(b) You must maintain records of the following information for each 30 day period:

(1) Hours of operation.

(2) Production rate of nitric acid, expressed as 100 percent nitric acid.

(3) NO_X mass emissions.

(c) You must maintain records of the following time periods:

(1) Times when you were not in compliance with the emissions standards.

(2) Times when the pollutant concentration exceeded full span of the NO_X pollutant monitoring equipment.

(3) Times when the volumetric flow rate exceeded the high value of the volumetric flow rate monitoring equipment.

(d) You must maintain records of the reasons for any periods of noncompliance and description of corrective actions taken.

(e) You must maintain records of any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications.

(f) For each malfunction, you must maintain records of the following information:

(1) Records of the occurrence and duration of each malfunction of operation (*i.e.,* process equipment) or the air pollution control and monitoring equipment.

(2) Records of actions taken during periods of malfunction to minimize emissions in accordance with section 60.72a(b), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

§ 60.77a Reporting.

(a) The performance test data from the initial and subsequent performance tests and from the performance evaluations of the continuous monitors must be submitted to the Administrator at the appropriate address as shown in 40 CFR 60.4.

(b) The following information must be reported to the Administrator for each 30 day period where you were not in compliance with the emissions standard:

(1) Time period.

(2) NO_X emission rates (lb/ton of acid produced).

(3) Reasons for noncompliance with the emissions standard; and description of corrective actions taken.

(c) You must also report the following whenever they occur:

(1) Times when the pollutant concentration exceeded full span of the NO_X pollutant monitoring equipment.

(2) Times when the volumetric flow rate exceeded the high value of the volumetric flow rate monitoring equipment.

(d) You must report any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications.

(e) As of December 31, 2011 and within 60 days after the date of completing each performance evaluation or test required under this subpart, you must submit the relative accuracy test audit data and performance test data by successfully submitting the data electronically to EPA's Central Data Exchange (CDX) by using the Electronic Reporting Tool (ERT) (see *http://www.epa.gov/ttn/chief/ert/ert_tool.html/*).

(f) If a malfunction occurred during the reporting period, you must submit a report that contains the following:

(1) The number, duration, and a brief description for each type of malfunction which occurred during the reporting period and which caused or may have caused any applicable emission limitation to be exceeded.

(2) A description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with 60.72a(b), including actions taken to correct a malfunction.

[FR Doc. 2011–26089 Filed 10–13–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2011–0007]

RIN 0920–AA37

Foreign Quarantine; Etiological Agents, Hosts, and Vectors

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations that cover the importation of etiological agents and the hosts and vectors of human disease. The changes are proposed to improve CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.

DATES: To be assured consideration, comments must be received on or before December 13, 2011. Comments received after the close of the comment period will be considered to the fullest extent possible.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0920–AA37 in the heading of this document, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: SAPcomments@cdc.gov.* Please include the RIN number in the subject line of the message.
- *Fax:* 404–718–2093.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, ATTN: Importation Regulations, 1600 Clifton Road, NE., MS A–46, Atlanta, Georgia 30333.
- *Hand Delivery/Courier:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, ATTN: Importation Regulations, 1600 Clifton Road, NE., MS A–46, Atlanta, Georgia 30333.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE., Atlanta, GA 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Select Agents and Toxins to schedule your visit. Our general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change.

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, PhD, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30333. Telephone: 404–718–2000.

SUPPLEMENTARY INFORMATION: The Preamble to this notice of proposed rulemaking is organized as follows:

I. Background

A. HHS/CDC Authority

This NPRM is proposed under the authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). This provision authorizes the Health and Human Services (HHS) Secretary to make and enforce such regulations as in her judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the HHS Secretary may authorize a variety of public health measures, including inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures.

The Foreign Quarantine regulations (42 CFR part 71) set forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Part 71, Subpart F (Importations) contains provisions for importation of etiological agents, hosts, and vectors (42 CFR 71.54), requiring persons to obtain a permit issued by the CDC before importing or distributing after import of these materials.

II. Proposed Changes to 42 CFR 71.54

This document proposes to revise the regulations that cover the importation of etiological agents and the hosts and vectors of human disease (42 CFR 71.54) as described below. We will consider comments that are received within 60 days of publication of this notice in the **Federal Register**.

A. Section Heading and Definitions

The heading for 42 CFR 71.54 would be changed from ''Etiological agents, hosts, and vectors.'' to ''Import Regulations for Infectious Biological Agents, Infectious Material, and Vectors'' to clarify proposed changes discussed below. Under the proposed changes, only the following infectious biological agents, materials, and vectors would require a permit issued by the CDC Director prior to entry into the United States, or subsequently being transferred within the United States:

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

Infectious material. Any material which is known or suspected to contain a biological agent infectious to humans.

Vector. Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system known to transfer or capable of transferring an infectious biological agent to a human (*e.g.,* a mosquito).

We also propose to remove the term ''host'' because we believe ''host'' means the same as the current proposed definition for ''vector.'' However, CDC is interested in comments concerning the removal of the term ''host'' from the proposed language. CDC is also interested in comments concerning the scope of the definition for ''vector'' and whether it should be limited in some manner to exclude animals intended to be exhibited in zoos or mounted animals or hides intended for museum displays while remaining broad enough to include mosquitoes that carry the malaria parasite *Plasmodium* between humans.

B. Biosafety and Inspection Provisions

The key principle in selecting the appropriate safeguards for the conduct of the microbiological research is ''risk assessment.'' Risk assessment is a process used to identify the hazardous characteristics of a known infectious agent or potentially infectious agent or material, the activities that can result in exposure to such an agent, the likelihood that such exposure will cause a laboratory-acquired infection (LAI), and the probable consequences of such an infection. The information identified through risk assessment is used to guide the selection of appropriate microbiological practices, safety equipment, and facility safeguards (biosafety measures) that, when used properly, can prevent exposures and dramatically reduce the incidence of LAIs. Risk assessment is a common first step in an overall risk-management process.

The safe possession and work with infectious biological agents, infectious material, and vectors requires that importers have the appropriate biosafety measures in place for imported material. Accordingly, CDC proposes that import regulations clearly state that the applicant have biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use. These biosafety measures may be entity-wide, laboratory-specific, or agent-specific. CDC believes importers engaged in microbiological research and related activities utilizing safe laboratory practices, safety equipment, and facility safeguards will reduce the incidence of LAIs and other incidents and will protect the public health and environment.

In developing the appropriate biosafety measures, importers working with infectious biological agents, infectious material, and vectors should use the appropriate microbiological practices, safety equipment, and facility safeguards that, when used properly, can prevent exposures and dramatically reduce the incidence of LAIs. An applicant should consider: (1) The CDC/National Institutes of Health (NIH) publication, ''Biosafety in Microbiological and Biomedical Laboratories'' (BMBL), including all appendices. Copies may be obtained at the CDC Web site at *http://www.cdc.gov/* and (2) The ''NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).'' Copies may be obtained from the NIH Web site at *http://oba.od.nih.gov/rdna/nih_guidelines_oba.html.*

To implement CDC's inspection authority as provided under 42 U.S.C. 264(a), CDC proposes that prior to CDC issuing a permit, it may inspect the applicant's facility to evaluate whether the importer's implementation of its biosafety measures (*e.g.,* physical structure and features of the facility, and operational and procedural safeguards) are effective and commensurate with the risk posed by the infectious biological agent, infectious material, and/or vector, and the level of risk given its intended use. CDC will use the following specific criteria to determine which entities are to be inspected—(1) facilities that request to perform research with imported agents that would need to be conducted in a biosafety level (BSL)–3, BSL–4, Animal biosafety level (ABSL)–3, ABSL–4 or BSL–3 Agriculture laboratory as described in the BMBL (*e.g., Mycobacterium tuberculosis*), and (2) that have not been inspected by CDC's Select Agent Program.

Even though CDC is proposing that the import regulations specifically state a requirement for appropriate biosafety measures as a prerequisite for the

issuance of a permit, we believe, based on our experience with import permit submissions addressing the capabilities of the receiving laboratories, that most, if not all, importers of etiological agents already have written biosafety plans. Based on permit applications submitted to CDC between March 1, 2011, and July 22, 2011, the total number of applicants with adequate written biosafety plans was 632 out of 644 or 98%. Based on the content of those plans, CDC is confident that each of them would meet the requirement for appropriate biosafety measures of this NPRM. If an importer's biosafety measures were found to be inadequate, CDC would offer to work with the entity to address any biosafety issues prior to denying the permit.

C. Permit Exemptions

Select Agents and Toxins

Currently, in accordance with 9 CFR part 121 and 42 CFR part 73 (Select Agent Regulations), only individuals or entities registered with the CDC or U.S. Department of Agriculture, Animal and Plant Health Inspection Service's (APHIS') Select Agent Program can legally import select agents (*i.e.,* biological agents and toxins that could pose a severe threat to public health and safety) into the United States. A select agent may only be imported under the conditions described in 9 CFR 121.16 and 42 CFR 73.16 and must be authorized by APHIS or CDC prior to importation. Therefore, we are proposing that importation of select agents in accordance with the Select Agent Regulations be exempted from the requirement to have an additional import permit under 42 CFR 71.54.

Diagnostic Specimens

As defined by the proposed rule, a diagnostic specimen is any specimen of human or animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or an environmental sample. CDC's policy regarding diagnostic specimens is that only diagnostic specimens that are known to contain, or are suspected of containing, an infectious biological agent require a permit issued by the CDC Director prior to entry into the United States or subsequent transfer within the United States. CDC proposes to clarify this policy in the regulation by adding a provision that a permit is not required for a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known or suspected to contain an infectious biological agent. Importers would not be required to perform confirmatory tests on these specimens, only certify in writing that they have no reason to believe that the samples contain an infectious biological agent. Examples of these types of diagnostic specimens not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent may include urine samples submitted for urine drug screens or serum samples submitted for cholesterol testing.

Genomic Material

Genomic material from infectious biological agents can consist of Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA). The nucleic acid comprising the genome may be single-stranded or double-stranded, and in a linear, circular or segmented configuration. Single-stranded viral genomes may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two). Viral genomes which consist of positive sense RNA are infectious when the purified viral RNA is applied to permissive cells in the absence of any viral proteins. In some cases, viral genomes which are composed of double-stranded DNA are also infectious (*e.g.,* genome of Cercopithecine Herpesvirus 1 (Herpes B virus)). If genomic material being imported does not encode for infectious and/or replication competent forms of an infectious biological agent then a permit is not required. For example, a permit would not be required for RNA obtained from negative stranded RNA viruses or for genomic DNA isolated from bacteria. As such, CDC proposes to clarify this policy by adding a provision in the regulation that a permit is not required for nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent. Importers would not be required to perform confirmatory tests on these specimens, only certify in writing that they have no reason to believe that the samples can produce infectious forms of any infectious biological agent.

Regulated Products

CDC proposes to exempt material contained in certain products from the requirement to obtain a CDC Permit for importation into the United States or subsequent transfer within the United States. If the material is contained in a product that is cleared, approved, licensed, or authorized under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or the Virus-Serum-Toxin Act (21 U.S.C. 151–159), CDC has determined that it is unlikely that material in these products would present a risk of the introduction, transmission, or spreading of a communicable disease. This exemption would include all investigational products for which an Investigational New Drug application (IND) is in place with the U.S. Food and Drug Administration (FDA). Examples of products that have been cleared, approved, licensed, or authorized by the FDA include FDA-licensed live attenuated vaccines and diagnostic test kits authorized for marketing or investigational use. Examples of products for Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262) or the Virus-Serum-Toxin Act (21 U.S.C. 151–159) include vaccines, antibody products, and blood products.

CDC proposes to clarify this policy by adding a provision in the regulation that a permit is not required for a product that is cleared, approved, licensed, or is otherwise authorized under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq*), Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or the Virus-Serum-Toxin Act (21 U.S.C. 151–159).

D. Transportation

During the importation of the infectious biological agents, infectious material, or vectors, the importer must be in compliance with all applicable laws concerning the packaging and shipment of infectious substances, including the following:

- Agriculture (9 CFR parts 92, 94, 95 96, 121, 122, and 130),
- Occupational Health and Safety Administration (29 CFR 1910.1030),
- Transportation (49 CFR parts 171 through 180), and
- Postal Service (39 CFR part 111).

As such, CDC proposes to clarify this policy by adding the language ''The importer is in compliance with all applicable laws concerning the packaging and shipment of infectious substances'' at § 71.54(b)(4).

E. Appeals Process

Since 2003, CDC has denied 2 applications for permits. CDC proposes to provide applicants with an opportunity for a written appeal in the

event that the CDC Director denies a request for a permit to import infectious biological agents, infectious material, or vectors under this part. Under the proposal, an applicant who wishes to make such an appeal would have 30 calendar days after receiving the denial to submit the appeal in writing to the CDC Director. The appeal must state the factual basis for the appeal and provide any supporting documentations to justify the appeal (*e.g.,* documents that demonstrate the facility has the appropriate biosafety measures in place for working safely with requested imported material). CDC would then issue a written response, which would then constitute final agency action. CDC invites comments on this process.

F. Alternatives Considered

In researching the proposed changes, we reviewed how U.S. Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS) regulates the importation plant and animal products and the Federal Select Agent Program regulates the possession, use, and transfer of select agents and toxins. We learned that HHS/CDC identified, through its Select Agent Program inspection program, specific biosafety measure implementation issues in 81 of the 316 the entities inspected by CDC since 2003. Some of the biosafety measure implementation issues were serious enough to require the suspension of registration or other restrictions on biological work at these facilities. USDA/APHIS has identified similar biosafety issues.

Thus, in the proposed rule, import regulations clearly state that the applicant have biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use. The safe possession and work with infectious biological agents, infectious material, and vectors requires that importers have the appropriate biosafety measures in place for imported material. These biosafety measures may be entity-wide, laboratory-specific, or agent-specific. HHS/CDC believes importers engaged in microbiological research and related activities utilizing safe laboratory practices, safety equipment, and facility safeguards will reduce the incidence of LAIs and other incidents and will protect the public health and environment. HHS/CDC also considered a requirement that the applicant must develop and implement a written biosafety plan that is commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use, including what elements of the plan are essential to prevent exposures and dramatically reduce the incidence of LAIs and protect the public health and environment. However, we believe that most, if not all, importers of etiological agents already have such biosafety plans based on our experience with import permit submissions addressing Section G (Receiving Laboratory Capabilities) of the permit application. The total number of applicants estimated to have biosafety plans from March 2011 to the present is 632 out of 644 or 98%. CDC would be interested in comments concerning the cost and burden of formalizing a written biosafety plan.

Finally, we also provided exemptions to allow importers to import certain material that is already approved or authorized by another agency or material that has been determined not to be an infectious biological agent. We believe this will reduce burden for clinical/diagnostic laboratories or small business selling manufactured goods.

III. Required Regulatory Analyses Under Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Based on past experience, we estimate that there will be approximately 2,000 applications for both import and distribution permit requests each year and that the average response time to complete the application is 20 minutes. We believe that the burden has been limited to requesting only essential information on the application, verifying information, when required, by telephone, and mailing information to the appropriate parties.

With regard to the new proposed requirement to have in place biosafety measures, our current experience with reviewing the information submitted for the import permit applications addressing Section G (Receiving Laboratory Capabilities) (*e.g.,* detailed description of any required personal protective equipment (PPE)), and laboratory equipment (*i.e.,* biosafety cabinets, autoclaves) that ensures materials are properly handled and contained indicates that the vast majority of importers of etiological agents already have instituted such biosafety measures. In fact, based on the review of applications received since March 2011, we estimated that 98% (632 out of 644) of the applicants possess written biosafety plans and already follow standard biosafety practices and procedures.

With regard to whether CDC will inspect an import facility, as noted above, CDC will use the following specific criteria to determine which entities are to be inspected—(1) facilities that request to perform research with imported agents that would need to be conducted in a BSL–3, BSL–4, ABSL–3, ABSL–4 or BSL–3 Agriculture laboratory as described in the BMBL (*e.g., Mycobacterium tuberculosis*), and (2) that have not been inspected by CDC's Select Agent Program.

Since 2009, we have refined the CDC import permit database to include better descriptions of material being imported, the biosafety level of the laboratory where the work will be performed, and the type of work to be conducted (*e.g.,* diagnostic, research). To estimate the number of facilities that we anticipate would require a biosafety inspection; we first identified those facilities that applied to import ''BSL–3 agents'' for research. From that list, we deleted those facilities already receiving periodic biosafety from either CDC or APHIS inspections due to their registration with the Federal Select Agent Program and concluded that approximately 25 facilities would need to be inspected per year to verify that they have in place the appropriate biosafety measures that are commensurate with the risk posed by the infectious biological agent, infectious material, and/or vector, and the level of risk given its intended use. We based our estimate on fact that the remaining facilities would not need to be inspected based on our current experience with reviewing the information contained in the import permit applications which address in detail the capabilities of receiving laboratories (description of any required personal protective equipment and laboratory equipment (biosafety cabinets, autoclaves), which if used properly ensures materials are properly

handled and contained). We therefore anticipate that this requirement will impose only a minimal burden on importers. However, we believe that the addition of this requirement is important to ensure that current and future importing facilities have and maintain the appropriate biosafety measures for working safely with imported infectious agents by inspecting these facilities. HHS/CDC's belief in the importance of including a requirement that importers are subject to an inspection to verify the implementation of appropriate biosafety measures is based on our eight years of experience in the area of select agent regulatory oversight. While 100% of entities registered for the possession, use, or transfer of select agents and toxins (42 CFR part 73) had appropriately filled out their application and had an adequate written biosafety plan, HHS/CDC identified, through its Select Agent Program inspection program, specific biosafety measure implementation issues in 81 of the 316 the entities inspected by HHS/CDC since 2003. Some of the biosafety measure implementation issues were serious enough to require the suspension of registration or other restrictions on biological work at these facilities. USDA/APHIS has a similar experience with those Select Agent entities for which it has principle oversight. Thus, we have learned from inspecting entities registered with the HHS/CDC's Select Agent Program that the ''trust'' approach to accepting information received from paperwork is ineffective. We found that the information provided in the paperwork did not always match the biosafety practices that are employed by the facility. As such, we believe that HHS/CDC's Permitting Program should adopt a parallel program to verify biosafety measures.

We also anticipate that there will be no cost to CDC to implement these recommended changes since we already review documents regarding biosafety and have a staff of fully trained and experienced biosafety inspectors. Finally, we believe the projected travel costs to perform these inspections will be at no additional cost to CDC since we plan to coordinate these inspections with those we are already conducting under the Federal Select Agent Inspection Program.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 601 *et seq.*), agencies must consider the impact of regulations on small entities and analyze regulatory options that would minimize a rule's impacts on these entities. Alternatively, the agency head may certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. As discussed above, CDC does not anticipate that this NPRM will have a significant economic impact on a substantial number of small businesses and other small entities. Of the entities impacted by this rule, CDC estimates that approximately 100 applications received out of 2000 applications are from small businesses. U.S. Small Business Administration defines a small business concern as one that is independently owned and operated, is organized for profit, and is not dominant in its field. Depending on the industry, size standard eligibility is based on the average number of employees for the preceding twelve months or on sales volume averaged over a three-year period. For example, annual receipts may not exceed $2.5 to $21.5 million for services provided or maximum number of employees may range from 100 to 500 depending on the particular product being provided. Based on this definition, we did not consider universities or major pharmaceutical companies as small businesses. CDC would be interested in comments concerning the cost and burden of this proposed rule, especially from an importer that might be considered a small business or entity or from the private sector.

IV. Other Administrative Requirements

A. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), HHS/CDC has determined that the information collection and recordkeeping requirements included in this proposed rule are already approved by OMB under OMB control number 0920–0199, expiration 1/31/2014. There are no new information collection or recordkeeping requirements in the proposed rule.

In the past, CDC has denied applications for permits. Thus, in this rule, CDC proposes to provide applicants with an opportunity for a written appeal in the event that the CDC Director denies a request for a permit to import infectious biological agents, infectious material, or vectors under this part. Under the proposal, an applicant who wishes to make such an appeal would have 30 calendar days after receiving the denial to submit the appeal in writing to the CDC Director. The appeal must state the factual basis for the appeal and provide any supporting documentations to justify the appeal (*e.g.,* documents that demonstrate the facility has the appropriate biosafety measures in place for working safely with requested imported material). CDC would then issue a written response, which would then constitute final agency action. CDC estimates the time to prepare and submit such a request is 4 hours. CDC invites comments on this process.

B. Executive Order 12988, Civil Justice Reform and Executive Order 13132, Federalism

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform, and Executive Order 13132, Federalism. This rule: (1) Preempts all State and local laws and regulations that are in conflict 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.

C. Plain Language in Government Writing

Pursuant to Presidential Memorandum of June 1, 1998 Plain Language in Government Writing (63 FR 31885), Executive Departments and Agencies are directed to use plain language in all proposed and final rules. CDC believes it has used plain language in drafting of the proposed rule and would welcome any comment from the public in this regard.

List of Subjects in 42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

Dated: June 20, 2011.

Kathleen Sebelius,

Secretary.

For the reasons stated in the preamble, the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, proposes to amend 42 CFR part 71, subpart F, as follows:

PART 71—FOREIGN QUARANTINE

1. The authority citation for part 71 continues to read as follows:

Authority: 42 U.S.C. 243, 248, 249, and 264–272.

2. Revise § 71.54 to read as follows:

§ 71.54 Import Regulations for Infectious Biological Agents, Infectious Material, and Vectors.

(a) Definitions:

Animal. Any member of the animal kingdom except a human.

Diagnostic specimen. Specimens of human and animal matter (including tissue, blood, body discharges, fluids, excretions or similar material), or environmental samples.

Genomic material. Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) comprising the genome or organism's hereditary information may be single-stranded or double-stranded, and in a linear, circular or segmented configuration and may be positive sense (same polarity as mRNA), negative sense, or ambisense (mixture of the two).

Infectious biological agent. A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.

Infectious material. Any material which is known or suspected to contain a biological agent infectious to humans.

Select agents and toxins. Biological agents and toxins that could pose a severe threat to public health and safety listed in 42 CFR 73.3 and 73.4.

Vector. Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system known to transfer or capable of transferring an infectious biological agent to a human.

(b) Unless excluded pursuant to paragraph (f) of this section, a person may not import into the United States any infectious biological agent, infectious material or vector unless:

(1) It is accompanied by a permit issued by CDC. The possession of a permit issued by CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

(2) The importer is in compliance with all permit requirements and conditions.

(3) The importer has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use.

(4) The importer is in compliance with all applicable laws concerning the packaging and shipment of infectious substances.

(c) If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious material or vector within the United States will require an additional permit issued by the CDC.

(d) A permit is valid only for:

(1) The time period and/or term indicated on the permit, and

(2) Only for so long as the permit conditions continue to be met.

(e) A permit can be denied, revoked or suspended if:

(1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious materials, or vector, and the level of risk given its intended use; or,

(2) The permit holder fails to comply with all conditions, restrictions and precautions specified in permit.

(f) A permit issued under this part is not required for an item if:

(1) It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.

(2) It is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.

(3) It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.

(4) It is a product that is cleared, approved, licensed, or otherwise authorized under any of the following laws:

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

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

(iii) The Virus-Serum-Toxin Act (21 U.S.C. 151–159).

(g) To apply for a permit, an individual must:

(1) Submit a signed, completed CDC Form 0.753 (Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States) to the CDC Import Permit Program.

(2) Have in place biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use.

(h) Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures (*e.g.,* physical structure and features of the facility, and operational and procedural safeguards) are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector, and the level of risk given its intended use.

(i) Denial, suspension, or revocation of a permit under this section may be appealed to the CDC Director. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the denial, suspension, or revocation of the permit. CDC will issue a written response to the appeal, which shall constitute final agency action.

[FR Doc. 2011–26656 Filed 10–13–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 24 and 52

[FAR Case 2010–013; Docket 2010–0013; Sequence 1]

RIN 9000–AM02

Federal Acquisition Regulation; Privacy Training, 2010–013

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to require contractors to complete training that addresses the protection of privacy, in accordance with the Privacy Act of 1974, and the handling and safeguarding of personally identifiable information.

DATES: Interested parties should submit written comments to the Regulatory Secretariat at one of the addresses shown below on or before December 13, 2011 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR case 2010–013 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by inputting ''FAR Case 2010–013'' under