

SUPPORTING STATEMENT OF THE REQUEST FOR OMB REVIEW AND APPROVAL
OF
HAZARDOUS SUBSTANCES EMERGENCY EVENTS SURVEILLANCE
(OMB # 0923-0008)

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This request for continued approval to conduct Hazardous Substances Emergency Events Surveillance (HSEES) is in partial fulfillment of the authorizing legislation of the Agency for Toxic Substances and Disease Registry (ATSDR) as found in Sections 104(i)(4) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) [42 U.S.C. 9604 (i)(4) and (15)] (Appendix 1). This legislation provides that ATSDR will conduct activities to help determine the relationship between exposure to hazardous substances in the environment and adverse health outcomes. The goal of HSEES is to reduce morbidity and mortality occurring as a result of hazardous substances emergency events, which is consistent with this mandate. This information collection is an extension with no change to forms or methodology.

The initial clearance for this package was granted in June 1992. At the last OMB renewal in 2004, there were 16 states (Alabama, Colorado, Iowa, Louisiana, Minnesota, Missouri, Mississippi, New York, New Jersey, North Carolina, Oregon, Rhode Island, Texas, Utah, Washington, and Wisconsin).

HSEES events are defined as sudden, uncontrolled, or illegal releases of at least one hazardous substance that had to be removed, cleaned up, or neutralized according to federal, state, or local law. A substance is considered hazardous if it might reasonably be expected to cause adverse human health outcomes. Threatened releases also are included in HSEES if 1) the

amount threatened to be released would have required removal, cleanup, or neutralization under federal, state, or local law, and 2) the threat led to an action to protect the public health (e.g., rerouting traffic, closing a road, or ordering an evacuation). Events involving only petroleum are excluded from HSEES.

The state health departments collect data using the OMB approved form (currently replicated on the web-based computer entry screen) and an accompanying training manual to ensure standardization of data collection. Information collected on events includes: where the event occurred, contributing factors, type of industry, chemicals released, victims and their injuries, and evacuations. State health department personnel use a variety of sources (e.g., records and oral reports of state environmental agencies, police and fire departments, and hospitals) to collect information about the hazardous events. All data are entered into a web-based data entry system and is immediately available to ATSDR for quality control checks and analysis.

Until this system was developed and implemented, there was no national public health-based surveillance system to coordinate the collection, analysis, and distribution of data on the impact of hazardous substance emergencies on the health of the population of the United States. With the continued success of this program and the recognized national need to be prepared for chemical and biological disasters and terrorism, more states have expressed interest in participating. It is possible that this data collection process may occur on a national basis in the future.

The data collection has allowed ATSDR to describe the characteristics of hazardous substances

emergency events and of events that result in public health consequences. The characteristics of the victims, the types of adverse health effects reported, and the substances associated with adverse health effects have been identified. Every year ATSDR publishes an annual report with the results of the previous year's data collection. This report is widely disseminated. It is also made available on the ATSDR website. HSEES data is also presented by ATSDR staff at many regional and national conferences per year. For example, yearly presentations are made at the annual meetings of the Mary Kay O'Connor Process Safety Center, American Public Health Association, Council of State and Territorial Epidemiologists, among others. Forty-seven journal articles and Morbidity and Mortality Weekly Reports (MMWR) have been published since May 2000 and several others have been submitted or are being worked on (Appendix 2). The 2007 MMWR on mercury releases in antiques was written when HSEES staff noticed several related releases. The MMWR subsequently spawned a multitude of news articles worldwide. The article made recommendations for persons who handle these mercury containing antique items to be aware of this situation and to properly protect themselves.

Participating state health departments submit yearly prevention plans. Some examples of activities include fact sheets on frequently released chemicals, presentations to a variety of target audiences, journal articles, development of websites, targeting prevention messages to antique dealers and collectors, providing the state environmental agency with data to and ATSDR respond to many requests for information and presentations beyond their planned activities. ATSDR has a form for states and ATSDR to record all of their activities, including audience number and type, information requested, etc. This allows ATSDR to measure the impact of HSEES and to analyze the current target audience and their needs. This all would not

have been possible without HSEES.

A.2. Purpose and Use of the Information

The primary purpose of this activity is to develop, implement, and maintain a state-based surveillance system for hazardous substances emergency events in order to reduce morbidity and mortality from these events. The data collection form and the request for data form are attached to this supporting statement (Appendix 3). This surveillance system allows the state health department to better understand the public health impact of hazardous substances emergencies by developing, implementing, and evaluating a state-based surveillance system. A surveillance system for this data would not exist in most of these states without ATSDR support. The objectives of this data collection are to:

- 1) describe the distribution of hazardous substances emergencies;
- 2) describe the type and cause of morbidity and mortality experienced by employees, first responders, and the general public as a result of hazardous substance releases;
- 3) develop and propose strategies to reduce subsequent morbidity and mortality when comparable events occur in the future.

The state health departments use the data to accomplish items 1-3 above for their state. ATSDR is responsible for analyzing data from all participating states. This is being distributed locally, nationally, and internationally. Requests for reprints of publications, additional data analysis, and for the HSEES dataset have been received from many different sources. Some examples of requesters include academia (Texas A & M University), government (Occupational Safety and Health Administration and Chemical Safety and Hazard Investigation Board), and

other interested parties. Each year, every participating state is expected to conduct at least two prevention activities based on their cumulative data and evaluate their effectiveness. Some of these activities have included providing data to Local Emergency Planning Committees, State Emergency Response Committees, fire departments, police, other first responders, state agencies, industries, and the general public for training of emergency response workers. Users, producers, and transporters of most frequently spilled chemicals have also received information from HSEES. For example, in Iowa there were numerous agricultural spills related to ammonia nurse tanks. The Iowa HSEES coordinator produced a sticker for farmers to put on their tractor to remind them of safe ammonia handling procedures

HSEES has created a database to track the number of people who receive data from the program, either through direct requests, mailings or presentations. For Fiscal year 2007 the numbers totaled over 210,000. This data will allow HSEES to analyze the impact of the system and evaluate the data that people are most interested in.

A.3. Use of Information Technology and Burden Reduction

ATSDR has used a web-based data entry system in since January 1, 2000. The web-based application provides an easy way to enter data for qualifying emergency events into a centralized computer database. This technology was chosen because the data entry screen is set up like a typical Windows program for simplicity. If modifications need to be made to the system or associated chemical database, it can be easily done, since the user accesses the latest version every time they log in. Only one version of the dataset exists, on a secure ATSDR server, with nightly backup. Edits only need to be made in one place. This program can be

accessed from any computer that can connect to the internet as long as the client receives appropriate security privileges. The security architecture and database variables were designed to conform to all CDC/ATSDR standards. All data will be electronically collected, the data collection tool that we propose using (Appendix 3) will be completed on the computer screen. We would like to continue using the same form so that our data collection and analysis for calendar year 2008 will be consistent.

Another exciting feature of this system is real-time data entry. ATSDR monitors and can analyze entries into the system on a continuous basis. States can do the same with their own data. The data entry system was designed to reduce user burden by prefilling some of the information (e.g., entry date, day of week), performing checks to curtail erroneous data, and ATSDR's GIS server completes the variables for latitude and longitude, population estimates for surrounding areas, and whether there are certain locations (schools, nursing homes, day care centers, other businesses, hospitals and residences) within a quarter mile. This enhancement will save the states a considerable amount of time and effort and make the calculations more consistent among states. A training manual (Appendix 4) is also provided to each of the participating states to maintain consistency.

As the state health departments are notified of events that meet the case definition, they enter the preliminary data into the web-based data entry system. Preliminary data on an event should be in the database within 48 hours of occurrence. Each event has a unique, sequential identification (ID) number which is generated by the software each time a new event is entered into the system. New information about an event can be entered into the computer by re-opening a particular event ID.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ATSDR is not aware of any other agency that is presently collecting exactly this type of data. This knowledge comes from literature searches and through a study funded by ATSDR. There are three national sources of spills data: the NRC, the EPA , and the DOT. When trying to assess both the number and the effects of hazardous substances emergencies from any one of these single national reporting sources, each has its own specific shortcomings. These other data are not actively collected and, therefore, can contain duplicates and only preliminary data and may not have all qualifying events. These agencies also have differing reporting requirements, so they do not cover all releases. Additionally, these federal agencies focus on the release of hazardous substances into, and the effects of these releases on the environment as end-points, with a purpose of regulation and response. These data are not adequate to fully investigate the many risk factors associated with the human morbidity and mortality resulting from the release of those hazardous substances. HSEES actively gathers data from many varied sources (including NRC, EPA, and DOT) into one complete and comprehensive public health database. It is therefore necessary to continue and improve HSEES which focuses on the public health, and not just the environmental impact of hazardous substance emergencies.

An additional feature of the HSEES database is that it allows for the entry of non-qualifying events as long as they are marked as such. This is a great advantage to the state because they do not have to develop a separate system for other types of events they may want to track, e.g., petroleum events, terrorist threats or hoaxes, and chronic events that do not meet the

HSEES case definition.

A.5. Impact on Small Businesses or Other Small Entities

Small businesses and other small entities will only be marginally involved in this information collection process if an emergency spill or episode occurs at a small business or other small entities; and then, they will not be the primary responders. Questions have been held to the absolute minimum required for the intended use of the data.

A.6. Consequences of Collecting the Information Less Frequently

It is the requirement of the protocol (Appendix 5) that as the state health departments are notified of events that meet the case definition, they enter the preliminary data into the web-based data entry system. The real-time data entry requirements are consistent with the goals and objectives of the project, and allow for monitoring temporal and spatial trends of hazardous substance emergencies so that they may be acted upon in a timely manner if necessary. If data are collected less frequently, the quality and accuracy of the dissemination of the information would be greatly jeopardized. There are no legal obstacles to reducing the burden.

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

The respondent is expected to enter preliminary data in to the computer database within 24 hours of being notified of the event. The reason for this time frame is to take full advantage of the features of a web-based system. Data will be available to ATSDR for surveillance purposes as soon as it is entered. Therefore, HSEES can be used as a resource for terrorism

surveillance. The respondent is expected to enter data directly into the computer, the use of the long paper form is not required. This can save the state a lot of time and space. Many states have chosen to develop an abstract sheet to use for easy data-entry. Additionally, the computer will print out a completed form at the user's request that mimics the long form or they can print out a condensed form as well.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult

Outside the Agency

A. A Federal Register Notice (Appendix 6) soliciting comments on the HSEES data collection was published on Thursday January 10, 2008, Volume 73, Number 7, pages 1889-1890. No comments were received.

B. Because this form is expiring mid-year, and because ATSDR does not currently have the capability to make changes to the computer program that collects the data, the form is not being revised at this time. A committee is being formed to carefully analyze every question and solicit feedback from diverse stakeholders and a new form will be submitted for clearance in June 2008 to begin 2009 data collection with.

A.9. Explanation of Any Payment of Gift to Respondents

There are no payments or gifts made to the respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The CDC/ATSDR Privacy Act Officer has reviewed this application and has

determined that the Privacy Act is not applicable. No assurance of confidentiality will be provided to the states because no personal identifiers will be collected. Data is collected on emergency events and not individuals. Information collected on injuries does not contain personal identifiers. ATSDR is responsible for security and limits access to the data to selected ATSDR staff.

When information on an event involves victims, numbers are the key factor, and only limited demographics (e.g., sex; age) are requested. The only incidental identifiable information being collected is the name of the person who contacted the state health department about the event. Including full name is optional, and data in this system are not filed and retrieved by the name of that individual, hence no Privacy Act system of records exists.

To help states elicit cooperation from reporters and responsible parties, the HSEES data entry system encrypts names, street addresses, telephone numbers, and geographic coordinates of notification contacts and responsible parties. Interpretation of the results of the analyses is conducted by ATSDR staff and by the states for their state-specific data.

A.11. Justification for Sensitive Questions

No information on sensitive human behavior, attitudes, religious beliefs, or any other matters commonly considered to be of a private nature will be collected under this study.

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimate of Annualized Burden Hours

| Number of Respondents | Number of Responses per Respondent | Average Time per Response (in hrs.) | Annual Response Burden (in hrs.) |
|---|------------------------------------|-------------------------------------|----------------------------------|
| 14 state health department HSEES coordinators | 536 | 45/60 | 5,628 |
| 500 persons interested in HSEES data through the Web site | 1 | 6/60 | 50 |
| Total | 514 | | 5,678 |

The number of respondents (14) is based on the number of states that are presently involved in the surveillance system. The cooperative agreement for these 14 states is due to end in 9/2009 and whether it will be continued is dependent upon funding. The annual burden estimate is based on experience with this data collection for 11 years working with 16 states. The 536 responses per respondent number is an average. Our experience has shown a wide range of responses per respondent (state) which is largely due to state size, geographic composition (urban/rural), and population density. The same amount of time (0.75 hour) is required to do data collection for an event regardless of an individual state's characteristics. The process is as

follows: The state health department employee receives notification of an event. They review it to determine if it meets the case definition. Preliminary data are entered into the database. Then they obtain any missing information by telephone or fax. The event is geocoded to obtain the latitude and longitude coordinates and the number of people living in a 1/4, 1/2, and one mile radius of the event. The additional and/or revised information is added /updated in the database. This process takes approximately 45 minutes. The estimate for requests for data through the HSEES Web site, 500, is based on the number of requests ATSDR receives. There is a brief form to fill out to request materials or to download the public use data set. It takes on average 1 minute to complete.

B. Estimate of Annualized Costs

There are no costs to the respondents. The states are collecting this information in the course of exercising their authority to protect public health and to deliver public health program services.

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record keepers

There are no capital or maintenance costs associated with this data collection.

A.14. Annualized Cost to the Government

The total cost to the Federal Government for the collection of this information for the three-year project is \$5,858,808 as itemized below. Therefore, the average annual cost for this project is \$1,952,936. This estimate includes salaries and fringe benefits, overhead, supplies, travel, and contract costs.

| | |
|--------------------------------------|-----------|
| Three-Year Costs | |
| State Labor and Fringe Benefits | 3,719,096 |
| Overhead | 557,286 |
| Office supplies, printing, mailing | 62,344 |
| Travel | 88,468 |
| ATSDR Personnel | 600,000 |
| Database Contract | 513,614 |
| Chemical Coding and Support Contract | 318,000 |
| Total Federal Costs | 5,858,808 |

This is a request for the continuation of data collection. The decrease in burden hours from 7,356 to 5,678 represents a decrease of 1,728 hours since the last approval. The average response time has remained the same, however the average number of responses per respondent

has decreased with the implementation of a revised case definition, which removes stack emissions of carbon monoxides, sulfur dioxide, and oxides of nitrogen because they are very common and infrequently have public health consequences. Plus there has been a decrease in the number of respondents (states), from 15 to 14.

A.16. Plans for Tabulation and Publication and Project Time Schedule

As the state health departments are notified of events that meet the case definition, they enter the preliminary data from their records into the web-based data entry system. Every May the data from the previous year is finalized. The data are analyzed by both the state and ATSDR and Annual reports are written. Annual reports are disseminated to all interested, state, local, and private parties. These reports are consistent with the goals and objectives of the project, and present information regarding temporal and spatial trends of hazardous substance emergencies, information on the chemicals released (e.g., names, classes, amount), and information on the morbidity and mortality that resulted from these events. National or international presentations and journal articles on specific topics will also be produced dependent upon the results of the annual report and requests for information. The timeline for these special requests can not be anticipated, but previous publications and Annual reports are provided. The schedule is as follows:

December 2007- Submit OMB package for review

After Approval of OMB Package

March 2008-Do quarterly tally of HSEES data requests.

May 2008-Complete data collection of 2008 HSEES data, begin data analysis.

June 2008- Do quarterly tally of data requests.

October 2008- Do quarterly tally of data requests

Dec 2008 - ATSDR 2008 HSEES Annual Report Completed.

Do quarterly tally of data requests.

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

The expiration date for OMB approval of the information collection will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for the Paperwork Reduction Act submission.

B. Collections of Information Employing Statistical Methods

No statistical sampling methods are used for data collection for HSEES. Participating state health departments are notified of all accidental or emergency hazardous substance releases. They enter all of those meeting the HSEES case definition into the HSEES database and then investigate them more thoroughly. Participating states were not chosen at random, but rather, were selected through a competitive announcement. Currently, the 14 participating states cover approximately 42% of the U.S. population. Since the data collection for HSEES does not involve statistical sampling methods, the information collected may not be representative of the whole U.S. No statistical estimations are made for the entire U.S. However, information from HSEES is representative of the participating states and is very valuable in understanding

accidental and emergency releases of hazardous substances and their impact on public health.

