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Health Hazard Evaluation/Technical Assistance and Emerging Problems

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Part A: Justification

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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 7.5 million work sites (U.S. Census Bureau, http://censtats.census.gov/cgi-bin/cbpnaic/cbpsel.pl, accessed July 25, 2007) far exceeds the capacity of each agency.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   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 420 such requests. NIOSH conducts approximately 80 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 A) 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 13,600 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 2004 – FY 2006, NIOSH received and responded to 1,190 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 also increase with the agency's increasing outreach activities to its partners and customers through the National Occupational Research Agenda or NORA (http://www.cdc.gov/niosh/nora/).

Because of the number of investigations conducted each year, the need for rapid response by NIOSH to requests for assistance, and the varied 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 B).

Annually, NIOSH estimates that it receives approximately 420 requests from employers and employees/employee representative for Health Hazard Evaluations and 8 requests from other federal/state/local agencies for technical assistance. NIOSH does approximately six self-initiated feasibility studies of emerging problems each year. Approximately 50 FTEs and 7.7 million dollars are currently allocated to these 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. The median time to complete a Health Hazard Evaluation field study (that is, to issue the final report) for requests received from 2004-2006 was 12 months.

Twenty-five to fifty percent of the 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. About 50% of these initial site visits are 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 may or may 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)) and, as appropriate, other state and federal agencies. The reports are available on the NIOSH internet site and are announced in NIOSH eNews (http://www.cdc.gov/niosh/enews/default.html) The availability of final reports is also announced to all state epidemiologists and epidemiologic intelligence officers. This is done 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
- 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. Obtaining clearance for each of these studies would not be possible within this period.

(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 worksites 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) The number of studies involved. It would be administratively difficult to process 80-90 requests annually for OMB clearance for Health Hazard Evaluations. OMB clearance of each of these studies would more than double the median time to completion.

Consequently, NIOSH is proposing a reinstatement of the clearance for field investigations of this type.

2. Purpose and Use of the Information Collection

The Health Hazard Evaluation program assists NIOSH in recommending new standards for workers exposed to harmful physical agents or toxic substances, in assessing the validity of existing standards, and in providing 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. 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).

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. Because the surveys are completed by various individuals (i.e., a mix of managers [sometimes from disparate geographic locations], and supervisory and nonsupervisory employees) for whom we don't have information regarding their access to computers it is neither efficient nor cost effective to develop an electronic version of the questionnaires.

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.

6. Consequences of Collecting the Information Less Frequently

   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.

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

   There are no special circumstances associated with this data collection activity.

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

   (a) A notice of this proposed project was published in the Federal Register, Volume 73 Number 70, on April 10, 2008, pages 19504-19506 as required by 5 CFR 1320.8(d). (Attachment C). One request for a copy of the Supporting Statement was requested from the public and a copy was sent electronically (Attachment D).

   (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. 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 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. They will be informed in the consent form that providing the information is voluntary and that the information is being used to evaluate a hazard in the employee's workplace. 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.

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 (CDC) and NIOSH Human Subject Review Board (HSRB) clearance procedures. Most studies do not involve sensitive questions or unusual medical tests and therefore do not require HSRB approval. A generic consent form, however, is reviewed and approved annually by the NIOSH HSRB. (Attachment E) 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 three years, the numbers have ranged from 385 to 419. Considering this, and looking at previous trends, the average number of Health Hazard Evaluation requests for FY 2007 and

beyond is currently estimated to be 420. Table 12A shows that at an estimated average of 12 minutes for completing and submitting a Health Hazard Evaluation request, the result is an estimated 84 burden hours. 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 (http://www.cdc.gov/niosh/nora/).

Approximately 210 Health Hazard Evaluation requests will require that NIOSH conduct an initial site evaluation. An average of 20 employees will be informally interviewed at each establishment 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 HHE specific example of what may be covered in these interviews is provided in Attachment F, used for an evaluation addressing potential workplace lead exposures among jockeys. Based on a 15-minute interview, this equates to 1050 burden hours, as shown in Table 12A. In about 105 of the 210 establishments, a more in-depth evaluation, involving environmental sampling and questionnaires, will be needed. 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 of an HHE specific questionnaire used in an investigation addressing tuberculosis concerns among emergency medical technicians is provided in Attachment G. In addition, an estimated six additional short-term field investigations each year will be initiated by NIOSH to assess the feasibility of further study of emerging problems. For these 111 evaluations, an average of 40 employees will complete a questionnaire. Based on a 30-minute questionnaire, this equates to 2220 burden hours as shown in Table 12A.

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 210 HHE requests where there was an onsite evaluation. Based on recent experience, an average of four respondents will participate for each HHE. Based on 840 respondents completing two 10-minute questionnaires in the first year (Attachments H and I) and one 15-minute questionnaire in the second year (Attachments J), this equates to 280 and 210 burden hours, respectively, as shown in Table 12A.

Follow-back evaluations will be done with the primary requestors for a sample of the HHE requests where there was not an onsite evaluation. Based on recent experience, approximately 55 of these follow-backs will be done, with one respondent for each. Based on 55 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 9 and 14 burden hours, respectively, as shown in Table 12A.

The estimate of time required for interview and questionnaires is based on the prior experience of the Health Hazard Evaluation program. The total burden hours (4007) are about equal to that in prior years (3901).

Table 12A

Estimate of Annualized Burden Hours

Type of Respondent	Form	No. of respondents	No. of responses per respondent	Average Burden per response in hours	Total Burden Hours
Employees and Representatives	Health Hazard Evaluation Request Form	302	1	12/60	60
Employers	Health Hazard Evaluation Request Form	118	1	12/60	24
Employees	Health Hazard Evaluation specific interview example	4200	1	15/60	1050
Employees	Health Hazard Evaluation specific questionnaire example	4440	1	30/60	2220
Followback for onsite evaluations for Management, Labor and Requester	Initial Site Visit survey form	840	1	15/60	210
Followback for onsite evaluations for Management, Labor and Requester	Closeout for HHE with an OnSite Evaluation	840	1	15/60	210
Followback for onsite evaluations for Management, Labor and Requester	1 year Later HHE with an On Site Evaluation	840	1	15/60	210
Followback for evaluations for Management, Labor and Requester without onsite evaluation	Followback I Survey cover letter and Forms	55	1	10/60	9
Followback for evaluations for Management, Labor and Requester without onsite evaluation	Followback II Survey Cover Letter and Forms	55	1	15/60	14
Total Burden Hours					4007

Table 12B Estimated Annualized Burden Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Employees and Representatives	60	$19.29	$1,157
Employers	24	$19.29	$463
Employees (interview)	1050	$19.29	$20,255
Employees (questionnaire)	2220	$19.29	$42,824
Follow-back for onsite evaluations	210	$19.29	$4,051
Follow-back for onsite evaluations	210	$19.29	$4,051
Follow-back for onsite evaluations	210	$19.29	$4,051
Follow-back for evaluations without onsite	9	$19.29	$174
Follow-back for evaluations without onsite	14	$19.29	$270
TOTAL			$77,296

(b) Data collection for a Health Hazard Evaluation generally occurs during a respondent's usual work hours. Assuming an average civilian hourly wage in the US of $ 19.29 (based on a 35.6-hour work week and an average weekly wage of $686.72, [from the Bureau of Labor Statistics, National Compensation Survey: Occupational Wages in the United States, June 2006, (http://www.bls.gov/ncs/ocs/sp/ncbl0910.pgf) dated June 2007]), the annualized respondent cost is $77,296.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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 7.7 million dollars, which covers $5.9 million for 49 FTEs in FY 2006 and $1.7 million in discretionary costs. The estimated cost for preparing, administering, and processing questionnaires related to this program is $385,000

15. Explanation for Program Changes or Adjustments

This is a continuing information collection request. The total burden (4007) is about equal to that in prior years (3901).

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 results are usually available and sent two to three months after testing. For Health Hazard Evaluation requests received from 2004-2006, the median time to complete the evaluation for those involving field studies (that is, to issue the final report) was 12 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 generally 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 journals. Some report summaries are compiled by NIOSH and published on specific topics. Reports often are cited in other NIOSH publications, furthering their dissemination.

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.