Supporting Statement for the Revision to the
Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)
(OMB Control No. 0920-0576)

A. Justification

This is request for revision to OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins; Final Rule. The data collection and reporting requirements are required under 42 CFR Part 73 (Attachment 1). This request reflects revisions to the forms approved in February, 2005 based on changes in the Final Rule. The original forms approved in February, 2005 are found in Attachment 3. The revised forms are found in Attachment 4 and all revisions made to the forms are found in Attachment 5. The revisions to the data collection are primarily changes to the guidance documents and forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. The Centers for Disease Control and Prevention (CDC) is requesting a 3-year approval for this data collection. CDC in conjunction with U.S. Department of Agriculture/ Animal and Plant Health Inspection Service will be using the same forms for this data collection.

1. Circumstances Making the Collection of Information Necessary

On June 12, 2002, the President signed the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Act specifies that the Secretary of Health and Human Services (HHS) shall provide for the establishment of standards and procedures governing the possession, use, and transfer of select biological agents and toxins. The Act further specifies that entities that possess, use, and transfer these agents and toxins register with the HHS Secretary. The HHS Secretary has designated the Centers for Disease Control and Prevention (CDC) as the agency responsible in HHS for collecting this information.

In addition, the Act specifies that the Secretary of Agriculture (USDA) provide for the establishment of standards and procedures governing the possession, use, and transfer of high consequence livestock pathogens and toxins. Entities that possess, use, and transfer these pathogens and toxins must register with the USDA Secretary. The USDA Secretary has designated the Animal and Plant Health Inspection Service (APHIS) as the agency responsible in USDA for collecting this information.

The agents and toxins subject to the HHS data collection are those that pose a serious threat to public health and safety. These agents and toxins are further identified as non-overlap or overlap agents or toxins. The overlap agents and toxins are those that pose a serious threat to public health and safety as well as a threat to animal health or animal products. These agents and toxins are subject to requirements promulgated by HHS under this part and also subject to corresponding regulations promulgated by USDA at 9 CFR Part 121.

CDC promulgated regulations concerning the possession, use, and transfer of select agents and toxins as the Final Rule under 42 CFR Part 73 (Attachment 1). Under the regulations, entities are required to follow measures designed to ensure the health and safety of their workers and the public. Entities must register with CDC, identify individuals who require access to these agents and toxins; train these individuals, establish biosafety, security, and incident response plans; and maintain records of all such activities. The entity, responsible official, and individuals requiring access to these agents and toxins must request a security risk assessment check from the Department of Justice.

This information collection request describes the collection procedures and forms under the Final Rule. CDC is requesting a 3-year approval from OMB to collect data under the Final Rule under OMB Control No. 0920-0576. This information collection request includes standardized forms, non-standardized data collection, and recordkeeping requirements.

CDC collects this information through the use of five separate forms. These forms are: 1) Application for Registration; 2) Request to Transfer Select Agent or Toxin; 3) Report of Theft, Loss, or Release of Select Agent or Toxin; 4) Report of Identification of Select Agent or Toxin; and 5) Request for Exemption. The currently approved forms can be found in Attachment 3. The revised forms can be found in Attachment 4.

The Application for Registration (42 CFR, 73.7(d)) is used by entities to register with CDC. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information.

Entities may amend their registration (42 CFR, 73.7(h)(1)) if any changes occur in the information submitted to CDC. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) is used by entities requesting pre-authorization from CDC to receive or send a select agent or toxin.

The Report of Theft, Loss, or Release of Select Agent or Toxin form (42 CFR 73.19(a)(b)) is completed by entities whenever there is theft, loss, or release of a select agent or toxin.

The Report of Identification of Select Agent or Toxin form (42 CFR 73.5(a)(b) and 73.6(a)(b)) is used by clinical or diagnostic laboratories and other entities to notify CDC that a select agent or toxin identified as the result of diagnosis, verification, or proficiency testing have been disposed of in a proper manner.

The Request for Exemption form (42 CFR 73.5(d)(e) and 73.6(d)(e)) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins or in cases of public health emergency.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or may make a request of the HHS Secretary in writing. An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. CDC has not developed standardized forms to use in the above situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)).

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)).

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)).

An entity or an individual may request administrative review of a decision denying or revoking certification of registration (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review.

Finally, an entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17).

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 also specifies that entities and those individuals needing access to select agents and toxins must undergo a security risk assessment by the Department of Justice. The Federal Bureau of Investigation has responsibility for this activity and has obtained OMB approval for that data collection.

2. Purpose and Use of Information Collection

This information will assist CDC in meeting the goals of the Act and in ensuring that select agents or toxins are managed appropriately to prevent any threats to human health or safety. Information submitted to CDC through the reporting requirements in the Final Rule will be used to track the use of select agents and toxins and to meet the requirements of the Act.

3. Use of Improved Technology and Burden Reduction

CDC has awarded a contract for the development of an electronic data collection system. The electronic forms are expected to be available at the CDC website in a pdf-fillable format for electronic submission by the next approval period. We anticipate that it will take respondents more than one session to complete the form. Using a pdf-fillable format, it will be possible for respondents to save the document to their local drive, complete the form, and then upload the form to CDC. We are following this protocol for several reasons. First, this procedure provides for security of data entry. Data entry occurs at the entity and there is no possibility of another entity overwriting another's submission. Data entry at the local level is considered unclassified data and no special security measures are required. Finally, the entity will have an electronic copy of their submission. This will make it easier for the entity to amend any future submissions.

CDC and APHIS are also committed to developing a single shared web-based system that will allow the regulated community to conduct transactions electronically with either agency via a single web portal. By providing a single web portal, CDC and APHIS will be able to interact efficiently and effectively with the regulated community while reducing the burden on the public. We envision that this system will enable the entity to dynamically communicate with CDC and APHIS in a digitally secured environment using a single web portal. This environment will provide for the electronic exchange of information for creating, amending, and submitting registration applications and requests for approvals for transfers, exemptions, or exclusions.

4. Efforts to Identify Duplication and Use of Similar Information

The regulation describes requirements for hazardous materials training for individuals. Most entities already meet these requirements under Occupational Safety and Health Act (OSHA) regulations. CDC recognizes those requirements and the training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030.

In developing the data collection instruments, CDC has worked very closely with APHIS. One of the requirements of the Act was the development of a common registration system. This proposed data collection meets that requirement. In addition, CDC and APHIS signed a Memorandum of Understanding in December, 2002 that describes how the two agencies will share data and administer the program on common overlap agents and toxins.

5. Impact on Small Businesses or Other Small Entities

CDC recognizes that a small number of entities affected by the data collection requirements of this regulation (especially in the overlap agents and toxins section) may be small businesses. For this reason, the information needed in the data collection has been kept to a minimum.

6. Consequences of Collecting the Information Less Frequently

Entities will be required initially to re-register and to renew their registration every three years. To amend their registration, entities need only submit the revised sections of their registration application form. The other forms described in this data collection will be used by entities as needed.

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

There are no special circumstances relating to the guidelines of 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 March 17, 2008, Vol. 73, No. 52, Page 14252-14253. A 60 day comment period was given for public comments. Four public comments were received. A copy of the Notice, public comments, and responses are found in Attachment 2A.

A8B. CDC has worked with the following representatives of APHIS to develop the data collection instruments for the Final Rule:

Robert Rice, Select Agent Program Security Specialist, Veterinary Services, 301-734-5557, Robert.L.Rice@aphis.usda.gov
Sherylyn Roberson, Veterinary Program Assistant, Veterinary Services, 301-734-5960, Sherylyn.R.Roberson@aphis.usda.gov
Gwen Burnett, Regulatory Permit Specialist, Plant Protection and Quarantine, 301-734-7211, Gwendolyn.L.Burnett@aphis.usda.gov
Cassie Armiger, Regulatory Permit Specialist, Plant Protection and Quarantine, 301-734-0859, Cassie.C.Armiger@aphis.usda.gov

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Assurance of Confidentiality Provided to Respondents

ICRO has reviewed this application and determined that the privacy act does apply to this data collection.

A Notice of a New System of Records was published in the Federal Register on July 2, 2007, Vol. 72, No. 126, Page 35993-35997 related to the personal information on the Responsible Official, alternate Responsible Official, owners of non-governmental entities, the individuals who have access or who have applied to have access to select agents and toxins that is collected on the Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1).

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

Authorized Users: A database security package is implemented on CDC computers to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have routine access to these records are limited to Select Agent Program staff (DSAT FTEs and contractors) who have responsibility for conducting regulatory oversight of individuals and entities that possess, use, or transfer select agents.

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 a proper mix of portable fire extinguishers is located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure location. 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 log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure off-site 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. When possible, 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 DSAT 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.

The USDA/APHIS maintains similarly stringent safeguards that are discussed within that agency's Select Agent system of records notice.

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 COTPER 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.

Because of the national security sensitivity of the information in this database, CDC has determined that making this information available through a public database would compromise one of the primary purposes of the legislation. Therefore, CDC will not create a publicly available database of information. Disclosure of any registration or transfer documentation by the federal government is prohibited by P.L. 107-188.

11. Justification of Sensitive Questions

These questions in the forms may be considered sensitive from a national security standpoint. However, this information is needed in order to help ensure that select agents and toxins are managed appropriately to prevent any threats to human health or safety. This information will be used to track the possession, use, and transfer of select agents and toxins and to meet the requirements of the Act.

12. Estimates of Annualized Burden Hours and Costs

CDC is proposing to collect this information through the use of five separate forms. These forms are: 1) Application for Registration; 2) Request to Transfer Select Agent or Toxin; 3) Report of Theft, Loss, or Release of Select Agent or Toxin; 4) Report of Identification of Select Agent or Toxin; and 5) Request for Exemption and can be found in Attachment 4.

The Application for Registration (42 CFR, 73.7(d)) will be used by entities to register with CDC. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with the select agent or toxin. CDC estimates that entities will need an additional 45 minutes for each additional principal investigator or agent. Based on the data obtained from the 264 entities registered with CDC (this number excludes registered federal government entities), there are approximately 2 principal investigators for each registered entity. For new applications submitted to the CDC since the last submission, CDC estimates based on the information obtained from the database that 5 applications will be submitted from entities wishing to register with CDC to possess, use or transfer select agents and toxins on an annual basis. We have used these figures to calculate the

burden for this section. Estimated burden for the Application for Registration is 22.5 hours.

Entities may amend their registration (42 CFR, 73.7(h)(1)) if any changes occur in the information submitted to CDC. To apply for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to CDC. Estimated time to amend a registration package is 1 hour. Based on the data regarding amendments received from registered entities since the last submission, CDC estimates 5 amendment request to entity's certificate of registration will be received on an annual basis.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility. CDC in conjunction with APHIS has revised the Request to Transfer Select Agent or Toxin form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur. Estimated average time to complete this form is 1 hour, 30 minutes. Based on data regarding the transfer requests received since the last submission, CDC estimates 4 transfers requests submitted per registered entity on an annual basis.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 60 reports will be received on an annual basis.

The Report of Identification of Select Agent or Toxin form 42 CFR 73.5(a)(b) and 73.6(a)(b)) will be used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form will be used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. CDC in conjunction with APHIS has revised the Report of Identification of Select Agent or Toxin form to ensure duplicate reports are not submitted by requesting the entity that makes the final identification report the select agents or toxins identified as the result of diagnostic or verification testing. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 10 reports per respondent will be received on an annual basis.

The Request for Exemption form (42 CFR 73.5 (d)(e) and 73.6 (d)(e)) will be used by entities that are using an investigational product that are, bear, or contain select agents or toxins or in cases of public health emergency. An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). The estimated time to gather the information and submit this request is 1 hour. Based on data regarding the requests received since the last submission, CDC estimates that 5 requests will be received on an annual basis.

In addition to the standardized forms, this regulation also outlines situations in which an entity

must notify or may make a request of the HHS Secretary in writing. An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. The estimated time to gather the information and submit this request is 30 minutes. CDC has not developed standardized forms to use in the above situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)). CDC estimates, that, on average, such documentation will take 1 hour with an estimated annual burden of 264 hours.

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)). Estimated time for this documentation is 2 hours per entity.

An individual or entity may request administrative review of a decision denying or revoking certification of registration or an individual may appeal a denial of access approval (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

An entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17(b)). The time to implement such a system is estimated to average 4 hours.

Prior to issuance of a certificate of registration, CDC inspects entities to ensure compliance with this regulation (42 CFR 73.18). As part of the inspection process, the entity may need to respond to written requests from CDC. CDC estimates the time to prepare and submit a response for the inspection is 8 hours. To estimate the burden, we use the total number of registered entities since each entity will be inspected at least once during the course of their registration. The estimated annual burden is 2,112 hours.

Table A12A. Annualized Burden Hours

CFR Reference	Data Collection	Number of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden (in hours)
73.7(d)	Registration Application	5	1	4.5	22.5
73.7(h)(1)	Amendment to Registration Application	264	5	1	1320
73.19(a)(b)	Notification of Theft, Loss, or Release form	60	1	1	60
73.5 & 73.6 (d-e)/ 73.3 & 73.4 (e)(1)	Request for Exemption/ Exclusion	5	1	1	5
73.16	Request to Transfer Select Agent or Toxin	264	4	1.5	1,584
73.5 & 73.6 (a) (b)	Report of Identification of Select Agent or Toxin form	264	10	1	2,640
73.10(e)	Request expedited review	10	1	0.5	5
73.9(a)(5)	Documentation of self-inspection	264	1	1	264
73.15(c)	Documentation of training	264	1	2	528
73.20	Administrative Review	15	1	4	60
73.17	Ensure secure recordkeeping system	264	1	4	1,056
73.18	Inspections	264	1	8	2,112
	Total				9,656.5

Table A12B. Estimates of Cost to Respondent

CFR Reference	Data Collection	Total Annual Burden (in hours)	Hourly Wage Rate	Cost
73.7(d)	Registration Application	22.5	$30.61	$ 688.73
73.7(h)(1)	Amendment to Registration Application	1320	$30.61	$ 40405.20
73.19(a)(b)	Notification of Theft, Loss, or Release form	60	$30.61	$ 1836.60
73.5 & 73.6 (d-e)/ 73.3 & 73.4 (e)(1)	Request for Exemption/ Exclusion	5	$30.61	$ 153.05
73.16	Request to Transfer Select Agent or Toxin	1,584	$30.61	$ 48486.24
73.5 & 73.6 (a) (b)	Report of Identification of Select Agent or Toxin form	2,640	$30.61	$ 80810.40
73.10(e)	Request expedited review	5	$30.61	$ 153.05
73.9(a)(5)	Documentation of self-inspection	264	$30.61	$ 8081.04
73.15(c)	Documentation of training	528	$30.61	$ 16162.08
73.20	Administrative Review	60	$30.61	$ 1836.60
73.17	Ensure secure recordkeeping system	1,056	$30.61	$ 32324.16
73.18	Inspections	2,112	$30.61	$ 64648.32
	Total			$295585.47

To estimate cost to respondents, CDC assumed that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an estimated average hourly respondent labor rate of $46.22 for managerial staff and $15.00 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $30.61. These

rates were obtained from the Bureau of Labor Statistics, from the 2007 Occupational Employment Statistics Survey by Occupation.

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

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 cost for implementing these regulatory activities budgeted for Fiscal Year 2008 is $13,376,078.00 and includes 20 FTE's and two contracts.

Personnel:	$2,535,920.00
Travel:	$180,000.00
Transportation (shipping & handling):	$ 9,000.00
Contractual:	$10,473,166.00
Supplies:	$106,492.00
Equipment:	$71,500.00
Total:	$13,376,078.00

15. Explanation for Program Changes or Adjustments

This submission includes an increase in burden due to changes in the estimates for the number of respondents and the estimated average burden per response based on current experiences of the program. The revisions to the data collection are primarily changes to the guidance documents and forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of this data. The effective date for this regulation went into effect on April 18, 2005.

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

None.

18. Exceptions to Certification for Paperwork Reduction Act Submission

None.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

There are approximately 264 entities registered with CDC. These entities included any government agency (federal, state, or local), academic institutions, corporation, company, partnership, society association, firm, sole proprietorship, or other legal entity, including an individual acting on his or her own.

2. Procedures for the Collection of Information

Entities are required to register to possess, use, or transfer select agents or toxins. Entities must register with CDC if they possess HHS only select agents or toxins. Entities that possess agents or toxins on the overlap list may register with either CDC or USDA/APHIS. The Application for Registration is found in Attachment 4.

Entities may add, delete or change information on their registration by completing sections contained in the application and returning the form to the appropriate agency.

To request pre-authorization to transfer a select agent or toxin, the intended Responsible Official (RO) should complete the appropriate sections of the form and submit it to APHIS or CDC. CDC or APHIS will then fax the form back to the sender with an authorization number after verification of the information on the form. The recipient will verify the receipt of the select agent and toxin by faxing the form to APHIS or CDC.

Entities should use the other forms as necessary. All forms are available on the CDC and APHIS website.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The final rule has been in effect since April 18, 2005. In the registration application, entities will be reminded of the criminal penalties for non-compliance with the regulation. CDC expects full compliance by the affected entities.

4. Tests of Procedures or Methods to be Undertaken

CDC has not conducted any tests of procedures. However, CDC has made minor revisions to the previously approved forms based on changes in the Final Rule.

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

Individuals from CDC and USDA/APHIS worked together to develop common data collection instruments. They are:

CDC: James Blaine, Ph.D.
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List of Attachments

Attachment 1	Possession, Use and Transfer of Select Agents and Toxins (42CFR Part 73) – Final Rule
Attachment 2	Federal Register Notice
Attachment 2A	Public Comments and Responses
Attachment 3	Data Collection Instruments (Expiration date of 12/31/08) - Application for Registration - Request to Transfer - Report of Theft, Loss, or Release - Report of Identification - Request for Exemption
Attachment 4	Revised Data Collection Instruments - Application for Registration - Request to Transfer - Report of Theft, Loss, or Release - Report of Identification - Request for Exemption
Attachment 5	Listing of revisions to forms - Application for Registration - Request to Transfer - Report of Theft, Loss, or Release - Report of Identification - Request for Exemption