Air, based on the United Nations (UN) recommendations for the domestic and international transport of infectious substances and clinical (diagnostic) specimens.

—IATA publishes the Dangerous Goods Regulations (DGR), which further describe for IATA member airlines, the national and international recommendations for air transport of infectious substances and clinical (diagnostic) specimens. The IATA DGR are followed by the domestic and international member airlines.

CDC's regulation, currently at 42 CFR part 72, provides packaging and labeling requirements for shipments of infectious materials. There are several reasons why CDC regulates this area in addition to the other agencies listed above. The focus of the CDC regulation is on protection of the public health by minimizing the potential for (1) Direct physical contact with package contents by persons handling such packages during transit, (2) Contamination of the environment, and (3) The spread of disease into the community. The CDC regulations serve by filling the gaps where there is no governance, by complementing the requirements of other agencies where there is overlapping authority, and by providing CDC as a central reporting authority assures availability of CDC's infectious

disease expertise to assist in the response when packages are damaged.

Although there had been some review of the requirements of other agencies when developing the 1990 NPRM, there had not been any comprehensive attempt to harmonize the various requirements. When comments to the 1990 NPRM were reviewed, it became clear that there was confusion among shippers and handlers as to how all the various requirements of other agencies related to the CDC regulations. Because of substantive differences in the requirements and use of different terminology, there was a clear need to harmonize the various requirements.

In response to the comments on the 1990 NPRM, and as part of the regulatory reform/reinventing government initiative, CDC has collaborated with the other agencies and groups to prepare revised proposed CDC regulations that are in harmony with the other requirements, thereby reducing the burden on shippers while still maintaining, or even improving, packaging standards to protect the public health. In some instances, one or more of the other agencies/groups will also be revising their requirements as part of our joint effort to achieve complementary regulations. We invite specific comment on any requirements contained in the proposed CDC regulations which are thought to be inconsistent or unclear in relation to the requirements of any other regulatory authority.

CDC also serves as a Center for Applied Biosafety and Training for the World Health Organization (WHO) and for the UN. In conjunction with the National Institutes of Health, CDC has participated in developing revised international guidelines for the shipment of infectious materials and diagnostic specimens. This NPRM also reflects the recommendations of the WHO biosafety advisory group, as published in 1997, in Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens.

As a result of this extensive collaboration, significant changes have been made to the 1990 NPRM, and a new NPRM is being published to provide the opportunity for laboratories and other shippers of infectious materials, persons who transport or handle packages, public health officials and other affected parties to comment on these proposed regulations to ensure that the final regulations are both complementary to other packaging and shipping requirements and protective of the public health.

CDC believes these regulations will not be an additional burden to shippers because shippers interested in ensuring the integrity of their packages are already utilizing comparable packaging. These regulations will help to ensure that all shippers are aware of and utilize appropriate packaging when shipping infectious substances, thereby protecting the public health.

Comparison of CDC's Proposed Packaging and Labeling Requirements With Other Agencies' and Groups' Packaging and Labeling Requirements

This NPRM proposes packaging and labeling requirements for: (1) Clinical specimens because they may contain infectious agents, and (2) materials known or suspected of containing infectious substances or toxins.

Table 1 shows which types of infectious materials are covered by each regulating authority and the scope of that coverage. As noted in the table, no single agency covers all aspects regarding the shipment of infectious substances.

TABLE 1.—INFECTIOUS SUBSTANCES: COMPARISON OF THE CDC NPRM [1] WITH OSHA,[2] DOT,[3] USPS,[4] AND IATA [5] PACKAGING AND LABELING REQUIREMENTS

Requirements	CDC NPRM [1]	Regulations			
		OSHA [2]	DOT [3]	USPS [4]	IATA [5]
Infectious materials:					
Biological products	+	+	−[6]	+	+
Clinical (diagnostic) specimens	+	+	−[6]	+	+
Cultures and reference stocks	+	+	+	+	+
Packaging materials:					
Watertight primary receptacle	+	+	+	+	+
Absorbent material	+	na	+	+	+
Watertight secondary packaging	+	na	+	+	+
List of contents	+	na	+	−[7]	+
Outer packaging	+	na	+	+	+
Packaging performance standards	+	na	+	+	+
Packaging labels:					
Infectious substance/biohazard symbol label	+	+	+	+	+
Shipping label,[8] outer packaging	+	na	−[9]	+	+
Shipping label, secondary packaging	+	na	na	+	na
Tracking special infectious substances	+	na	na	na	na
Terminology	+	+	+	+	+
Shipping modes covered	All	All	All	Mail only	Air only

Legend: + = same or very similar to the CDC NPRM; − = significantly different from the CDC NPRM; na = not addressed in regulation.

[1] CDC: Centers for Disease Control and Prevention, 42 CFR Part 72 as proposed in this NPRM.
[2] OSHA: Occupational Safety and Health Administration, 29 CFR 1910.1030.
[3] DOT: Department of Transportation, 49 CFR Parts 171–180.
[4] USPS: United States Postal Service, Domestic Mail Manual CO23.
[5] IATA: International Air Transport Association, Dangerous Goods Regulations.
[6] Only those biological products and clinical specimens known to contain infectious substances are covered under 49 CFR 173.134.
[7] USPS requires a list of contents (manifest) for all sharps mailing containers, but only requires a list of contents for other items sent via air transportation
[8] Shipping label: Names, addresses, contact names and phone numbers of person shipping the package and intended recipient (addressee).
[9] DOT specifies that the shipper include an emergency response telephone number on the shipping documents (49 CFR 172.604).

II. Proposed Rule

This proposed rule would amend the existing regulations at 42 CFR part 72 concerning the interstate shipment of infectious substances to clarify and expand the existing requirements for proper packaging and handling of these agents. The purpose of this regulation is to ensure that all biological materials that contain, or may contain, an infectious substance are packaged for interstate shipment in a manner that minimizes the potential for leakage and possible contamination of the environment, or direct physical contact with the contents by persons handling such packages during transit. This rule will also require that infectious agents and toxins capable of causing serious infection, illness or death be labeled and tracked during shipment.

It also updates the requirements for facilities transferring or receiving select agents, incorporating by reference the 4th edition of the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories.

A. Definitions

Biological products—Biological product means a biological product that is subject to preparation and manufacture in accordance with the provisions of 9 CFR part 102 (Licensed Veterinary Biological Products), 9 CFR part 103 (Biological Products for Experimental Treatment of Animals), 9 CFR part 104 (Imported Biological Products), 21 CFR part 312 (Investigational New Drug Application), or 21 CFR parts 600–680 (Biologics) and that, in accordance with such provisions, may be shipped in interstate traffic. FDA-approved vaccines are exempt from this regulation.

Only biological products that are known or presumed to contain an infectious substance are subject to this regulation.

Clinical Specimens—A clinical specimen is any human or animal material including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluids, that is collected for the purpose of diagnosis, research, or other purposes. Formalin-fixed specimens are excluded. Animal material clinical specimens are subject to the regulation only if known or suspected of containing human pathogens.

Under the concept of Universal Precautions all bodily fluids of human origin must be handled as if they are infectious in order to minimize the potential for exposure to bloodborne pathogens. Section 72.3 in this NPRM meets those requirements.

Some clinical specimens are known or presumed to contain viable infectious micro-organisms that could result in an infection if an exposure occurred during a transport mishap. These specimens must be packaged and labeled as infectious substances (see § 72.4(a)). If exposure could result in an extremely serious infection or illness in an exposed worker or the public, such specimens are considered special infectious substances and must be tracked during shipment.

Infectious substance—CDC has replaced the term ''etiologic agent'' with the DOT and international term ''infectious substance''. For purposes of this regulation, an infectious substance is any substance, clinical specimen or culture, isolate, or other derivative of a clinical specimen that contains, or is suspected of containing a viable infectious virus, prion, or a viable microorganism, such as a bacterium, rickettsia, parasite or fungus, that is known or reasonably believed to cause disease in humans. Toxins known to be pathogenic are to be packaged and shipped either as infectious substances or as special infectious substances (§ 72.5), as applicable.

Examples of infectious substances include:

1. All cultures containing or suspected of containing a microorganism that causes or may cause disease in humans;
2. All human or animal clinical specimens that are known or suspected of containing an infectious microorganism or toxin;
3. Environmental samples to the extent that they are suspected of containing human pathogens at a level that presents risk of infection.
4. Other specimens not included above and designated as infectious by a qualified person (e.g., physician, scientist, veterinarian, nurse).

To maintain consistency with DOT regulations, a qualifying sentence has been added to the definition of an infectious substance that states that a microbial toxin that causes disease in humans will be packaged and shipped as an infectious substance.

Packaging—A change in this NPRM is the adoption of DOT and IATA terminology to clarify that there is agreement among the various organizations involved in regulating this area. The terms ''primary container'', ''secondary container'', and ''outer container'' have been replaced with the DOT terms and definitions of ''primary receptacle'', ''secondary packaging'', and ''outer packaging'.

Special infectious substance means any of the microbiological agents or toxins listed in § 72.5 or appendix A to part 72 (proposed to be recodified as appendix to subpart B). These special infectious substances include those agents listed in the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories, as biosafety level (BSL) 4 and most of the BSL3 agents. Special infectious substances present a potentially high risk of infection and/or death to persons exposed to them through either direct contact, aerosol or ingestion. Therefore, shipments of special infectious substances are tracked to assure their safe arrival.

B. Transport of Clinical Specimens

Clinical specimens are to be packaged in such a manner that they will remain intact under conditions that normally occur during transit. If the primary receptacle were to break or leak during transit, the specimen would be contained by the absorbent material and by the secondary packaging, so no material would leak to the outside surface of the outer packaging.

Packaging requirements for clinical specimens proposed in this NPRM are similar to those for infectious substances, except that the proposed performance standards are less rigorous. These packaging and labeling requirements meet the specifications established by OSHA and various international agencies.

C. Transport of Infectious Substances

Infectious substances are to be packaged in such a manner that they would withstand conditions which would normally occur during transit and would not leak even if the primary receptacle were to break. In addition, the proposed packaging requirements have been enhanced by adding a requirement that the packaging be capable of passing a drop test. The completed package must be capable of passing the tests specified in 49 CFR 178.609. The requirements established in this NPRM meet those of DOT, OSHA, various international agencies and are consistent with the 1999 IATA Dangerous Goods Regulations.

In keeping with DOT and the international guidelines and regulations, volume/weight limits have been changed to four liters or four kilograms in a single package (excluding the packaging and coolant weights). An itemized list of contents must be enclosed between the secondary packaging and outer packaging. The proposed rule also details provisions associated with substances shipped refrigerated or frozen (prefrozen packs,

wet or dry ice), shipped in liquid nitrogen, or as lyophilized materials.

The proposed rule requires on the outer packaging a black and white label bearing the words ''Infectious Substance'', CDC's telephone number for reporting damaged packages, and the biohazard symbol. The proposed rule also would require that the name, address, and telephone number of both the shipper and recipient be affixed to the outer package.

D. Transport of Special Infectious Substances; Failure to Receive

This proposed rule would be unique in requiring that the most dangerous human pathogens be shipped as ''special infectious substances''. These agents include those identified for work at biosafety level 3 and 4 as specified in the Biosafety in Microbiological and Biomedical Laboratories publication.

Special infectious substances must be shipped by the carrier and a system that provides for tracking the shipment and notifying CDC if the packages are not received. Information gathered by CDC from such notifications will be useful in identifying problems and implementing corrective actions.

E. Select Agents

Some of the microorganisms listed as special infectious substances are also considered to be ''select agents'' and are regulated in 42 CFR 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents) (proposed here to be renumbered as Section 72.11). The only changes in this proposed rule to § 72.6 are at § 72.6 (a)(5) (now § 72.11 (a)(5)), and § 72.6 (c)(1) (now § 72.11(c)(1)), which are revised to incorporate the 4th edition of the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories.

F. Variations

To promote innovation and allow for new technologies, the proposed rule would allow the Director, CDC, to approve variations from the requirements of this subpart if, upon written application, it is found that such variations provide protection at least equivalent to that provided by the requirements in this subpart, as finalized, and such findings are made a matter of official written record.

G. Penalties

Violations of the rule would be subject to criminal penalties as prescribed in 42 U.S.C. 271 and 18 U.S.C. 3559, 3571. Specifically, individuals in violation of the rule would be subject to a fine or imprisonment of not more than one year, or both.

III. Procurement of Labels

Shippers will be able to order a supply of the two shipping labels described in the regulations from private printers by furnishing them the exact specifications provided in the final rule, or by purchasing the labels from the Superintendent of Documents (U.S. Government Printing Office, Mail Stop: SSOP, Washington, D.C. 20402–9328).

IV. Analysis of Impacts

A. Review Under Executive Order 12866, Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (P.L. 104–4), and by the Regulatory Flexibility Act (5 U.S.C 603–605)

The Department has examined the potential impact of this proposed rule as directed by Executive Order 12866, by sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4), and by the Regulatory Flexibility Act (5 U.S.C. 603–605).

Executive Order 12866 directs Federal agencies to assess the costs and benefits of available regulatory alternatives, and, when regulation is necessary, to select regulatory approaches that maximize net benefits. This proposed rule is designed to ensure that all biological materials that contain, or may contain, an infectious substance are packaged in a manner for interstate shipment that minimizes the potential for leakage and possible contamination of the environment or direct physical contact with the contents by persons handling such packages during transit. The proposed rule is designed to complement other shipping requirements developed by the Departments of Commerce, Agriculture, and Transportation, the USPS, OSHA, and the International Air Transport Association and, thereby, to reduce the burden on shippers while imposing minimal administrative costs, and to prevent possible serious, harmful effects to public safety and health. (The proposal has been reviewed by the Office of Management and Budget under the terms of the Executive Order.)

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. 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 does not know how many small entities will be impacted by this regulation, and does not know what the economic impact on those small entities would be. However, CDC believes that packaging requirements set forth in this rule would not be an additional burden on shippers because this is an amendment to existing PHS rules with which shippers must comply. In addition, it will harmonize these rules with other existing regulations that shippers must follow. CDC believes that this rule will lessen confusion regarding proper packaging and shipping of infectious materials and will bring HHS regulations into conformity with other regulations. CDC is requesting information/comments on the number of small entities that would be impacted by this NPRM, the economic burden on those small entities and why the Secretary should not certify that this rule will have no significant impact on small entities. CDC is also requesting comments/recommendations on other possible less burdensome approaches to ensuring that all infectious or potentially infectious materials are packaged and shipped in a way that minimizes risks to workers, the public and the environment.

These regulations will help to ensure that all shippers are aware of and utilize appropriate packaging when shipping infectious substances, thereby protecting the public health.

B. Review Under the Paperwork Reduction Act of 1995

The proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description and respondent description of the information collection are shown below with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, gathering and maintaining the necessary data, and completing and reviewing the collection of information. With respect to the following collection of information, CDC invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of CDC's public

health functions, including whether the information shall have practical utility; (b) the accuracy of CDC's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automatic collection techniques or other forms of information technology.

Title: Packaging and Handling of Infectious Substances and Select Agents.

Description: The CDC proposes to amend the regulations concerning the interstate shipment of infectious substances in order to clarify and expand requirements for proper packaging and handling of these agents. The proposed rule would ensure that all biological materials that may contain an infectious substance are packaged for interstate shipment in a manner that minimizes the potential for leakage and possible contamination of the environment or direct physical contact with the contents by persons handling such packages during transport. It also updates the requirements for facilities transferring or receiving select agents, incorporating by reference the 4th edition of the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories.

Anyone handling damaged or leaking packages of infectious substances during interstate shipment must isolate the package, notify the shipper and intended recipient immediately and notify CDC as soon as feasible (1–800–232–0124). When notifying CDC, the caller should provide a description of the condition of the package, the name, address and telephone number of the shipper, and any other pertinent information, so that information and assistance can be provided, as necessary, regarding appropriate decontamination and disposal procedures.

Persons who ship packages containing special infectious substances must notify the addressee of the date of shipment, and the addressee must confirm receipt by telephone or other electronic means. If the shipper does not receive such confirmation within 3 days of anticipated delivery, the shipper must then contact CDC within 24 hours to enable the agency to determine whether a public health response is necessary. Information gathered by CDC from such notifications will also be useful in identifying problems and implementing corrective actions.

Description of Respondents: Government agencies, universities, research institutions, laboratories, private companies and others that ship or receive infectious substances, and government or commercial carriers of infectious substances.

ESTIMATED ANNUAL REPORTING BURDEN

CFR section	Number of respondents	Frequency of reporting	Total annual responses	Hours per response	Total hours
72.4(b)	500	1x/yr	50	0.1	5
72.5(b)	200	10/yr	2,000	0.1	200
72.5(c)	200	10/yr	2,000	0.1	200
72.5(d)	20	1/yr	20	0.2	4
Total					409

Reporting or Disclosures: These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on past experiences of respondents reporting such information to CDC. There are no capital costs or operating and maintenance costs for the respondents associated with this information collection.

The agency has submitted a copy of this proposed rule to OMB for its review of this information collection. Interested persons are requested to submit written comments regarding this information collection, including suggestions for reducing the burden, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW, Rm. 10235, Washington, DC 20503, Att.: Desk Officer for CDC.

List of subjects in 42 CFR Part 72

Biologics, packaging and containers, Transportation.

Dated: March 12, 1999.

Jeffrey Koplan,

Director, Centers for Disease Control and Prevention.

Dated: May 31, 1999.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

For the reasons stated in the preamble, it is proposed to amend 42 CFR Chapter I, part 72, as follows:

PART 72—PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS

1. The authority citation for Part 72 is revised to read as follows:

Authority: 42 U.S.C. 216, 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; 42 U.S.C. 262 note.

2. The heading of part 72 is revised to read as set forth above.

3. Sections 72.1–72.5 are revised.

4. 72.6 is redesignated as § 72.11.

5. A new § 72.6 is added.

6. A heading for subpart A is added and sections §§ 72.1–72.6 are transferred to subpart A.

7. A heading for subpart B is added and redesignated section 72.11 is transferred to subpart B and amended by revising paragraphs (a)(5) and (c)(1).

8. Section 72.7 is redesignated as section 72.21.

9. A heading for subpart C is added and redesignated section 72.21 is transferred to subpart C.

10. Appendix A to Part 72 is transferred to subpart B and the heading is revised to read ''Appendix to Subpart B''.

The additions and revisions to part 72 read as follows:

Subpart A—Interstate Shipment of Biological Materials That Contain or May Contain Infectious Substances

§ 72.1 Purpose.

The purpose of this regulation is to ensure that all materials that contain or may contain an infectious substance are packaged for interstate shipment in a manner that minimizes the potential for leakage and possible contamination of the environment or direct physical contact with the contents by persons handling such packages during transit.

The rule also requires the tracking of shipments of special infectious substances and requires registration of certain select agents. The requirements of this subpart are in addition to and not in lieu of any other packaging or other requirements for the transportation of infectious substances in interstate traffic as prescribed by the US Department of Transportation, the US Postal Service and other agencies of the Federal Government.

§ 72.2 Definitions.

As used in this subpart:

Absorbent material means material that is capable of absorbing liquids. It may be either particulate or non-particulate, but if particulate, it shall be contained so it does not leak out of the package.

Biological product means a biological product that is subject to preparation and manufacture in accordance with the provisions of 9 CFR part 102 (Licensed Veterinary Biological Products), 9 CFR part 103 (Biological Products for Experimental Treatment of Animals), 9 CFR part 104 (Imported Biological Products), 21 CFR part 312 (Investigational New Drug Application), or 21 CFR parts 600–680 (Biologics) and that, in accordance with such provisions, may be shipped in interstate traffic. Only biological products that are known or presumed to contain an infectious substance are subject to this regulation. FDA-approved vaccines are exempt from this regulation.

Clinical specimen (diagnostic specimen) is any human or animal material including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluids, that is collected for the purposes of diagnosis, research, or other purposes. Formalin-fixed specimens are exempt from this regulation. Animal material clinical specimens are subject to this regulation only if known or suspected of containing human pathogens. All human clinical specimens are covered.

Coolant material means material such as ice, dry ice, liquid nitrogen, and gel packs, that is included in the package to cool the contents.

Infectious substance (etiologic agent) and infectious material are considered synonymous. An infectious substance is defined as a substance containing or suspected of containing an infectious virus, prion, or a viable microorganism, such as a bacterium, rickettsia, parasite or fungus, that is known or reasonably believed to cause disease in humans. Toxins known to be pathogenic to humans are to be packaged and shipped as infectious substances or special infectious substances (§ 72.5). The term ''infectious substance'' excludes any medical waste that is regulated under other federal regulations. For purposes of this regulation, infectious substances include:

(1) All cultures containing or suspected of containing a microorganism that causes or may cause disease in humans;

(2) All human or animal clinical specimens that are known or suspected of containing an infectious microorganism or toxin;

(3) Environmental samples if they are suspected of containing human pathogens at a level that presents risk of infection.

(4) Other specimens not included above and designated as infectious by a qualified person (e.g., a physician, scientist, veterinarian, nurse).

Interstate traffic means the movement, including any portion entirely within a State or possession, from a point of origin in any State or possession or from outside the Untied States, to a point of destination in any other State or possession; or form any State or possession to another country; or between a point of origin and a point of destination in the same State or possession but through any other State, possession or contiguous foreign country.

Outer packaging means the container in which a primary receptacle and secondary package, together with any absorbent materials and cushioning, is shipped.

Primary receptacle means a tube, vial, bottle, ampule, or similar item that contains the material being shipped.

Secondary packaging means a container into which the primary receptacle is placed.

Special infectious substance means any of the microbiological agents or toxins listed in § 72.5 or appendix to subpart B of this part, including any human or animal specimens known or suspected of containing such a microbial agent, or any other microorganism that could cause serious infection and/or death in persons exposed to them through either direct contact, aerosol or ingestion. Additional changes to this list may be made through publication of a notice in the **Federal Register.**

§ 72.3 Transportation of clinical specimens; minimum packaging requirements.

(a) *General requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any clinical specimen unless such material is packaged, labeled, and shipped in accordance with the requirements of this section. However, any clinical specimens known or suspected to contain an infectious substance shall be labeled and packaged as described under § 72.4.

(1) Clinical specimens shall be packaged to withstand conditions incident to ordinary handling in transit, including shocks and pressure changes, so that if leakage of the primary receptacle(s) occurs during transit, the contents will be contained within the outer packaging. Required packaging and components are as follows:

(i) A watertight primary receptacle.

(ii) Watertight secondary packaging.

(iii) Absorbent material must be placed between the primary receptacle(s) and the secondary packaging. If multiple primary receptacles are placed in a secondary packaging, they msut be placed so as to ensure that contact between them is prevented. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.

(iv) Outer packaging must be of adequate strength for its capacity, mass and intended use. Any package with liquid contents shall have sturdy outer packaging constructed of corrugated cardboard, fiberboard, wood, metal, or rigid plastic. Styrofoam, plastic bags and paper envelopes are unacceptable outer packaging for such packages.

(2) The size of the outer package must be at least 100 mm (3.9 inches) in the smallest overall external dimension.

(3) The primary receptacle and the secondary packaging must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95kPA (0.95 bar, 13.8lb/in^2) in the temperature range of −40° C to +55° C (−40° F to 131° F).

(4) An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(5) For substances shipped at ambient temperatures or higher, means of ensuring a leak-proof seal of the primary receptacle, such as a heat seal, skirted stopper or metal crimp seal must be provided. Screw caps must be reinforced to ensure they do not leak. Evacuated specimen collection tubes such as Vacutainer® (Becton-Dickinson, Franklin Lakes, NJ) tubes do not require additional sealing.

(6) For substances shipped refrigerated or frozen (wet ice, prefrozen packs, dry ice), ice or dry ice must be placed outside the secondary packaging(s). Interior support must be provided to secure the secondary packaging(s) in the original position as the ice or dry ice melts or sublimates, respectively. If ice is used, the outer

packaging must be leak-proof. If dry ice is used, the outer packaging must permit the release of carbon dioxide gas. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

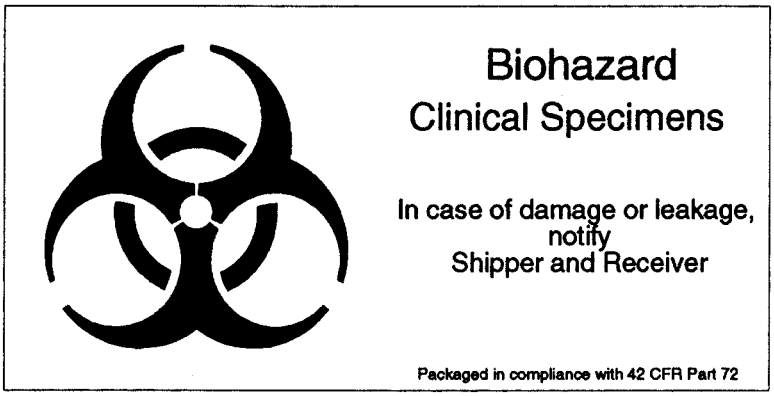
(7) *For substances shipped in liquid nitrogen,* a watertight material, capable of withstanding cryogenic temperatures must be used as the primary receptacles. Secondary packaging must also withstand very low temperatures. All requirements for shipment of liquid nitrogen must also be observed. The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

(8) *For lyophilized substances,* primary receptacles capable of containing lyophilized substances must be used (including, but not limited to, flame-sealed glass ampules or rubber-stoppered glass vials with metal seals).

(9) The completed package must be capable of withstanding at least a 1.2 meter drop on a hard unyielding surface without release of its contents.

(10)(i) Biohazard Labeling is required for the primary receptacle and outer packaging as described in 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens.

(ii) The outer packaging shall bear a label as illustrated and described below:



(A) The color of material on which the label is printed shall be bright orange; the printing shall be black. The color of the biohazard symbol shall be black.

(B) The label shall be a rectangle measuring 51 mm (2 inches) high by 102.5 mm (4 inches) long.

(C) The biohazard symbol, measuring 40 mm (1.56 inches) in diameter, shall be centered on a square measuring 51 mm (2 inches) on each side.

(D) Size of the letters (Helvetica) on the label shall be as follows:

Biohazard—16 pt.
Clinical specimens—14 pt.
Packaged in compliance with 42 CFR part 72—6 pt.
In case of damage or leakage, notify—10 pt.
Shipper and Receiver—10 pt.

(iii) The outer packaging shall also bear a shipping label with the names, addresses, and contact names and telephone numbers of the individual/institution sending the package and the intended recipient (addressee).

(b) *Leaking packages.* The carrier, the receiver, or anyone handling a package described in paragraph (a) of this section that is leaking, shall upon discovery of leakage, isolate the package, and immediately, or as soon as feasible, notify the shipper and intended recipient to receive instructions on clean-up and disposition of the package.

§ 72.4 Transportation of infectious substances; minimum packaging requirements.

(a) *General requirements.* No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any infectious substance, including clinical specimens or biological products that are known or presumed to contain infectious substances, unless such material is packaged, labeled, and shipped in accordance with the requirements of this section.

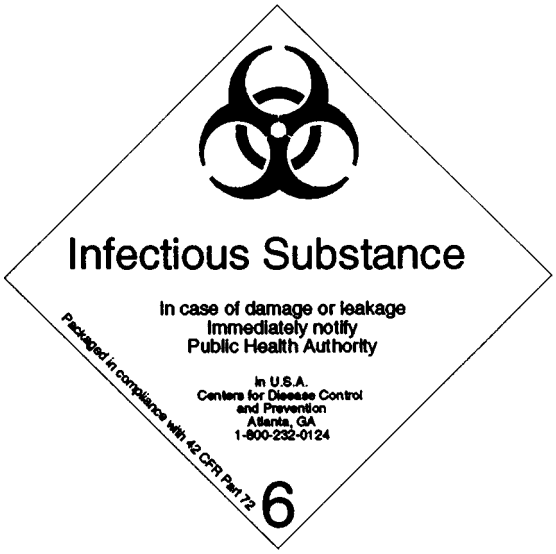
(1) Infectious substances shall be packaged to meet the requirements of § 72.3(a) (1)–(8).

(2) The maximum amount of infectious substances that may be placed in a single outer shipping package shall not exceed four liters or four kilograms, excluding the packaging and coolant weights.

(3) In addition, each complete package must be capable of passing the tests specified in 49 CFR 178.609.

(4)(i) Biohazard Labeling is required for the primary receptacle and outer package as described in 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens.

(ii) The outer packaging shall bear a label as illustrated and described below:



(A) The color of material on which the label is printed shall be white and the printing shall be in black; the biohazard symbol shall be in black.

(B) The label shall be a diamond-on-point measuring, at a minimum, 51 mm (4 inches) on each side.

(C) The black biohazard symbol, measuring 21 mm (.81 inches) in diameter, shall be centered on a square measuring 51 mm (2 inches) on each side.

(D) Size of the letters (Helvetica) on the label shall be as follows:

Infectious Substance—16 pt.
Packaged in compliance with 42 CFR Part 72—5 pt.
In case of damage or leakage—7 pt.
Immediately notify—7 pt.
Public Health Authority—7 pt.
In U.S.A.—5 pt
Centers for Disease Control and Prevention—5 pt.
Atlanta, GA—5 pt
1–800–232–0124—5 pt.
6—24 pt.

(E) The number 6 (mandated by the DOT) shall be centered at the bottom of the label.

(iii) The outer packaging and the secondary packaging shall also bear labels with the names, addresses, and contact names and telephone numbers of the individual/institution sending the package and of the intended recipient (addressee).

(b) *Damaged or leaking packages.* The carrier, the receiver, or anyone handling a package described in paragraph (a) of this section that is damaged or leaking, shall upon discovery of damage or leakage, isolate the package and immediately, or as soon as feasible, in order to receive instructions on appropriate decontamination and disposal, notify the shipper, receiver, and the Centers for Disease Control and Prevention by telephone at 1–800–232–0124. The caller shall provide a description of the condition of the package; the name, address and telephone number of the shipper; and other pertinent information.

(This information collection has been approved by OMB (0920–0199)).

§ 72.5 Packaging and method of shipment of special infectious substances; failure to receive.

(a) *List of special infectious substances.* (1) The following microorganisms and toxins are considered special infectious substances because they present a potentially high risk of infection and/or death to persons exposed to them through either direct contact, aerosol or ingestion. Shipments of special infectious substances must be tracked to assure their safe arrival.

Bacterial Agents

Bacillus anthracis
Bartonella bacilliformis
Brucella, all species
Burkholderia (Pseudomonas) mallei
Burkholderia (Pseudomonas) pseudomallei
Clostridium botulinum
Francisella tularensis
Mycobacterium tuberculosis (drug-resistant strains)
Yersinia pestis

Viral and Rickettsial Agents

Arboviruses assigned to Biosafety level 3 or 4 in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories, which may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Other Viral Agents

Crimean-Congo hemorrhagic fever virus
Eastern Equine Encephalitis virus
Ebola virus
Hantaan virus (Korean hemorrhagic fever virus)
Hantavirus (all viruses of genus)
Herpesvirus simiae (B virus)
Lassa fever virus
Lymphocytic choriomeningitis virus
Marburg virus
Pox viruses pathogenic for humans (e.g., smallpox, monkeypox)
South American Hemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
Tick-borne Encephalitis complex viruses
Venezuelan Equine Encephalitis virus
Yellow fever virus

Rickettsial Agents:

Rickettsia rickettsiae
Rickettsia prowazekii
Coxiella burnetti

Fungal Agents

Coccidioides immitis
Histoplasma capsulatum
Histoplasma duboisii

Toxins

Toxins listed in appendix to Subpart B of this part are to be shipped as special infectious substances. Other microbial toxins known to be pathogenic shall be shipped as infectious substances, as provided under § 72.4.

(2) This list may be supplemented through publication of a notice in the **Federal Register**. Call 1–888–232–3299 (the FAX Information system in CDC's Office of Health and Safety) for a copy of the current list, or check the CDC website at http://www.cdc.gov/od/ohs.

(b) *Packaging and method of shipment.* All materials that contain or are reasonably believed to contain a special infectious substance shall be packaged and labeled for interstate shipment according to the requirements of § 72.4. In addition, the shipper shall: Use a shipping system that provides for tracking during transport (e.g., registered mail or those of certain

private carriers); Provide 24 hours-per-day telephonic response to emergency calls from carriers in case of a spill or incident involving a package containing a special infectious agent; and, Notify the addressee by telephone or other electronic means of the date of shipment on the date of shipment, or provide a written schedule of shipment in advance, and request confirmation of receipt of each shipment. Records of such notifications shall be retained by the shipper until notified of receipt.

(c) *Confirmation of receipt.* Upon receipt, the addressee shall provide confirmation to the shipper by telephone or other electronic means.

(d) *Failure to receive.* When confirmation of receipt of material designated in paragraph (a) of this section is not received by the shipper within 3 days following anticipated delivery of the package, the shipper shall notify the carrier which shall immediately seek to ascertain the disposition of the package. In addition, the shipper shall notify the Centers for Disease Control and Prevention within 24 hours by telephone at 1–800–232–0214 to enable the agency to determine whether a public health response is necessary.

§ 72.6 Requirements; variations.

The Director, Centers for Disease Control and Prevention, may approve variations from the requirements of this subpart if, upon written application, review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this subpart, and such findings are made a matter of official written record.

§ 72.7 [Redesignated as § 72.21]

Subpart B—Handling of Select Agents

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

(a) * * *

(5) The requirements for BSL–2, 3, and 4 operations pertaining to this section 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, 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.

* * * * *

(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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Subpart C—Penalties

§ 72.21 [Redesignated from § 72.7]

Appendix A to Part 72 [Transferred to Subpart B and heading revised]

Appendix to Subpart B

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[FR Doc. 99–27640 Filed 10–27–99; 8:45 am]

BILLING CODE 4163–18–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1825 and 1852

Standard Clause for Export Controlled Technology

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: This is a proposed rule amending the NASA FAR Supplement (NFS) to add a contract clause the purpose of which is to assure contractors (and offerors) understand that they are responsible for controlling export compliance in accordance with law and regulation, and that they should not rely on NASA to obtain necessary licenses in execution of the contracted work. This clause complies with performance based contracting principles. It notifies the contractor of its responsibilities under the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations (EAR) during contract performance. Additional, tailored clauses may be required when specific exemptions or licenses are applicable, as, for example, with the International Space Station. These clauses would be developed on a case-by-case basis.

DATES: Comments should be submitted on or before December 27, 1999.

ADDRESSES: Interested parties should submit written comments to Patrick Flynn, NASA Headquarters, Office of Procurement, Contract Management Division (Code HK), Washington, DC 20546. Comments may also be submitted by e-mail to patrick.flynn@hq.nasa.gov.

FOR FURTHER INFORMATION CONTACT: Patrick Flynn, NASA, Office of Procurement, Contract Management Division (Code HK), (202) 358–0460.

SUPPLEMENTARY INFORMATION:

A. Background

The potential for disclosure of military or dual-use technology to foreign powers is a serious concern throughout the Government. The acquisition community should take steps to control exports of sensitive data, and hardware, and services at all levels of contract management, including subcontracts and technical interchanges. In response to field center requests, NASA proposes an ''Export Licenses'' clause and guidance for the NFS. The clause notifies contractors they are responsible for obtaining all required licenses when exporting.

B. Regulatory Flexibility Act

NASA certifies that this regulation will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it does not impose any new requirements.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the NFS do not impose any record keeping or information collection requirements, or collections of information from offerors, contractors, or members of the public that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 1825 and, 1852

Government procurement.

Tom Luedtke,

Associate Administrator for Procurement.

Accordingly, 48 CFR Part Parts 1825 and 1852 are proposed to be amended as follows:

1. The authority citation for 48 CFR Parts 1825 and 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).