# Revision Package: OMB 0920-0260

# **Health Hazard Evaluation/Technical Assistance and Emerging Problems**

### **Section A**

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The following justification and attachments for the information collection request (ICR) identified as OMB No. 0920-0260 is a revision of the ICR by the same OMB number previously approved in November 2011. The English and Spanish Health Hazard Evaluation (HHE) request forms are unchanged. The example interview and questionnaire are unchanged. The Employee Contact Postcard is a new information collection form. This new form is available in both English and Spanish. Revisions made to the five followback questionnaires are re-wording and re-ordering of a few questions to improve the ease of responding.

Annualized burden hour estimates for the ICR forms covered by this package are associated with conducting an estimated 300 HHE requests plus 6 emerging problem investigations (from burden tables on pages 14 and 15). Revised burden estimates draw upon the HHE program's recent experience. The burden changes from the 2011 OMB ICR are:

•	Employee, union, employer HHE requests				
•	HHE specific interviews				
•	HHE specific questionnaires				
•	Employee Contact Postcard (New)				
•	Followback questionnaires for HHEs with onsite evaluations:				
	0	Post-site visit questionnaire	- 12 hrs		
	0	Post-final report questionnaire	- 17 hrs		
	0	One year later impact/outcome questionnaire	- 17 hrs		
•	<ul> <li>Followback questionnaires for HHEs without onsite evaluations:</li> </ul>				
	0	Post HHE closeout questionnaire	- 5 hrs		
	0	One year later impact/outcome questionnaire	- 8 hrs		
•	Total	ICR burden hour change from 2011 OMB renewal:	+ 170 hrs.		

### Health Hazard Evaluation/Technical Assistance and Emerging Problems

The total annualized burden hour estimate for all forms is 3020 hours.

Various programs in the federal government address issues related to occupational safety and health. The National Institute for Occupational Safety and Health (NIOSH), in the Department of Health and Human Services, and the Occupational Safety and Health Administration (OSHA), in the Department of Labor, provide services to individual facilities throughout the United States. Each agency has a unique mission and offers services that complement rather than duplicate each other. Unlike the OSHA consultation programs and other compliance assistance initiatives, the NIOSH Health Hazard Evaluation program is authorized to respond to requests from employees and their authorized representatives. In addition, the Health Hazard Evaluation program works collaboratively with other public health entities at the federal, state, and local level to ensure that fundamental public health measures are in place. The Health Hazard Evaluation program has the unique ability to assemble an interdisciplinary team (e.g., industrial hygienists, engineers, occupational physicians, epidemiologists, psychologists) who not only conduct exposure assessments, but also assess the relationship between workplace exposures and employee health. The NIOSH focus is on health, rather than safety, which accounts for much of the work of the OSHA compliance assistance

programs. The Health Hazard Evaluation program has the ability to provide assistance focused not only on hazards addressed by specific OSHA standards, but also on a broad range of workplace health concerns. In fact, NIOSH receives referrals from the OSHA consultation programs when specific health issues can be better addressed by NIOSH.

The Health Hazard Evaluation program communicates with the relevant entities within OSHA to guard against redundancy. Appropriate entities within OSHA are informed of NIOSH plans for on-site evaluations before they are undertaken. When NIOSH learns an OSHA program is currently working in a specific facility, NIOSH defers to OSHA until the OSHA activity is completed and then becomes involved only if OSHA did not address specific issues. Moreover, NIOSH frequently refers health hazard evaluation requesters to OSHA when their specific concerns clearly relate to a specific OSHA standard and could better be addressed by OSHA.

Thus, while NIOSH and OSHA both are addressing workplace hazards, the programs offered by the two agencies complement each other to protect the health of workers in the United States. Even with OSHA and NIOSH working together, the need for occupational health and safety services to the nation's 7.4 million work sites (U.S. Census Bureau [2011]. Statistics of U.S. Businesses (SUSB) Main: Latest SUSB Annual Data-U.S. all industries.[http://www.census.gov/econ/susb/]. Date accessed: March 2014.) far exceeds the capacity of each agency.

#### A. Justification

1. <u>Circumstances Making the Collection of Information Necessary</u>
In accordance with its mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, NIOSH responds to requests for Health Hazard Evaluations to identify chemical, biological, or physical hazards in workplaces throughout the United States. Each year, NIOSH receives approximately 300 such requests. NIOSH conducts approximately 90 short-term field evaluations each year to identify potential chemical, biological, or physical hazards in a given workplace. For the remaining requests, NIOSH responds by letter or telephone. This authority forms the basis for the NIOSH "Health Hazard Evaluation" program. NIOSH uses its general research authority found in Section 20(a)(4), 20(a)(6), and 20(a)(7) of the Occupational Safety and Health Act and Sections 301(a) and 501(a)(5) of the Federal Mine Safety and Health Act (Attachment A1) to respond to requests for similar investigations from other federal agencies, and state and local institutions – i.e., "technical assistance" and to perform self-initiated short term studies of "emerging problems."

#### Requirements in these two Acts

(a) Provide a practical means to assure that workers exposed to the thousands of substances for which standards have not yet been developed are properly protected, and

(b) Obtain information on health hazards at current workplace exposure levels. This information may indicate the need for changes in existing health standards.

Since 1970, NIOSH has responded to over 15,500 Health Hazard Evaluation requests. The main purpose of a Health Hazard Evaluation is to help employers and employees identify and eliminate work hazards. Nearly all Health Hazard Evaluations are in response to specific requests for assistance by employers, employees, employee representatives, other federal agencies, and state and local agencies. In the three years from FY 2011 – FY 2013, NIOSH received and responded to 687 Health Hazard Evaluation requests from a variety of workplaces including health care facilities, industrial settings, and non-industrial indoor environments. Each year NIOSH initiates a few Health Hazard Evaluations in response to new information obtained by NIOSH regarding chemical, biological, or physical agent hazards and for which NIOSH needs to assess the feasibility of conducting a long-term research investigation. In these situations, a relatively small respondent burden is involved, using environmental and medical investigative procedures that are highly specific to the hazard and workers involved.

NIOSH anticipates that the number of requests received may increase with the agency's increasing outreach activities to its partners and customers through the National Occupational Research Agenda or NORA (<a href="http://www.cdc.gov/niosh/nora/">http://www.cdc.gov/niosh/nora/</a>). Based on a program review completed by an expert panel of the National Academies, the HHE Program continues unprecedented efforts to expand awareness of the program. It also is strengthening its initiative to conduct followback evaluations for completed investigations, and continues to conduct a small number of research oriented and emerging issue Health Hazard Evaluations. Two examples of emerging issues for which the Health Hazard Evaluation program are actively involved are "green" industries and pharmaceutical exposures.

Because of the number of investigations conducted each year, the need for rapid response by NIOSH to requests for assistance, and the unpredictable and changing nature of the investigations, consolidated clearance is requested for data collection activities related to Health Hazard Evaluations. The implementing regulations for these programs are 42 CFR Parts 85 and 85a (Attachment A2).

#### 1.1 Privacy Impact Assessment

Personally identifiable information collected during the HHE process is retained for a period of 20 years after a cutoff date. The cutoff date for HHEs initiated in a fiscal year is the last close date of the HHE projects that opened in the same fiscal year as the HHE project of interest. Identifiable information is required to submit and validate an HHE request. Individually identifiable information is collected during the HHE investigation. This information is used to identify study participants and their associated exposures and health

experiences so that a determination may be made whether a workplace associated health hazard exists. The amount of personally identifiable information obtained depends upon the nature of the workplace health concern NIOSH has been asked to evaluate.

- 1. Annually, NIOSH estimates that it receives approximately 300 requests from employers and employees/employee representatives for Health Hazard Evaluations. A small number of requests (generally less than 10 per year) come from other federal/state/local agencies for technical assistance. NIOSH does approximately six self-initiated feasibility studies of emerging problems each year. Approximately 40 FTEs and 5.1 million dollars are currently allocated to the total Health Hazard Evaluation efforts. Individual investigations vary widely in terms of the number of potential hazards assessed – generally from one to 11, the number of workers involved – generally from 10 to 300, the nature of environmental and medical tests involved, and consequently the time required to complete the study and produce a final report – normally from two months to approximately one year. Seventy three percent of field studies initiated in Fiscal Years 2011-2013 were completed as of February 28, 2014. For these, the median time to complete the evaluation after the initial visit was 14 months. Prior to completion, however, interim findings are reported and recommendations are made to address identified hazards in a timely manner.
- 2. About 40% percent of the 300 Health Hazard Evaluation requests NIOSH receives need an on-site evaluation to address the issues of concern to the requester. Although each on-site evaluation may look at the effects of different chemical, biological, or physical hazards, or a set of agents or other types of problems, the studies are similar. They all involve an initial site visit to evaluate available data, meet with management and employee representatives, observe operations and potential exposures and working conditions, review exposure and health data, and conduct informal interviews with employees. Initial visits may be followed by subsequent environmental or medical investigations at the establishment. The medical investigations may entail use of questionnaires to ascertain health symptoms and conditions and factors that may affect them. Although each questionnaire is specific to a work site and its hazards and health problems, questionnaires are based on standard medical and epidemiologic tools. Questionnaires generally do not involve sensitive information.

Final reports of the investigations, including recommendations to address hazards found, are distributed to requesters, employers, employee representatives, the Department of Labor (OSHA and Mine Safety and Health Administration (MSHA)), state and local health departments, and, as appropriate, other state and federal agencies. The reports are available on the NIOSH internet site and are announced in NIOSH eNews (<a href="http://www.cdc.gov/niosh/enews/default.html">http://www.cdc.gov/niosh/enews/default.html</a>). The availability of final reports is announced to all State Epidemiologists and Epidemic Intelligence

Officers. This occurs through Epi-X, a secure electronic communication network maintained by the Centers for Disease Control and Prevention for public health agencies nationwide. All published reports include medical information in summary form only, and do not contain personal identifiers of individual participants.

Health Hazard Evaluations addressed through an on-site evaluation are of most benefit to those who requested them, that is, the employer and employees at a given work site. A Health Hazard Evaluation can be particularly useful when one of the following criteria is met:

- workers have illnesses from an unknown cause
- workers are exposed to chemical, biological, or physical agents or processes that are not regulated
- workers experience adverse health effects from workplace exposures, even though exposure standards are not exceeded
- medical doctors or epidemiologists are needed to fully evaluate the hazard
- there is concern that the incidence or prevalence of a disease is higher than expected
- the hazard is new or previously unrecognized
- conventional processes or materials with previously recognized hazards are used in a new process or novel application
- combined effects of several hazards are suspected

The reasons for requesting a consolidated clearance for these studies are as follows:

- (a) The need to respond quickly. Health Hazard Evaluation requests usually concern important public health problems that need to be addressed within a short time frame. Typically, NIOSH investigators arrange to visit the establishment within 6-10 weeks following a request.
- (b) The unpredictability of the study. Most requesters do not have a clear idea as to what the hazard is that is causing adverse health effects. NIOSH investigators enter work sites with hypotheses about specific exposure agents and disease outcomes but, during their investigation, may discover other more serious hazards or health problems. Thus, the nature of the investigation frequently changes during the course of the evaluation. Often, studies need to be designed around periods of specific climatic conditions or work processes and schedules. It is not possible to design a standard questionnaire before visiting the work site, nor ascertain the type of medical examination or test that would be most appropriate to gather the desired information.
- (c) <u>The number of studies involved.</u> It would be a significant administrative burden to process the large number of requests each year that would

require OMB clearance for Health Hazard Evaluations. Doing so one by one would increase the time to completion and, thus, not be responsive to stakeholder needs.

Consequently, as in the past, NIOSH is proposing a consolidated clearance for Health Hazard Evaluation field investigations. This revision package reflects modifications to that approved in 2011. Modifications are:

- Reduction in the number of HHE requests from 320 to 300 to align estimates with recent experience
- Introduction of a form for obtaining employee contact information. In accordance with a new NIOSH policy (2013), this information enables NIOSH to provide participants with their personal exposure monitoring results.
- Changes in the numbers used to create the burden estimates that reflect recent experience regarding the frequency and extent of information collection from interviews and questionnaires.
- Minor wording revisions of followback questionnaires to make their completion easier for respondents
- Reduction of the estimated completion time for the Initial Site Visit Followback Survey Form from 15 to 10 minutes.

### 2. Purpose and Use of the Information Collection

The Health Hazard Evaluation program provides individual work sites with a resource for determining if toxic substances or harmful physical agents are present in the environment and pose a health hazard to employees. Health Hazard Evaluations are essential to NIOSH for meeting its legislated function to determine the toxic or hazardous effects of substances or physical agents found in places of employment. Information collected is integral to identifying the workers who may be exposed to a potential hazard in the workplace. Defining health impacts the workforce may be experiencing also requires this information. Identifiable information is used to insure the integrity of data collected and that it is not comingled with other workers' information within the same study. Additionally this information is used to verify that health effects experienced by workers is occurring among workers encountering the workplace hazard of concern. Similarly, collection of workplace exposure monitoring requires that it be linkable with workers where the exposure may occur. NIOSH staff and NIOSH contractors responsible for doing the Health Hazard Evaluation use the collected information to complete the requested workplace investigations. Health Hazard Evaluation reports presenting the study findings use only de-identified data to report results.

Current information collection methods facilitate NIOSH investigators' ability to obtain the required information for requested work place investigations to determine the existence and magnitude of workplace hazards of concern. This collection of information enables NIOSH to fulfill its obligations under law

[Section 20(a)(6) of the Occupational Safety and Health Act of 1970; Section 501(a)(11) of the Federal Mine Safety and Health Act of 1970; Attachment A1]. NIOSH Health Hazard Evaluation findings presented in a report format to employer and employees of the facility evaluated answer workplace health concerns identified in the Health Hazard Evaluation request. Health Hazard Evaluation results may be used by employers and employees to identify and reduce or eliminate hazardous workplace exposures; assess their need to improve or implement workplace health and safety programs; obtain input on the effectiveness of their workplace health and safety; or obtain specific assistance to solve a workplace related health concern.

Followback information collection provides the NIOSH Health Hazard Evaluation program with a mechanism for obtaining feedback on the effectiveness of the program. Employers and employee representatives may provide input to NIOSH from their perspective about what worked well and any suggestions that might improve the Health Hazard Evaluation program. NIOSH uses feedback to evaluate the usefulness of the program to employers and employees. NIOSH periodically reviews responses to help identify program areas that may be improved.

In addition to the direct benefit to the specific establishment studied, the majority of short-term field investigations done in response to Health Hazard Evaluation requests result in a report that is deemed of sufficient general interest that the report is made available to a wider audience through the internet. Reports can also be obtained by calling the CDC-NIOSH toll-free assistance number (1-800 CDC INFO) or through the National Technical Information Service (NTIS). These reports also become the basis for additional dissemination efforts such as publishing findings in scientific and trade publications.

#### 2.1 Privacy Impact Assessment

- 2.1.1. While the project is ongoing the personal information is kept in a locked file cabinet, accessible to NIOSH staff involved in the data collection activities. All NIOSH staff are required to maintain and protect private information according to the 2011 NIOSH Sensitive Data Security Program. Results of individual medical tests (and other examinations) and individual exposure monitoring are shared with the individual. These results may also be provided to the employee's personal physician upon the employee's written request.
- 2. A statement detailing the impact the proposed collection will have on the respondent's privacy: To minimize the risk of loss of privacy, NIOSH investigators use identification numbers and do not put names on specimens or medical questionnaires. The intent of the program is not to impact the privacy of individuals. NIOSH investigators are required to follow the 2011 NIOSH Sensitive Data Security Program.

- 3. *Use of Improved Information Technology and Burden Reduction* 
  - Questionnaires are designed to collect only the minimal information necessary to address the issues of concern. A routine part of the initial site visit is to gather industrial hygiene, medical, and epidemiological data that are germane to the issues. Available data, collected by consultants and the employer, are utilized when possible to avoid collecting redundant information. Interviews are conducted to be as unobtrusive as possible and to minimize employees' time away from the job. There are no legal obstacles to reduce the burden. Use of electronic surveys is not feasible in the workplace setting of most health hazard evaluations. Information from past mailed survey respondents indicates that electronic surveys are not acceptable to a large percentage. Moreover, the burden on individual respondents would likely not change significantly with alternative data collection methods.
- 4. Efforts to Identify Duplication and Use of Similar Information

Previous information is used whenever appropriate to a study. Some Health Hazard Evaluation requests that involve issues of compliance with OSHA and MSHA standards are referred to those agencies. Before initiating a field investigation, local OSHA or MSHA offices are contacted to determine if a relevant investigation is ongoing or has recently been completed at the establishment. In addition, state health departments are informed of the Health Hazard Evaluation request and asked to contact NIOSH if they have relevant information about the establishment. It is important to note that the NIOSH Health Hazard Evaluation program is not primarily oriented to assisting employers to comply with OSHA or MSHA regulations and, unlike the compliance assistance, consultation, or alliance programs of those agencies, is authorized to respond to requests from employees and their representatives, as well as employers.

### 5. *Impact on Small Businesses or Other Small Entities*

Every effort is made to minimize the burden on all employers (including small businesses) when collecting information. Health Hazard Evaluation field investigations are conducted in a manner that precludes unreasonable disruption of the operations of the establishment. The dates for the investigation generally are set in consultation with the employer. NIOSH investigators work closely with employers to establish the logistics of the visit. Employee interviews and questionnaires are designed to be as brief as possible while still obtaining the essential information needed for the evaluation. Paragraph (e) in Section 85.7 of 42CFR85 requires the conduct of Health Hazard Evaluations shall be such as to preclude unreasonable disruption of the operations of the employer's establishment.

6. <u>Consequences of Collecting the Information Less Frequently</u>
Responses to Health Hazard Evaluations are initiated only upon receipt of a
Health Hazard Evaluation request. Typically, respondents reply only one time

during the field investigation. For the follow-back surveys, respondents may be asked to complete two questionnaires within a one-year period. This is needed to ensure that feedback is timely and information is accurate, and permits the assessment of changes over time. There are no legal obstacles to reduce the burden.

The consequences to the agency of not collecting the information needed to validate and conduct Health Hazard Evaluations is that NIOSH will not be able to initiate and complete evaluations. Section 20(a)(6) of the Occupational Safety and Health Act of 1970 and Section 501(a)(11) of the Federal Mine Safety and Health Act of 1970 require NIOSH to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found following a request for a Health Hazard Evaluation.

Eliminating the collection of privacy act information required during a workplace Health Hazard Evaluation would substantially reduce the ability to independently verify and evaluate reported and potential health hazards in the workplace. Omitting contact information would impede the ability of NIOSH to meet ethical and legislative obligations for notifying both employers and affected employees of investigation findings. It would further reduce the ability of the program to determine program impact and outcomes.

- 7. <u>Special Circumstances Relating to the Guidelines of 5 CFR 1320.5</u>
  There are no special circumstances associated with this data collection activity.
- 8. <u>Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency</u>
  - (a) A notice of this proposed project was published in the Federal Register, Volume 79 Number 67, on April 8,, 2014, pages19337- 19338 as required by 5 CFR 1320.8(d). (Attachment B). CDC received no comments or requests for information during the 60 day comment period.
  - (b) Because most of these studies are relatively small-scale efforts requiring a timely response, it is not always practical to obtain outside consultations. However, local OSHA and MSHA staff are contacted to determine if they have relevant information or activities relating to the Health Hazard Evaluation request (Attachment C English and Spanish versions). As noted above, the state health department is also requested to provide similar information to NIOSH. Project review is conducted with persons outside NIOSH on an informal basis. Prior to or during a particular investigation, it may be necessary to contact individuals in academia (as recognized experts in specific scientific areas) for consultation. When appropriate, procedures for human subjects review are followed, which in a few instances may involve statistical and peer review. For most investigations involving questionnaires or medical exams/tests, statistical consultation is provided in-house.

9. *Explanation of Any Payment or Gift to Respondents* Remuneration of respondents is not provided.

# 10. Assurance of Confidentiality Provided to Respondents

A review of this project has determined that the Privacy Act is applicable. Full names are collected because interviews are often required; medical histories, testing, and physical examinations are frequently determined to be a necessary part of the investigation of possible work hazards; and names are needed to enable NIOSH to notify individual employees of their own medical test and exposure monitoring results. Data will be covered under CDC Privacy Act System Notice Number 09-20-0147, Occupational Health Epidemiological Studies and Energy Employees Occupational Illness Compensation Program Act. Respondents are assured that information received will be maintained in accordance with the Privacy Act (5 USC 522a) and the Department's regulations under that law contained in Title 45, Part 5b of the Code of Federal Regulations. Participants are informed that NIOSH is authorized to collect their personal information and will protect it to the extent allowed by law. They are notified that there are conditions under the Privacy Act where their information may be released to collaborators or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices.

Health Hazard Evaluations are a public health activity, not research, and would not typically undergo review by an institutional review board. For a small number of Health Hazard Evaluations where the investigation meets specific criteria of a research study, those Health Hazard Evaluations are individually required to go through an institutional review board review.

#### 10.1 Privacy Impact Assessment Information

- 1. Participants are notified during investigations that their participation is voluntary and that they may withdraw from participating at any time.
- 2. Consent forms are used for participants involved in medical testing [Attachment D2 one for specimens retained, one for specimens discarded]. Participants are notified that their participation is voluntary and that they may withdraw from participating at any time. They are also notified that their information will be protected to the extent permitted by law.
- 3. Questionnaires used for medical evaluations [Attachment F] notify participants on the first page that their participation is voluntary and that the information will be protected to the extent permitted by law.
- 4. The safeguarding measures that will be in effect to protect the records include locked files in locked rooms in a restricted access facility, password protection for computer files, and access being restricted to NIOSH personnel with a bona fide need for the data in order to perform their official duties.
- 5. A system of records will not be created for this project, since it is covered under the CDC Privacy Act System Notice Number 09-20-0147.

# 11. Justification for Sensitive Questions

The questions asked are either necessary to identify respondents or relate to the objectives of the study. The respondents are informed that participation is voluntary. Medical reports and results are reported to the individual as required in 42 CFR Part 85 and 85a and by the Centers for Disease Control and Prevention and NIOSH Institutional Review Board (IRB) procedures. Most studies are not research in nature and do not involve sensitive questions or unusual medical tests; therefore they do not require IRB approval. A generic consent form, however, is reviewed and approved annually by the NIOSH IRB for medical testing. [Attachment D2] Specific findings and personal records concerning individuals are maintained in accordance with the Privacy Act of 1974 and are not disclosed except as provided in the Privacy and Freedom of Information Acts. Trade secret information is not divulged to outsiders in accordance with the provisions of 42 CFR 85 and 85a.

### 12. Estimates of Annualized Burden Hours and Costs

(a) The actual number of Health Hazard Evaluation requests received in a given year cannot be known in advance. Over the last ten years, the numbers have ranged from 178 to 419. The lowest numbers occurred in Fiscal Years 2009 through 2011 and 2013. This period of time included the longest and deepest U.S. economic slump in 70 years. NIOSH anticipates that the number of requests received will continue to increase with the agency's increasing outreach activities, particularly in newer areas (such as "green" industries) where occupational health hazards have not been well evaluated. An increase in the number of requests with recovery of the U.S. economy and as various industries initiate or ramp up their production/work force activities has begun to appear. Considering this, and looking at previous trends, the average number of Health Hazard Evaluation requests for FY 2014 and beyond is anticipated to increase upwards to an estimated 300. Table 12A, Row1 shows that at an estimated average of 12 minutes for completing and submitting a Health Hazard Evaluation request, the result is an estimated 60 burden hours.

On the basis of prior experience, NIOSH assumes that 40% of the 300 requests will require a site evaluation. In addition, six additional onsite evaluations will be done for emerging issue evaluations. Thus, a total of 126 on-site evaluations are used for calculating the burden of specific activities. The number of participants and time for completion described below are based on average experience in recent years.

Of the 126 onsite evaluations, NIOSH estimates that 89 (70%) will involve an initial site visit that includes informal interviews to gather information on exposures and health effects. These interviews do not entail use of a questionnaire; they are akin to a discussion between a doctor and their patient. An example of what may be covered in these interviews is provided in Attachment E. This interview form was used for an evaluation of workplace

lead exposures among jockeys. The interview form is used by the NIOSH investigator for consistency and is not distributed to individuals. The estimated time for an interview is 15 minutes. Assuming that 30 employees are interviewed at each of the 89 work sites, the burden from this activity is 668 hours, as shown in Table 12A, Row 2.

Of the 126 onsite evaluations, NIOSH estimates that 38 (30%) will involve employee questionnaires. As noted previously, a standard questionnaire is not used; questionnaires are developed to fit the unique needs of each situation, but are based on standard medical and epidemiologic tools. An example questionnaire used in an investigation addressing respiratory and skin effects of exposure to machining fluids is provided in Attachment F. The estimated time for completion of questionnaires is 30 minutes. Assuming that 100 employees complete a questionnaire at each of the 38 work sites, the burden from this activity is 1900 hours (Table 12A, Row 3).

Of the 126 onsite evaluations, NIOSH estimates that 89 (70%) will involve personal exposure monitoring of employees. These employees are asked to complete a contact information postcard (Attachment G), which enables NIOSH to provide them with their individual workplace exposure monitoring data. The estimated time to complete the postcard is 5 minutes. Assuming that 25 employees are monitored at each of the 89 work sites, the burden from this activity is 186 hours as shown in Table 12A, Row 4.

During the Health Hazard Evaluation and after the report is issued, NIOSH will distribute follow-back questionnaires to assess the effectiveness of the Health Hazard Evaluation. Follow-back evaluations will be done for all 126 onsite evaluations with two respondents per evaluation. Based on 252 respondents completing one 10- and one 15-minute questionnaire in the first year (Attachments H and I) and one 15-minute questionnaire in the second year (Attachment J), this estimated burden is 105 (42 and 63) hours in the first year and 63 hours in the second year, as shown in Table 12A, Rows 5, 6, and 7.

Follow-back evaluations will be done with the primary requestors for a sample of the HHE requests where there was no onsite evaluation. A 50% sample is selected by choosing every other request. Based on recent experience, approximately 90 of these follow-backs will be done, with one respondent for each. Based on respondents completing one 10-minute questionnaire in the first year (Attachment K), and one 15-minute questionnaire in the second year (Attachment L), this equates to about 15 and 23 burden hours, respectively, as shown in Table 12A, Rows 8 and 9.

The estimate of time required for interview and questionnaires is based on recent experience. The total burden hours (3020) is greater (5.1% or 146 hrs

greater) than that cited in the last ICR request (2874 hrs.). Were it not for the new form, however, the burden would have decreased (-1.4% or 40 hrs less).

Table 12A

Estimate of Annualized Burden Hours

Type of	İ	No. of	No. of	Axoraga	Total
U .	Form	No. of		Average	Total
Respondent		respondents	responses	burden	Burden
(row numbers			per	per	Hours
referred to in			respondent	response	
text)	TT 11 TT 1	200		in hours	00
1) Employees/	Health Hazard	300	1	12/60	60
employee	Evaluation				
representatives/	Request Form				
or employers*	Attachment C				
2) Employees	Health Hazard	2,670	1	15/60	668
	Evaluation				
	specific				
	interview				
	example				
	Attachment E**				
3) Employees	Health Hazard	3,800	1	30/60	1,900
	Evaluation				
	specific				
	questionnaire				
	example				
	Attachment F**				
4) Employees	Employee	2,225	1	5/60	186
	Contact Postcard				
	Attachment G				
5) Follow-back	Initial Site Visit				42
for onsite	Followback				
evaluations –	Survey form	252	1	10/60	
employer &	Attachment H				
employee					
representative					
Year 1					
6) - employer &	Closeout for	252	1	15/60	63
employee	Health Hazard				
representative	Evaluation				
Year 1	Followback				
	Survey with site				
	visit				
	Attachment I				
7) – employer &	1 Year Later for	252	1	15/60	63
employee	Health Hazard				

representative Year 2	Evaluation Followback Survey with site visit Attachment J				
8) Follow-back for evaluations without onsite – employer & employee representative Year 1	Closeout for Health Hazard Evaluation without site visit Attachment K	90	1	10/60	15
9) employer & employee representative Year 2	1 Year Later for Health Hazard Evaluation without site visit Attachment L	90	1	15/60	23
Total Estimate of Annual Burden Hours					3,020

<sup>\*</sup> Includes government, other, and joint requests.

Data collection for a Health Hazard Evaluation generally occurs during a respondent's usual work hours. Assuming an average civilian hourly wage (total compensation) in the US of \$ 31.57 (Wages and salaries for all workers in the private nonfarm economy excluding households and the public sector excluding the Federal government, [from the Bureau of Labor Statistics, Economic News Release Table 1. Civilian workers, by major occupational and industry group, September 2013

[http://www.bls.gov/news.release/ecec.t01.htm; accessed March 2014]), the annualized respondent cost is \$95,342 (\$31.57 x 3020 burden hours).

Table 12B

Estimated Annualized Burden Costs

Type of	Total Burden	Hourly Wage Rate	Total Respondent
Respondent	Hours		Costs

<sup>\*\*</sup>As described in Section A.1 above, each interview/questionnaire is specific to a work site evaluation and its hazard and health concerns. No specific interview form is distributed, questions pertain to concerns expressed in the HHE request and are asked in an open-ended manner. An HHE specific sample of what may be asked in the interviews is provided. An HHE specific questionnaire from another HHE is provided as an example of the questionnaire employees may complete as a part of the on-site investigation.

Employees/employee representatives/ employers	60	\$31.57	\$1895
Employees (interview)	668	\$31.57	\$21,089
Employees (questionnaire)	1900	\$31.57	\$59,983
Employees (contact postcard)	186	\$31.57	\$5,872
Follow-back for onsite evaluations			
Year 1	42	\$31.57	\$1,326
Year 1	63	\$31.57	\$1,989
Year 2	63	\$31.57	\$1,989
Follow-back for evaluations without onsite			
Year 1	15	\$31.57	\$474
Year 2	23	\$31.57	\$726
TOTAL	3020		\$95,342

# 13. <u>Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers</u> None

### 14. Annualized Cost to the Federal Government

The annual cost to the government for operating the Health Hazard Evaluation and Technical Assistance program is approximately 5.1 million dollars, which covers \$4.7 million for 40 FTEs in FY 2013 and \$400 thousand in discretionary costs. The estimated cost for preparing, administering, and processing questionnaires related to this program is \$450,000 (which includes FTE expenses and discretionary expenses).

### 15. Explanation for Program Changes or Adjustments

This is a revised information collection request. The revisions made in this package are minor re-wording and re-ordering of questions contained in the five Followback questionnaires to improve the ease of responding by the questionnaire recipients. A new information collection form is introduced that allows collection of the mailing address for employees participating in individual workplace exposure monitoring who wish to received their individual exposure results. This has been added because of a new NIOSH administrative policy. This form is included in Attachment G. The total burden of 3020 hours is 146 hours more (5.1% greater) than the 2011 OMB ICR renewal which was for 2874 hours. Excluding the new form, which requires an estimated 186 burden hours, the total burden hours would be 2834 hours. This is 40 hours less (1.4% less) than the last OMB ICR renewal.

16. Plans for Tabulation and Publication and Project Time Schedule

Typically, NIOSH investigators arrange to visit the establishment within 6-10 weeks following a request. Preliminary observations are reported at the end of the initial site visit; when available, interim results may be reported before a final report is completed. Environmental and medical data collection efforts for studies that require additional evaluation usually take about six months. Individual medical test and individual workplace exposure monitoring results are usually available and sent two to three months after testing. The median time to complete the evaluation after the initial visit for Fiscal years 2011-2013 was 14 months. Completion times vary according to the time to receive analytical results for environmental or biological samples, medical reports from consulting specialists, complexity of the data analysis, and competing demands on staff time.

A report of each Health Hazard Evaluation is prepared. Medical results are presented in summary fashion; personal identifiers are never included. The report is sent to employee and employer representatives, OSHA or MSHA as appropriate, and other government agencies, as needed. Reports are available to the public through the NIOSH web site and the NTIS. Findings may be published in scientific and trade journals. Reports often are cited in other NIOSH publications, furthering their dissemination.

- 17. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>
  No exemption is requested.
- 18. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>
  No exceptions are requested.