



DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: BioWatch Filter Holder Log, Filter Holder Log DHS Form 9500

AGENCY: Office of Health Affairs, DHS

ACTION: 60-Day Notice and request for comments; Extension without change of a currently approved collection.

SUMMARY: The Department of Homeland Security, Office of Health Affairs/OCMO Early Detection Division, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (P.L. 104-13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Office of Health Affairs/OCMO Early Detection Division, DHS Attn.: Daniel Yereb, djy1@dhs.gov 703-647-8052

SUPPLEMENTARY INFORMATION: Following collection, the filter samples are transported to a local Laboratory Response Network (LRN) laboratory for analysis. Should laboratory analysis determine the presence of one or more 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 record of the filter installed plus give a 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) 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 used for criminal prosecution (chain of custody is the tracking and documentation of the 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 (SWGMP) 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*.

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 is audited as part of the BioWatch Evaluation Program (BWEP) to monitor for system-wide problems and to ensure that written records are being maintained in accordance with BioWatch Program requirements.

A personal digital assistant (PDA) is used to collect many of the data elements captured by the filter holder logs. However due to mechanical failure, possibility of spooking there is a need for redundancy in the form of paper copies.

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 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.

There has been an increase in the annual burden associated with this collection. This increase is due to more locations using the holder filter log on a daily basis. Previously there were 522 locations and now there are 605 locations. This has increased the number responses annually by 30,817 and the hours by 515. There is no change in the burden time per response. 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).
- 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.

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
 2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
 3. Enhance the quality, utility, and clarity of the information to be collected;
- and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

ANALYSIS:

AGENCY: Office of Health Affairs/OCMO Early Detection Division, DHS/

Title: BioWatch Filter Holder Log

OMB Number: 1601-0006

Frequency: Daily

Affected Public: State, Local, and Tribal Governments

Number of Respondents: 605

Estimated Time Per Respondent: 1minute

Total Burden Hours: 3688 hours

Dated: July 18, 2013.

Margaret H. Graves
Acting Chief Information Officer.

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