Supporting Statement A

Import Permit Applications (42 CFR 71.54)

(OMB Control No. 0920-0199)

Revision

Centers for Disease Control and Prevention

Office of Readiness and Response

Division of Regulatory Science and Compliance

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- The goal of the study is to support Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.
- The intended use of the study is to fulfill the requirements promulgated by Health and Human Services under 42 CFR 71.54.
- The method used to collect data/information is an electronic data collection system that uses electronic forms, which are available on the Centers for Disease Control and Prevention's Import Permit website at https://www.cdc.gov/cpr/ipp/applications/index.htm.
- The subpopulation to be studied are those academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. The subpopulation are those facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease.
- This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54.

A. Justification

This request reflects revisions to the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form, the Application for Permit to Import or Transport Live Bats form and Application for Permit to Import Infectious Human Remains into the United States that the Office of Management and Budget (OMB)'s approved until August 31, 2024 (OMB Control No. 0920-0199). CDC plans to revise only the Application for Permit to Import Biological Agents, Infectious Substances. The Importer Certification Statement is a new form and will be used as an attestation by an importer stating that they are importing only noninfectious biological agent(s) or biological substance(s).

1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes that the Secretary of Health and Human Services (HHS) make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease

from foreign countries into the United States. Subpart F – Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC. The Centers for Disease Control and Prevention's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with these imported materials.

2. Purpose and Use of Information Collection

This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) (Attachment 1a) and prevents the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

The *Permit to Import Biological Agents and Vectors of Human Disease into the United States***(Attachment 4a2***)* is used by laboratory facilities, such as those operated by academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to:

(1) Add statement "No acronyms unless part of the legal name" to question 3, section A to reduce RFI if the applicant submits their application with acronyms.

(2) Add statement "Other qualified party/If no BSO, enter permittee contact info" to question 13, Section A to prevent an undue burden on applicants to have to determine what individual to list if their facility does not have a BSO or BSO title.

(3) Add statement "Or equivalent party" to questions 14 and 15, Section A to align with change to question 13, Section A.

(4) Add statement "Full name of organization preferred" to question 3, Section B to increase efficiency toward permit approval.

(5) Add/revise selection checkbox choices in question 4, Section D to clarify the type of animal or arthropod that will be inoculated. This will not affect burden hours, as these questions are asked as follow-up through a RFI for risk assessment purposes.

- The agent will NOT be used to inoculate animals or arthropods
- Nonhuman primates (NHPs)
- Rodent species
- Arthropods
- Other animal species (*Please list species:* open response)

(6) Revise question 4 "If yes, will this be by the aerosol route?" from section D and add more descriptive checkbox choices to specify the route of inoculation and clarify the difference between intranasal and aerosolized inoculations. The revised question is "If yes, what route will inoculation occur?"

- Intranasal
- Subcutaneous (SQ)
- Intramuscular (IM)
- Aerosol (NOT intranasal)

(7) Add yes/no question "Will necropsies be performed?" to question 4 Section D to gather information about higher risk work. This will not affect burden hours, as reviewers RFI regarding necropsies as part of the risk assessment.

(8) Add "Facilities" modal, which allows applicants to list all of the buildings and rooms the agent will be in. This reorganizes the table in Section D, questions 5-11 so that each agent will have all locations it will be stored/manipulated in associated with it in one row, rather than repetitive rows for the agent. This will reduce the burden hours for reviewers, as there will be concise rows for each agent that also list all the locations the agent will be in.

(9) Rephrase question 1 "Source of material(s) being imported" section E to "Original source of material(s) being imported" to clarify the request of where the material that includes the biologic agent(s) was sourced, and to reduce use of "other" category.

(10) Re-order questions 1 and 2 from Section E, so that "Description of material(s) containing the biologic agent(s)" is answered before "Source of material(s) being imported" to flow more logically.

(11) Add more specific and commonly used—via the "other" category—check box selection choices in question 2 "Description of material(s) being imported" to reduce the use of the "other" category.

- Keep: "Blood/blood products", "Tissues", "Organs/Body parts", "Other (*Please describe*: open text)".
- Revise: "Field-collected specimen" to "Environmental field-collected specimen".
    - Add check box selection choices "Soil", "Water", "Sewage", "Food products", "Isolate/Culture", and "Surface swab" as sub-options for the type of "Environmental field-collected specimen".
- Add: "Isolate/Culture", "Infectious clones", "Purified Nucleic acids", "Urine", "Feces", and "Sputum/Saliva".

(12) Revise check box selection choice "Infected or suspected infected human" in question 1, Section E to "Human" to improve clarity that the source of the material is human, since the material(s) are suspected to contain the agent(s) it is redundant.

(13) Revise check box selection choice "Infected or suspected infected vector" in question 1, Section E to "Arthropod Vector" to improve clarity that the source of the material is an arthropod vector, since the material(s) are suspected to contain the agent(s) it is redundant.

(14) Add check box selection choice "eggs/larvae" as sub option to question 1, Section E if "Arthropod Vector" is selected to clarify life stage of arthropod for risk assessment. Keep "Live" and "Dead" selection choices.

(15) Add check box selection choice "Animal" to question 1, Section E to improve clarity between arthropod vector and animals.

(16) Revise question 2*i* "Provide a detailed description of the material containing the biological agent" in Section E to "Provide a detailed description of the material containing the biological agent(s) in the following format: (Options selected in E1) from (Options selected in E2) that may contain (Infectious Biological Agent) to standardize free text and improve clarity of the DOM for reviewers. **E1=DOM and E2=Original source*

(17) Add/revise selection checkbox choices in question 1 "Primary containment to be

used" Section F to clarify types of primary containment and reduce the use of the "other" category.

- "None/open bench"
- "Downdraft table"
- "Backdraft table"
- "Fume Hood" with sub options "Class I", "Class II", "Class III"
- "Flexible film isolator with HEPA filtration"
- "Animal caging with HEPA filtration"
- No change: "Other: *please describe*"

(18) Add/revise selection checkbox choices in question 2 "Personal protective measures to be used" Section F to clarify types of PPE and reduce the use of the "other" category.

- No change: "Gloves", "Immunizations", "N95 or N100 Respirator"
- "Laboratory coat"
- "Sleeves"
- "Booties/Shoe covers"
- "Aprons"
- "Smocks"
- "Coveralls"
- "Scrubs"
- "Olefin suits"
- "Positive Pressure Encapsulating Unit (PPES)"
- "Eye protection"
- "Face shield"
- "Powered Air Purifying Respirator (PAPR)/Controlled Air Purifying Respirator (CAPR)"

(19) Revise selection choice in question 3 "Risk(s) associated with the imported biological agent(s)" Section F to "Risk(s) associated with manipulating or storing the imported biological agent(s)" to increase clarity that the applicant must acknowledge risk with any process involving the imported agent(s).

(20) Add check box selection choice to question 3 "Personnel training provided" Section F to reduce RFI and for reference when an inspection is conducted.

- "Visitor training"

(21) Relocate question 4 "Biosafety certification statement" Section F to end of application Section H as a required field that the applicant must acknowledge prior to submission. This reduces burden hours for reviewers.

*Question 5 "Anticipated disposition of infectious biological agent(s) and material containing it when work is completed" Section F will need to be renumbered as Q4 and Option C "Will be destroyed—Complete block 6" will need to be renumbered as "Complete block 5". Question 6 "If the agent(s) will be destroyed, list expected primary method(s) of destruction" Section F will need to be renumbered as Q5.

(22) Revise question 6 "If the agent(s) will be destroyed, list expected method(s) of destruction" Section F to "If the agent(s) will be destroyed, list expected primary method(s) of destruction".

(23) Revise check box selection choices in question 6 "If the agent(s) will be destroyed, list expected primary method(s) of destruction" Section F to align with most commonly used methods of destruction.

- No change: “Thermal-Onsite autoclave or Onsite incineration”, “Chemical (*Please describe:*), “Contracted hazardous waste disposal company *(name of company:)*”, “Other (*Please describe*:)”
- Add “Effluent decontamination systems (EDS)”
- Remove “Irradiation”

(24) Renumber question 1 “Will the permittee transfer the imported materials to locations not listed in Section D above? Yes (complete items 2-25)” Section G to “Will the permittee transfer the imported materials to locations not listed in Section D above? Yes (complete items 2-24)”, as the biosafety certification statement (Q25 Section G) will be moved to end of application to avoid redundancy and unnecessary RFI.

(25) Reflect the same changes proposed above—Add/revise selection checkbox choices in question 14, Section G to clarify the type of animal or arthropod that will be inoculated. This will not affect burden hours, as reviewers RFI if the permittee indicated they would inoculate animals/arthropods.

- The agent will NOT be used to inoculate animals or arthropods
- Nonhuman primates (NHPs)
- Rodent species
- Arthropods
- Other animal species (*Please list species:* open response)

(26) Reflect the same changes proposed above—Revise question 14 “If yes, will this be by the aerosol route?” from section G and add more descriptive checkbox selection choices to specify the route of inoculation and clarify the difference between intranasal and aerosolized inoculations. The revised question is “If yes, what route will inoculation occur?”

- Intranasal
- Subcutaneous (SQ)
- Intramuscular (IM)
- Aerosol (NOT intranasal)

(27) Reflect the same changes proposed above—Add yes/no question “Will necropsies be performed?” to question 14 Section G to gather information about higher risk work. This will not affect burden hours, as reviewers RFI regarding necropsies as part of the risk assessment.

(28) Reflect the same changes proposed above—Add “Facilities” modal, which allows applicants to list all of the buildings and rooms the agent will be in. This reorganizes the table in Section G, questions 15-21 so that each agent will have all locations it will be stored/manipulated in associated with it in one row, rather than repetitive rows for the agent. This will reduce the burden hours for reviewers, as there will be concise rows for each agent that also list all the locations the agent will be in.

(29) Reflect the same changes proposed above—Add/revise selection checkbox choices in question 22 “Primary containment to be used” Section G to clarify types of primary containment and reduce the use of the “other” category.

- “None/open bench”
- “Downdraft table”
- “Backdraft table”
- “Fume Hood” with sub options “Class I”, “Class II”, “Class III”
- “Flexible film isolator with HEPA filtration”
- “Animal caging with HEPA filtration”
- No change: “Other: *please describe*”

(30) Reflect the same changes proposed above—Add/revise selection checkbox choices in question 23 "Personal protective measures to be used" Section G to clarify types of PPE and reduce the use of the "other" category.

- No change: "Gloves", "Immunizations", "N95 or N100 Respirator"
- "Laboratory coat"
- "Sleeves"
- "Booties/Shoe covers"
- "Aprons"
- "Smocks"
- "Coveralls"
- "Scrubs"
- "Olefin suits"
- "Positive Pressure Encapsulating Unit (PPES)"
- "Eye protection"
- "Face shield"
- "Powered Air Purifying Respirator (PAPR)/Controlled Air Purifying Respirator (CAPR)"

(31) Reflect the same changes proposed above—Revise selection choice in question 24 "Risk(s) associated with the imported biological agent(s)" Section G to "Risk(s) associated with manipulating or storing the imported biological agent(s)" to increase clarity that the applicant must acknowledge risk with any process involving the imported agent(s).

(32) Reflect the same changes proposed above—Add check box selection choice to question 24 "Personnel training provided" Section G to reduce RFI and for reference when an inspection is conducted.

- "Visitor training"

(33) Reflect the same changes proposed above—Relocate question 25 "Biosafety certification statement" Section G to end of application Section H as a required field that the applicant must acknowledge prior to submission. This reduces burden hours for reviewers and reduces redundancy.

(34) Add question 4 "I attest that the permittee has implemented and will continue to implement biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use. ☐Accept and Submit" Section H. This combines the biosafety certification statement from questions 5 and 25 in Section F and G, respectively, which reduces burden hours on reviewers that RFI an application because the applicant selected "No" and submitted.

The *Application for Permit to Import or Transport Live Bats* **(Attachment 4b)** is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC does not plan to revise this application.

The *Application for Permit to Import Infectious Human Remains into the United States* (**Attachment 4c**) is used by facilities that will bury/cremate the imported cadaver and

educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. This form will request applicant and sender contact information; facility processing human remains; cause of death; biosafety and containment information; and final destination(s) of imported infectious human remains. CDC does not plan to revise this application.

The *Importer Certification Statement (***Attachment 4d***)* is an attestation used by an importer who is importing any noninfectious biological agent or biological substance. The noninfectious, imported agent or substance must be accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent or has been rendered noninfectious. This is a new form and requests a detailed description of the material, statements affirming that the material is not known or suspected to contain an infectious biological agent, and one of the following: 1) How the person knows that the material does not contain an infectious biological agent, or 2) Why there is no reason to suspect that the material contains an infectious biological agent, or 3) A detailed description of how the material was rendered noninfectious.

3. Use of Improved Technology and Burden Reduction

The electronic forms are available at the CDC's Import Permit website (https://www.cdc.gov/cpr/ipp/applications/index.htm) through the eIPP information system. eIPP information system is a secure, user-friendly, electronic information system through which those seeking import permits apply for the permit.

4. Efforts to Identify Duplication and Use of Similar Information

42 CFR 71.54 specifies that the importation permit is granted by CDC. No other component of HHS is involved in these procedures. The only way to obtain the necessary information is from the applicant.

5. Impact on Small Businesses or Other Small Entities

Collection of information may involve some small businesses or other small entities, but the burden has been limited to providing minimal information on forms, verifying information by telephone, and mailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

6. Consequences of Collecting the Information Less Frequently

There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for CDC to carry out its commitments to protect the public health as mandated by these regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8A. A **"60 Day Federal Register Notice"** was published in the Federal Register on February 5, 2024, Vol. 89, No. 24, Pages 7712-7714 (Attachment 2a). One comment was received regarding this notice (Attachment 2b). The commenter requested the U.S. Government increase border security and patrol due to the invasive, parasite of *Heterobilharzia americana*. CDC made no changes based on this comment as this recommendation did not request changes to the form, but requested changes that are outside of the scope of our regulatory authority since *Heterobilharzia americana* is currently already naturally found within the domestic United States, and also poses no threat to humans.

A8B. Consultation Outside the Agency

There has been no consultation outside the agency due to the delegation of responsibilities to the CDC as described herein.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the Privacy Office who determined that the Privacy Act does apply. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address. To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached *Federal Register* notice was published on August 27, 2020 for the System of Record Notice entitled, ''Electronic Import Permit Program Portal (eIPP Portal)" (**Attachment 3**).

The following special safeguards are provided to protect the records from inadvertent disclosure:

Authorized Users: Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have daily access to these records are limited to DRSC staff who have responsibility for conducting regulatory oversight of the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States.

Physical Safeguards: Paper records are maintained in locked cabinets in locked rooms in a restricted access location that is controlled by a cardkey system, and security guard service provides personnel screening of visitors. Electronic data files are password protected and stored in a restricted access location. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and the appropriate portable fire extinguishers are located throughout the computer room. Computer workstations, lockable personal computers, and automated records are located in secured areas.

Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system; mandatory password changes, limited logins, virus protection, and user rights/file attribute restrictions. Password protection imposes username and password log-in requirements to prevent unauthorized access. Each username is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure offsite storage is available for backup files.

Knowledge of individual tape passwords is required to access tapes, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer tapes and/or other magnetic media. A backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.

The DRSC and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel.

Appropriate Privacy Act provisions are included in contracts and the CDC Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

Implementation Guidelines: The safeguards outlined above are in accordance with the HHS Information Security Program Policy and FIPS Pub 200, `*Minimum Security Requirements for Federal Information and Information Systems*. Data maintained on CDC's Mainframe and the OPHPR Local Area Network (LAN) are in compliance with OMB Circular A-130, Appendix III.

Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications.

The CDC will follow its established policies and procedures in releasing and/or withholding trade secret and/or confidential or financial information, in accordance with the Freedom of Information Act.

Privacy Impact Assessment Information

The following information is collected from the applicant to receive an import permit as required under 42 CFR 71.54. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address.

The information is kept in a database which consists of permitted entities importing or subsequently transferring biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DRSC has access to the information, and disclosure of information is stringently limited.

To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached *Federal Register* notice was published on August 27, 2020 for the System of Record Notice entitled, ''Electronic Import Permit Program Portal (eIPP Portal)" (see Attachment 3).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This data collection does not include personal questions of a sensitive nature. Institutional Review Board approval is not required. These activities were determined to be public health non-research (Attachment 5).

12. Estimates of Annualized Burden Hours and Costs

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form (**Attachment 4a**2) is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. Based on information from eIPP information system, IPP receives approximately 3300 requests and 650 subsequent transfer requests per year. It takes the applicants 20 minutes to complete. There was a change in the total burden hours for the "Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States" from 667 hours to 1100. The change in burden accurately reflects the annual applications received by the program based on the number of applications received by the program in 2023. In addition, the form is used to indicate subsequent transfers of the imported biological agents, infectious substances, or vectors of human disease within the United States. Subsequent transfers requests are required for *Mycobacterium tuberculosis,* Coronaviruses (SARS-CoV-2, MERS-CoV), Influenza viruses (H2N2, low pathogenic avian H7N9), Viral hemorrhagic fevers (e.g., Tick-borne encephalitis viruses – Central European subtypes, Old World hantaviruses that

cause hemorrhagic fever with renal syndrome (HFRS)), Mpox (clade II) (formerly known as: Monkeypox – West African clade), and Poliovirus (serotypes 2, 3). The change in burden accurately reflects the annual applications received by the program based on the number of applications received by the program in 2023. Based on information from eIPP informatisystem, IPP receives approximately 650 requests per year. It takes the applicants 10 minutes to complete. There was a change in the total burden hours for the "Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States" from 63.3 hours to 108.3. The change in burden accurately reflects the annual applications received by the program based on the number of applications received by the program in 2023.

The Application Requesting to Import Live Bats (**Attachment 4b**) is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation of bats. Based on information from eIPP information system, IPP receives three requests per year. It takes applicants 20 minutes to complete the application. There was no change in the total burden hours.

The "Application for Permit to Import Infectious Human Remains into the United States" (**Attachment 4c**) is used by facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. the total burden hours for the "Application for Permit to Import Infectious Human Remains into the United States" decreased from 33 hours to 1. The change in burden accurately reflects the annual applications received by the program based on the number of applications received by the program in 2023.

The Importer Certification Statement (**Attachment 4d**) is an attestation used by an importer who is importing any noninfectious biological agent or biological substance. The noninfectious, imported agent or substance must be accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent or has been rendered noninfectious. This is a new form and requests a detailed description of the material, statements affirming that the material is not known or suspected to contain an infectious biological agent, and one of the following: 1) How the person knows that the material does not contain an infectious biological agent, or 2) Why there is no reason to suspect that the material contains an infectious biological agent, or 3) A detailed description of how the material was rendered noninfectious. Based on information from CDC's Division of Global Migration Health (DGMH), 5000 Importer Certification Statements are reviewed per year. It takes non-applicants 10 minutes to complete the certification statement.

Table A12A. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54)	3300	1	20/60	1100
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors – Subsequent Transfer	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54)	650	1	10/60	109
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats (42 CFR 71.54)	3	1	20/60	1
Applicants Requesting to Import Infectious Human Remains into the United States	Application for Permit to Import Infectious Human Remains into the United States (42 CFR 71.54)	3	1	20/60	1
Non-applicants (providing statement that material is non-infectious)	Importer Certification Statement	5000	1	10/60	833
Total					2044

Table A12B. Estimate of Annualized Cost to Respondent

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rates	Total Respondent Costs
Applicants	3300	1	20/60	$42.49	$ 46,739.00
Subsequent Transfer	650	1	10/60	$42.49	$ 4,603.08
Applicants	3	1	20/60	$42.49	$ 42.49
Applicants	3	1	20/60	$42.49	$ 42.49
Non-applicants	5000	1	10/60	$42.49	$ 35,408.33
Total					$ 86,835.39

When estimating the annualized burden costs, CDC assumes that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an average hourly respondent labor rate of $63.08 for managerial staff and $21.90 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $42.49. These rates were obtained from the Bureau of Labor Statistics, from the 2022 Occupational Employment Statistics Survey by Occupation (http://www.bls.gov/oes/).

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

14. Annualized Cost to the Government

The total annualized cost for implementing these regulatory activities budgeted is $19,274,049 and includes FTE's and contracts.

Compensation summary	$9,260,651
Personnel benefits	3,645,866
Travel & transportation	930,000
Printing & reproduction	1,969
Consulting and other services	5,352,898
Supplies & materials	63,812
Equipment	18,853
Grand Total:	$19,274,049

15. Explanation for Program Changes or Adjustments

The total response burden increased from 764 to 2044 hours. The change in burden is based on the current applicants that submitting received by the program in 2023 with the "Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States" from 667 hours to 1100, subsequent transfers from 63 hours to 109 and "Application for Permit to Import Infectious Human Remains into the United States" from 333 hours to 1. Change in burden also due to the new Importer Certification Statement.
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16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of this data. The data collection is used solely to carry out the provisions of the regulation.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments:

Attachment 1a	Public Health Service Act (42 U.S.C. 264)
Attachment 1b	Foreign Quarantine; Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors (42 CFR 71.54)
Attachment 2a	60-Day Federal Register Notice
Attachment 2b	Public Comment
Attachment 3	System of Record Notice
Attachment 4a1	Application for Permit to Import Infectious Biological Agents (Infectious Substance and Vectors) of Human Disease into the United States – old form with tracked changes
Attachment 4a2	Application for Permit to Import Infectious Biological Agents (Infectious Substance and Vectors) of Human Disease into the United States – revised/tracked changes form
Attachment 4b	Application for Permit to Import or Transfer Live Bats
Attachment 4c	Application for Permit to Import Infectious Human Remains into the United States
Attachment 4d	Importer Certification Statement