**An Assessment of the Utility of CDC’s Inventory Management and Tracking System (IMATS) by Public Health Emergency Preparedness Awardees**

OSTLTS Generic Information Collection Request

OMB No. 0920-0879

**SUPPORTING STATEMENT – Section A**

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**Section A. JUSTIFICATION**

1. Circumstances Making the Collection of Information Necessary

**Background**

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from one representative (i.e., designee) from CDC’s Public Health Emergency Preparedness (PHEP) awardees (50 states, New York City, Chicago, Los Angeles, Washington, D.C. and 8 island territories) and their localities that have evaluated the Inventory Management and Tracking System (IMATS), an informatics tool to track medical and non-medical countermeasure inventory and supplies (e.g., vaccines, antibiotics, surgical masks, etc.) used by state and local health departments during daily operations or an event. As part of the established process for evaluating IMATS, the CTS team would like to collect information from state and local awardees on the impact of IMATS in meeting the needs within their jurisdiction.

The purpose of IMATS is to increase the capacity of all levels of public health to track and manage inventory of medical and non-medical countermeasures during daily operations or an emergency response. The IMATS solution provides state and local public health providers with a tool to track quantities of inventory, monitor reorder thresholds, and facilitate warehouse operations including receiving, staging, and storing of inventory. All levels of public health benefit from IMATS, which provides a line of sight for medical and non-medical countermeasure inventory. At the federal level, IMATS will increase the efficiency of collecting data during an event and reporting data to CDC. This understanding is critical for decisions regarding allocation and re-supply of federal assets. IMATS is available free of charge to users and does not require additional development and maintenance fees. At the state and local level, IMATS allows inventory management and tracking of medical and non-medical countermeasures obtained from either commercial suppliers or the federal government. The use of IMATS improves event response coordination and communication of inventory information within a locality. IMATS also eases the burden of collecting critical inventory information and reporting it to CDC. Additionally, an IMATS training environment is available for users to conduct trainings and exercises without having to use or modify their live data.

The rationale for IMATS followed the 2009 H1N1 pandemic, which highlighted the need for a nationwide inventory management and tracking system with the capability to provide an inventory line of sight, detailing what is available and on-hand at all levels, including state, regional, local and point of dispensing levels. During the H1N1 event, the Centers for Disease Control and Prevention (CDC), Division of Strategic National Stockpile (DSNS) was tasked with tracking quantities of antiviral drugs and personal protective equipment distributed to states and local points of distribution. CDC staff had to email all PHEP awardees to collect and collate information in order to make a decision on which areas needed countermeasures.

CDC’s PHEP awardees were mandated to track this material, and reported inventory data to CDC via paper-based methods or through CDC’s Countermeasure and Response Administration (CRA) system. This data was merged with data from commercial drug suppliers to provide an overall picture of the countermeasure inventory supply chain. This information was aggregated, analyzed, and provided to federal government decision makers, and used to determine countermeasure allocation to the public.

The collection and analysis of the data proved to be an extremely time consuming and labor intensive process due to the variety of methods that PHEP awardees employed. In addition, the data that was received was not sufficient to provide full visibility of inventory at the local level. CDC was able to respond to requests for information from national leadership but could not provide for any plan-ahead capabilities, making it apparent that a more robust data collection tool was needed in order to capture an inventory line of sight down to the point of dispensing level. To ensure these issues were addressed for future events, DSNS partnered with CDC’s Division of Informatics Solutions and Operations (DISO) Countermeasure Tracking Systems (CTS) team (See **Attachment A – CTS brochure, Attachment B – CTS poster**) to initiate a new project to build a nationwide Inventory Management and Tracking System, which provides a more complete data set including state, regional, and local inventory data.

The CTS team applied innovative, user-centered design methods, incorporating user input throughout each stage of IMATS development. This approach ensured that this inventory management solution met user needs, preferences, goals and business objectives. To accomplish this, the CTS team engaged state and local designees across the nation and hosted online, virtual focus group meetings, technical requirements gathering webinars, system demonstrations, in-person user experience and usability workshops, and conference presentations.

As development began, a technical work group consisting of PHEP awardees and local jurisdiction representatives with emergency response and inventory management expertise met regularly via webinar meetings to define and review technical requirements, design layouts, screen mockups and business rules. An additional in-person meeting offered the work group members hands-on experience with IMATS and provided an opportunity to share their feedback on its usability well in advance of the initial release of the system.

In addition to ongoing collaboration with the technical work group, Agile Development Methodology was used for the software development process. The Agile process utilizes an iterative approach to software requirements, design, development, and testing activities. It is an empirical process that uses frequent inspection, collaboration, and adaptive responses to reduce risk and ensure delivery of a reliable, quality product. Work was divided into manageable “sprints,” which are iterations of a fixed 30 days duration (see **Attachment C – Agile Methodology)**. At the conclusion of each sprint, the accomplished work was presented to the technical work group for feedback, and changes were continuously incorporated. This process helped to identify issues early on during development and ensured the system met user needs.

Through the dedication of the technical work group and the CTS development team, IMATS was successfully launched on September 30, 2011 (see **Attachment D – Application Screenshots**). In addition to IMATS, an IMATS assessment environment was created in collaboration with the Informatics Research and Design Unit Lab to allow interested jurisdictions a chance to evaluate the system before they decide to implement it as their inventory management solution.

As of July 23, 2012, 14 PHEP awardees and 94 local jurisdictions have implemented IMATS as their primary or secondary inventory management system. Twenty-one PHEP awardees have adopted IMATS at either the state and/or local level (see **Attachment E – Implementation Map**). The collaboration with state and local end users ensures a solution that is intuitive, simple to use, and meets user needs. Users continue to impact future enhancements to the system through communication with the development team via a dedicated “help desk.”

The purpose of this data collection is to collect information from designees from state, county and territorial jurisdictions that have evaluated IMATS about how IMATS is working to meet their needs. User input and collaboration continuously impacts system enhancements to ensure that IMATS remains intuitive and meets user requirements.

**Privacy Impact Assessment**

Overview of the Data Collection System – The data collection system consists of a web-based questionnaire (see **Attachment F – IMATS Questionnaire** and **Attachment G – IMATS Screenshot of Online Questionnaire**) designed to collect data from designees from state, county and territorial jurisdictions that have assessed IMATS to determine whether the system meets their needs for inventory management. The data collection instrument will be administered as a web-based data collection tool. The data collection tool was pilot tested by four (4) public health professionals representing the target audience of state and local public health agencies. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the questions.

Items of Information to be Collected – There are a total of 26 questions in the questionnaire. Twenty-two of these are multiple choice or scale-based and four are open ended. Respondents have the opportunity to provide a narrative response at the end of each question. Open ended questions are limited to a maximum of 1000 characters in length. This questionnaire will be distributed and data collected using the web-based data collection tool, Survey Monkey®. The survey will collect information on the following:

1. respondent characteristics (optional) – public health agency; city; state (multiple response format)
2. respondent experiences with IMATS assessment – how respondents heard about IMATS, reasons for assessing IMATS, factors playing a role for system adoption, current inventory management system information (single response, multiple response, rating and open-ended format)
3. respondent criteria for system adoption – IMATS ease of use, suitability for an event, feature completeness (rating and open-ended format)

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age – The data collection system involves using a web-based data collection tool. Respondents will be sent a link directing them to the online data collection tool only (i.e., not a website). No website content will be directed at children.

1. Purpose and Use of Information Collection

The purpose of this data collection is to collect information from designees from state, county and territorial jurisdictions that have evaluated IMATS about how IMATS is working to meet their needs. User input and collaboration continuously impacts system enhancements to ensure that IMATS remains intuitive and meets user requirements.

The information obtained from this data collection will be helpful to understand the importance of certain criteria (ease of use, cost, etc.) to state and local public health providers when selecting an inventory management system. Developing an effective information system requires an understanding of the user’s ability to navigate the system easily and without confusion. By asking designees from state, county and territorial jurisdictions that have evaluated IMATS about their experience with IMATS and their confidence in the system to serve their needs during a major public health event, the CTS team will generate valuable information to guide decisions on how to improve and enhance the system to meet the needs of end users.

Furthermore, this assessment will enable the CTS team to gauge the needs of designees for an inventory tracking system. The data gathered from this assessment will allow the CTS team to prioritize functionality enhancements and features within IMATS. The proposed data collection activities will result in a system that is better able to meet the needs of PHEP awardees and subsequently, provide services to public health. In addition, the findings from this data collection will be shared via oral and poster presentations at relevant public health conferences.

The scope of data collection is limited to the responsibilities and duties of governmental employees acting in their official capacity, as such this data collection will not require IRB review.

CDC expects to use these findings to assess the knowledge of IMATS among state and local public health and use such knowledge in improving the system to better serve their needs.

Privacy Impact Assessment - No sensitive information is being collected through this data collection. All respondents will remain anonymous by choice. One optional question in the data collection tool provides the respondent an opportunity to provide their jurisdiction name and location if they choose to offer this information.

1. Considerations Given to Information Technology

Data will be collected via a web-based data collection tool, Survey Monkey®, allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The data collection was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 22 questions).

Web-based data collection tools reduce respondent burden by enabling them to easily access the data collection tool and complete it at a convenient time and location. The web-based data collection tool will use easy-to-read response scales or text boxes that are embedded in the online data collection tool. **Attachment F** consists of screen shots of the data collection instrument. **Attachment G** consists of the questionnaire in a Word document.

Survey Monkey® has a data center which is located in a SAS70 Type II certified facility, which is staffed and monitored 24/7. Their servers are kept in a locked cage, with digital surveillance equipment monitoring at the data center. Secure Sockets Layer (SSL) technology protects user information using both server authentication and data encryption, ensuring that data is safe, secure and available only to authorized persons in a password protected system. In addition, personally identified information will not be collected.

1. Duplication of Information

These data are unique to the assessment of IMATS and have not been previously collected. This new information collection will fill a gap in allowing CDC to evaluate its products and services intended for local and state health department support.

1. Reducing the Burden on Small Entities

No small businesses will be involved in this data collection.

1. Consequences of Not Conducting Collection

The purpose of this request is to ensure collection of data that is not otherwise available in current, time sensitive or relevant formats to specific or emergent priorities of HHS and CDC. Specifically, without this data there would be:

* No timely feedback regarding the usefulness of IMATS.
* Less effective interventions and data-driven decisions that often need to be made between CDC and state and local governmental health agencies.
* Limitations to effective and timely assessment of capacities of governmental agencies to fulfill their public health mission.
1. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the guidelines of 5 CFR 1320.5 and will be voluntary.

1. Consultation with Persons Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp.65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the ASTHO, the NACCHO, and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under the individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

1. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

1. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will not be asked to provide individually identifiable information.

This data collection is not research involving human subjects.

1. Justification for Sensitive Questions

No sensitive information will be collected.

1. Burden of Information Collection

The estimate for burden hours is based on a pilot test of the questionnaire by three current IMATS public health partners (PHEP awardee and local jurisdiction designees). In the pilot test, the average time to complete both parts of the data collection tool, including time for reviewing instructions, gathering needed information and completing the questions, was approximately 15-20 minutes. This was rounded up to 20 minutes for the purposes of our estimated burden hours.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of $35.00 is estimated for all respondents. The data collection tool will be sent to all designees who have completed an IMATS assessment. Only one individual from each jurisdiction will be asked to complete the questionnaire. The initial respondent total is 101. *EVERY SIX MONTHS* thereafter until March 31, 2014 (expiration date for this Generic ICR), the data collection tool will be sent to 60 respondents (designees) from jurisdictions that have completed an IMATS assessment as a routine part of the assessment process. Table A-12 shows estimated burden and cost information for the total 341 respondents.

**Table A-12:** Estimated Annualized Burden Hours and Costs to Respondents

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type of Respondents** | **Data Collection Period** | **Number of Respondents** | **No. Responses per Respondent** | **Hours per Response** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Cost** |
| PHEP awardee and local jurisdiction designees  | Jul 2012\* | 101 | 1 | 20/60 | 34 | 35 | 1,190 |
| PHEP awardee and local jurisdiction designees  | Jul-Dec 2012\* (Following close of initial data collection) | 60 | 1 | 20/60 | 20 | 35 | 700 |
| PHEP awardee and local jurisdiction designees | Jan-Jun 2013\* | 60 | 1 | 20/60 | 20 | 35 | 700 |
| PHEP awardee and local jurisdiction designees | Jul-Dec 2013\* | 60 | 1 | 20/60 | 20 | 35 | 700 |
| PHEP awardee and local jurisdiction designees | Jan-Mar 2014\* | 60 | 1 | 20/60 | 20 | 35 | 700 |
| **TOTALS** |  | **341** | **1** |  | **114** |  | **3,990** |

\*Estimated time

1. Costs to Respondents

There will be no direct costs to the respondents other than their time to participate in the data collection.

1. Cost to Federal Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff and contractors supporting the data collection activities and associated tasks.

The data collection tool will be prepared by CDC staff (FTE) and contractors. An FTE manager will review the data collection tool. A senior level FTE will review and approve the activities. The estimated cost to the federal government for the entire data collection period is $4190.00. Table A-14 describes how this cost estimate was calculated.

|  |
| --- |
| **Table A-14**: Estimated Annualized Cost to the Federal Government |
| **Staff or Contractor** | **Hours** | **Average Hourly Rate** | **Average Cost** |
| **Health Scientist (GS-13)**Lead on review and development of OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation | 30 | $45 | $1350.00 |
| **Public Health Analyst (GS-12)** Consultation, OMB package review, report preparation and review | 11 | $40 | $440.00 |
| **2 Business Analysts (Contractors to CDC)** OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation | 40(2) | $30 | $2400.00 |
| **Estimated Total Cost of Information Collection**  | $4190.00 |

The majority of hours contributed by all staff and contractors listed in Table A-14 are for the initial OMB package preparation. Therefore, hours contributed by each staff or contractor will be less during subsequent data collection periods. It is estimated that the Health Scientist will contribute 10 hours for the initial data collection period and 5 hours for each remaining period. The Public Health Analyst hours will be similarly distributed with 3 hours spent in the initial data collection period and 2 hours for each of the following periods. Both business analysts will contribute 20 hours to the initial data collection period and 5 hours for the subsequent periods.

1. Reason for Changes

This is a new data collection.

1. Tabulation of Results, Schedule, and Analysis Plan

The initial data collection will gather data from 101 respondents. *EVERY SIX MONTHS* thereafter through March 31, 2014 (expiration date for this Generic ICR), the data collection tool will be sent to 60 respondents (designees) from jurisdictions that have completed an IMATS assessment as a routine part of the assessment process. We plan to analyze the data using Microsoft Excel to gather descriptive statistics and create charts and graphics depicting the responses received. The results of this data collection will be used to support IMATS enhancements and to improve the content and delivery of communication materials to state and local public health partners. Following OMB approval, data collection will commence via e-mail communication (**see Attachment H – Introductory Email)** to all IMATS evaluators, seeking response within a period of 10 business days (14 calendar days). Two reminders will be sent to responders. The first will occur after five business days (seven calendar days) following the initial e-mail, the second reminder will be sent just prior to the 10th business day (**see Attachment I – Reminders**). At the close of the data collection period, a follow up email will be sent, thanking those respondents (**see Attachment J – Follow up email**).

Project Time Schedule

* Design data collection tool (COMPLETE)
* Develop data collection protocol, instructions, and analysis plan (COMPLETE)
* Pilot test data collection tool (COMPLETE)
* Prepare OMB package (COMPLETE)
* Submit OMB package (COMPLETE)
* OMB approval (TBD)
* Conduct initial data collection (Data collection open 2 weeks)
* Conduct data collection (Ongoing every six months until 3/31/2014)
* Code, quality control, and analyze data (Ongoing every six months until 3/31/2014)
* Prepare report (4 weeks)
* Disseminate results/reports (TBD)

Analysis Plan

This data collection will attempt to answer the following questions:

1. What avenues of communication are most effective to inform target jurisdictions about IMATS?
2. What are the reasons a jurisdiction chooses to adopt or not to adopt IMATS as a primary/backup inventory management system?
3. What are the important criteria used for evaluation in a jurisdiction’s decision to adopt an inventory management system?
4. Was participation in the IMATS assessment helpful in a jurisdiction’s decision to adopt IMATS?

Once analyzed, summaries of the information gained from analysis of the results may be used in conference presentations or future publications (TBD). This summary will also be provided to users who express interest in the outcome of the data collection. Findings from the data collection and analysis will help the CTS Team to understand user needs and inform future enhancements to IMATS. We hope that the findings will provide information about factors that are important in selecting an inventory management system and specific areas of IMATS functionality that need improvement or are especially useful. We also hope to understand reasons why systems other than IMATS are chosen for inventory tracking needs.

1. Display of OMB Approval Date

We are requesting no exemption.

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

**LIST OF ATTACHMENTS – Section A**

Note: Attachments are included as separate files, as instructed

1. **CTS Brochure**
2. **CTS Poster**
3. **Agile methodology**
4. **Application screenshots**
5. **Implementation map**
6. **Data Collection Instrument – Web version**
7. **Data Collection Instrument – Word version**
8. **Introductory e-mail**
9. **Reminders**
10. **Follow-up e-mail**