SUPPORTING STATEMENT
FOR
BioWatch Filter Holder Log
OMB Control No.: 1601-0006
Instrument: DHS Form 9500

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(i)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 of the OMB Form 83-I is checked "yes", Section B of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

Specific Instructions

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The filter holder log supports daily operations of the Department of Homeland Security (DHS) BioWatch Program.

The BioWatch Program operates aerosol collector equipment in approximately 30 U.S. jurisdictions to monitor for the presence of organisms that may be related to the deliberate release of a select subset of biological threat agents. Filter samples are collected on a daily basis by personnel employed by participating jurisdictions (either directly, or as contractors). Under certain circumstances (e.g., enhanced threat level), the jurisdiction may need to collect filter samples more frequently than once daily.

The number of aerosol collector devices varies by jurisdiction: samples may be collected from as few as six (6), and as many fifty three (53) sites daily in a given jurisdiction. One written filter holder log is created for each sample; the log is created when the new filter sample material is installed in the aerosol collector device, and is completed when the used filter sample is removed.

Following collection, the filter samples are transported to a local laboratory for analysis.

Should laboratory analysis determine the presence of one of the organisms of concern, additional analysis, collection, and response activities are conducted to determine the risk to public health, and to take appropriate public health, emergency response, and law enforcement actions.

The BioWatch Program provides funding to participating jurisdictions for the cost of collection and laboratory analysis activities, including the preparation and maintenance of required documentation. The filter holder log form is part of the documentation required by federal law enforcement for the BioWatch Program.

The filter holder log is required to create a unique written chain-of-custody record tied to each collected filter sample. In the event of a positive laboratory result and subsequent determination of the presence of an organism of concern, a variety of law enforcement organizations may become engaged in the process of determining if any criminal activity has taken place. The Federal Bureau of Investigation (FBI) has instructed the BioWatch Program to maintain a written record for each collected filter sample to support law enforcement activities, including criminal prosecution in the case of a deliberate release of a biological warfare agent. In addition, filter holder logs (chain-of-custody records) should be consistent nationwide for all BioWatch jurisdictions.

Written records are required to meet FBI evidentiary standards for establishing the chain of custody for any filter samples that form the basis for criminal prosecution (chain of custody is the tracking and documentation of physical control of evidence at all stages in the collection and analysis process). The memorandum from the FBI to DHS directing the creation of written records is included in Attachment 1.

Collection of written records establishing chain of custody for samples containing biological agents and toxins for the purpose of evidence in a criminal proceeding is consistent with the "Best Evidence Rule", Section 1002, of the federal Rules of Evidence (Attachment 2).

The FBI requirement levied on the BioWatch program is consistent with Section 7 of the FBI Quality Assurance Guidelines for Laboratories Performing Microbial Forensic Work, produced by the members of the Scientific Working Group on Microbial Genetics and Forensics (SWGMGF) Attachment 3. Such record keeping supports mandatory reporting requirements directed by The APHIS Interim Final Rule 7 CFR Part 331, repeated at 9 CFR Part 121 Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Interim Final Rule; FR citation: 67 FR 76908 and the CDC Interim Final Rule 42 CFR Part 73 Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule; FR citation: 67 FR 76886, *inter alia*.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Information is collected in writing by a representative of a local BioWatch jurisdiction (either an employee, or a contractor) assigned responsibility for filter installation, removal, and transportation using a standardized log developed by the BioWatch Systems Program Office (SPO) and supplied by the jurisdiction.

A filter holder log is initiated for each new filter sample on installation in the aerosol collector device, and is completed (normally) 24 hours later when the filter sample is removed from the device for transportation to the analysis laboratory. The completed logs are archived by the local BioWatch jurisdiction for a period of one year to support law enforcement activity. To date, no records have been provided to Federal government organizations to support operational events; however, local jurisdiction record keeping has been audited as part of the BioWatch Exercise and Evaluation Program (BWEEP) to monitor for system-wide problems and to ensure that written records are being maintained in accordance with BioWatch Program requirements.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

No automated, electronic, mechanical, or other technological collection techniques are used in the collection of filter holder logs.

A personal digital assistant (PDA) based data collection system – the BioWatch Sample Management System (SMS) – is used to collect electronic information related to sample management to support program operations and logistics. The SMS is a software system designed and implemented by the Los Alamos National Laboratory designed to track sample holders and other media from the time they are created, until they are delivered to the laboratory. The software monitors when the sample holder was assembled, deployed to the field, placed in the collector, removed from the collector, and delivered to the laboratory, along with who was responsible for each operation. The SMS software produces reports used by other software in the BioWatch system, such as the Centers for Disease Control Laboratory Results Messenger software. As directed by the FBI, a written record tied to each sample establishing chain of custody is to be created to support law enforcement activity; the FBI has informed the BioWatch Program of the determination that the electronic SMS cannot meet the FBI's evidence recording requirements.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The information collected in the filter holder log is unique and not collected by any other

means.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

Personnel collecting filter holder log information may be either direct employees of a local BioWatch jurisdiction, or may be contractors to those jurisdictions. The BioWatch Program reimburses participating jurisdictions for the cost of collection and laboratory analysis activities, including the preparation or handling of required documentation.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

In the event of federal criminal case arising from a BioWatch event, failure to generate a written record establishing chain of custody for the BioWatch filter sample might render that evidence inadmissible in a federal court, or might compromise the government's case.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- Requiring respondents to report information to the agency more often than quarterly;

Information is collected daily and stored by the local jurisdiction for use in the event of a positive laboratory result and subsequent law enforcement activity. The information is not submitted to DHS or any other federal government organization except as required to support law enforcement activity.

- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

Information is collected daily and stored by the local jurisdiction for use in the event of a positive laboratory result and subsequent law enforcement activity. Information is collected at the point of operation for each BioWatch aerosol collector, and must be collected immediately to ensure accurate data entry and the creation of a valid written record for chain of custody purposes.

- requiring respondents to submit more than an original and two copies of any document;

Not applicable: Each information collection event requires the creation of an original and two copies.

- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

Not applicable: BioWatch jurisdictions are required to retain copies for only one year.

- In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;

Not applicable: the collection activity is not connected to a statistical survey.

- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

Not applicable: the collection activity is not connected to a statistical survey.

- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

Not applicable: no pledge of confidentiality is required.

- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

Not applicable: respondents are not required to submit proprietary trade secrets or other confidential information.

8. If applicable, provide a copy and identify the data and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Draft notification attached.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A 60 Day Federal Register Notice soliciting for public comments was published on Monday, May 2, 2011 at 76 FR 24504. No comments were received.

A 30 Day Federal Register Notice soliciting for public comments was published on Monday, July 18, 2011 at 76FR 42130. No comments were received.

The BioWatch Program conducts regular consultation with the FBI and the Environmental Protection Agency (EPA) on the collection of information associated with the filter collection and transportation process. Consultation takes place through participation by the FBI and EPA as BioWatch Program Partners (CDC is the other BioWatch Partner agency). The initial version of the filter holder log was developed by EPA when BioWatch was deployed in 2003. Feedback on the content and format of the filter holder log and on the procedures for collecting filter sample information was solicited by EPA from both DHS and the FBI during BioWatch deployment. Updates to the format and to information collection procedures are discussed with designated FBI and EPA points of contact prior to implementation of changes. In addition, as part of the BioWatch Cooperative Agreement program, feedback on the collection of information and operational processes are solicited year-round from the participating local BioWatch jurisdictions through both formal and informal processes. The Program Terms and Conditions of the Cooperative Agreement, explicitly state: "The recipient is encouraged to provide feedback concerning the protocols/procedures during the implementation of this project. Feedback should be provided to the BioWatch Cooperative Agreements/Grants Program Manager." Furthermore, opportunity for feedback and consult is provided during the National BioWatch Annual Workshop ~~Meeting~~ each year.

> Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The BioWatch Program engages in an annual assessment program of all BioWatch jurisdictions as part of the BWEEP. All key components of field, laboratory, and (starting in FY07) public health operations are included in the BWEEP. BioWatch ~~Chem/Bio~~ Systems Program Office (SPO) representatives visit each jurisdiction and conduct a structured evaluation of local program operations, including collection of required information, such as the information collected in the filter holder log. The SPO representatives seek feedback from BioWatch jurisdiction personnel as part of this process. Feedback is consolidated and included in the annual BWEEP report, which includes recommendations for changes to program processes and procedures for action by the BioWatch Program Manager.

In addition to the BWEEP process, the BioWatch Program receives feedback from

BioWatch jurisdictions through regular meeting forums, including Regional Meetings (representatives from each jurisdiction attend at least one Regional Meeting annually), as well as the BioWatch Annual Workshop, which includes representatives from all jurisdictions as well as from all key federal and state stakeholders.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

Not applicable: no payments or gifts are provided to respondents. The costs of data collection for participating BioWatch jurisdictions are reimbursed as part of the Co-operative Agreements Grant Program.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Not applicable: no assurance of confidentiality is provided to respondents.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to person's form whom the information is requested, and any steps to be taken to obtain their consent.

Not applicable: no questions of a sensitive nature are asked of respondents.

12. Provide estimates of the hour burden of the collection of information. The statement should:
    - Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.

There are approximately 30 BioWatch jurisdictions collecting information using the filter holder log on a daily basis at 522 locations. The calculation of the total annual hour burden is as follows:

Total number of logs completed per day (1 per collector)	522
	x

Hours per log*	0.0167 (1 min)
	=
Daily hours burden	8.7174
	x
Days per year	365
	=
Annual hour burden	3173

*** Each log is completed over the course of two days: the form is begun when the filter is installed and completed when the filter is removed.**

The estimated number of hours required to complete each filter holder log is based on the results of the annual BWEEP site visits by the BioWatch SPO field operations team and Cooperative Agreement Site Visits.

- If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

Not applicable: only a single log is required.

- Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Not applicable: BioWatch jurisdictions are compensated for the time spent in completing the BioWatch filter holder log.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

- The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over

which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

Not applicable: BioWatch jurisdictions are compensated for the time and expenses spent in completing the BioWatch filter holder log.

- If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

Not applicable: BioWatch jurisdictions are compensated for the time and expenses spent in completing the BioWatch filter holder log.

- Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government or (4) as part of customary and usual business or private practices.

Not applicable: BioWatch jurisdictions are compensated for the time and expenses spent in completing the BioWatch filter holder log.

14. Provide estimates of annualized cost to the federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

BioWatch jurisdictions are compensated for the time and expenses spent in completing the BioWatch filter holder log. These expenses are paid for as part of the Co-operative Agreements Grant Program. Expenses to the federal government are as follows:

LABOR	
Annual hour burden	3,285
	x
Cooperative agreement average labor hour cost	$39.43
	=
Subtotal labor	$129,628
MATERIALS	
Total number of logs completed per day (1 one per collector)	522
	X
Number of Days	365
	=
Total number of logs completed per year	190,530
	x
Cost per log	$0.08
	=
Subtotal materials	$15,242
TOTAL LABOR AND MATERIALS	$144,770

The average labor hour cost is an average based on budget requests submitted and approved funding support for nine BioWatch jurisdictions as part of the FY2007 Cooperative Agreement Grant application process. Labor hour costs include salary and fringe.

The materials cost for the filter holder logs are based on a price quote for log production from a commercial vendor, quoted at a rate of $80.00 per 1,000 logs. Jurisdictions purchase the logs directly from commercial vendors using funds from the Cooperative Agreement Grant.

15. Explain the reasons for any program changes or adjustments reporting in Items 13 or 14 of the OMB Form 83-I.

- **There is no change (increase or decrease) in the annual burden associated with this collection. There is no change in the information being collection. However, there are proposed changes to DHS 9500, Filter Holder Log. These changes include:**
  - **Repositioning of Filter Installation and Filter Removal Tables. Currently the tables are viewed (top to bottom) Filter Installation then Filter Removal. These tables have been repositioned to align with the actual sequence of events at the work site…there is removal of the old filter first followed by installation of the new filter.**
  - **Site Name field changed to Number. This has been changed to comply with the BioWatch Standard Operation Procedure (SOP).**
  - **Removal of PSU and DFU check boxes. These have been removed because of the case of the DFU, this collector is no longer used by the BioWatch Program.**
  - **Within the Filter Installation table under Physical Security Check, On Arrival data elements have been removed. These elements no longer need to be collected because it is already covered in the Filter Removal portion of the procedure.**
  - **Within the Filter Removal and Filter Installation remove the word Collector and replace with PSU. This has been changed to reflect the type of collector, and its unique number.**

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Not applicable: information plans will not be published.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

DHS will continue to display the expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB 83-I.

Not applicable: no exception is sought.