

Supporting Statement B

Import Permit Applications (42 CFR 71.54)

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Revision

Centers for Disease Control and Prevention

Office of Readiness and Response

Division of Regulatory Science and Compliance

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B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54. The importation of infectious biological agents, infectious substances, and vectors are regulated by 42 CFR 71.54 and requires that the importation of such materials must be accompanied by a permit issued by CDC.

1. Respondent Universe and Sampling Methods

Respondents are 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.

2. Procedures for the Collection of Information

All forms are available on the CDC Import Permit website
<http://www.cdc.gov/od/eaipp/importApplication/>.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Any person violating any provision of 42 C.F.R. Part 71 shall be subject to a fine of not more than \$1,000 or to imprisonment for not more than 1 year. Participation is mandatory.

4. Tests of Procedures or Methods to be Undertaken

The burden estimates are based on historical experience with the forms.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Statistical methods will not be used for Foreign Quarantine; Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors (42 CFR 71.54). Therefore, a consultant was not required to address statistical aspects of the design of this project.

Records maintained in the CDC Import Permit Program information management system, are accessed by DRSC staff for data entry, data query, and routine reporting activities.