Use of a Reader Response Postcard for Workers Notified of Results of Epidemiologic Studies Conducted by the National Institute for Occupational Safety and Health (NIOSH)

0920-0566 - Reinstatement

Request for the Office of Management and Budget Review and Approval for Federally Sponsored Data Collection

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Table of Contents

A. Justification

- A1. Circumstances Making the Collection of Information Necessary
- A2. Purpose and Use of Information Collection
- A3. Use of Improved Information Technology and Burden Reduction.
- A4. Efforts to Identify Duplication and Use of Similar Information
- A5. Impact on Small Businesses or Other Small Entities
- A6. Consequences of Collecting Information Less Frequently
- A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A8. Consultations Outside the Agency.
 - A8.1 Federal Register Notice
 - A8.2 Consultations
- A9. Explanation of Any Payment or Gift to Respondents
- A10. Assurance of Confidentiality Provided to Respondents
- A11. Justification for Sensitive Questions
- A12. Estimate of Annualized Burden Hours and Cost
 - A12.1 Estimate of Annualized Burden Hours
 - A12.2 Estimate of Annualized Burden Costs
- A13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers
- A14. Annualized Cost to the Federal Government
- A15. Explanation for Program Changes or Adjustments
- A16. Plans for Tabulation and Publication and Project Time Schedule

A16.1 Project Time Schedule

- A16.2 Analysis and Publications Plan
- A17. Reason(s) Display of OMB Expiration Date is Inappropriate
- A18. Exceptions to Certification for Paperwork Reduction Act Submissions

Attachments

- Attachment 1: Copy of Data Collection Instrument
- Attachment 2: Copy of Authorizing Legislation
- Attachment 3: Sample Notification Materials to Workers: Notification Letter and Fact Sheet
- Attachment 4: Copy of 60 Day Federal Register Notice
- Attachment 5: Human Subjects Review Board Memo

A. JUSTIFICATION

This package is a reinstatement without change. The last time this package was approved was in 1999 and it expired in 2002. There are no substantive changes to the package. The title has been changed from "Evaluation of Worker Notification System" to "Use of a Reader Response Postcard for Workers Notified of Results of Epidemiologic Studies Conducted by the National Institute for Occupational Safety and Health (NIOSH)". With the increased cost of living, the costs to respondent to respond have risen.

A1. Circumstances Making the Collection of Information Necessary

The NIOSH Institute-wide Worker Notification Program routinely notifies subjects about the results of epidemiologic studies and the implications of the results. The overall purpose of the proposed project is to gain insight into the effectiveness of NIOSH worker notification in order to improve the quality and usefulness of the Institute's worker notification activities. Researchers from the NIOSH Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS) propose to provide notified workers with a Reader Response postcard (Attachment 1) for routinely assessing notified study subjects' responses to individual letter notification materials sent to them by NIOSH.

NIOSH, under Section 20(a)(1), (a)(4), (a)(7)(c), and Section 22 (d), (e)(5)(7) of the Occupational Safety and Health Act (29 U.S.C. 669), has the responsibility to "conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems." NIOSH also has the responsibility to "conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health [e.g., worker notification], which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of the Act." (Attachment 2).

Since 1977, the National Institute for Occupational Safety and Health (NIOSH) has been developing methods and materials for the notification of subjects of its epidemiological studies. NIOSH involvement in notifying workers of past exposures relates primarily to informing surviving cohort members of the findings of retrospective cohort studies conducted by NIOSH. Current policy within NIOSH is to notify subjects of the results of its epidemiologic studies. The extent of the notification effort depends upon the level of excess mortality or the extent of the disease or illness found in the cohort. Current notification efforts range from posting results at the facilities studied to mailing individual letter notifications to surviving cohort members and other stakeholders. The

Industrywide Studies Branch (IWSB) of NIOSH, Division of Surveillance, Hazard Evaluation, and Field Studies (DSHEFS), usually conducts about two or three notifications per year, which typically require individual letters mailed to cohorts ranging in size from 200 - 20,000 workers each. In order to assess the effectiveness of the notification materials received by the recipients and to improve future communication of risk information, the evaluation instrument proposed herein was developed for routine use.

Despite substantial literature on risk communication in the general population and on the communication of specific risks to workers, the impact and effectiveness of these communications still are not well known. Although there is consensus on the importance of risk communication in fulfilling citizens' right to know about risks and providing them opportunities to take action, how to accomplish this effectively remains the subject of extensive discussion. Evaluation forms with the specific kind of information useful for improving worker notification activities are currently not in use at NIOSH.

The routine evaluation proposed here will help assess the effectiveness of NIOSH notification materials routinely sent to workers (Attachment 3 contains a sample notification letter and fact sheet).

In evaluating notifications, the approach NIOSH has routinely used to date consists of a toll-free telephone number to allow for immediate questions and feedback from those notified. For every letter-type notification conducted since 1988, telephone calls to the NIOSH toll-free number have been received from workers giving feedback about the notifications. The Reader Response postcard will be an additional evaluation tool. The postcard will be enclosed with each individual letter notification mailed to workers.

A.2. Purpose and Use of the Information Collection

"Worker notification" is a means of informing subjects of NIOSH studies about the results and implications of the studies. The purpose of this activity is to routinely assess the effectiveness of each individual letter-type notification and the overall effectiveness of the worker notification program conducted by the NIOSH, IWSB as well as the overall effectiveness of the worker notification program. NIOSH conducts individual notifications regarding epidemiologic studies for which any of the following conditions apply: 1) the level of occupational disease risk has been determined to be significantly increased above the levels in the U.S. population (or other more local rates); 2) human subjects have actively participated; or 3) the level of public interest and controversy surrounding a study merits a response from NIOSH, regardless of the study's outcome. IWSB normally conducts two or three individual letter notifications per year. Worker notifications routinely include a letter from NIOSH to study subjects, plus other enclosures such as fact sheets and color brochures.

The results from the Reader Response postcards will be used to help notification officers

refine notification activities and develop materials which are more readable, understandable, informative and useful to notified workers, their families, and other stakeholders. In addition to answering the questions identified on the card, the respondent will have the opportunity to fill in comments, suggestions, or ask for additional information from NIOSH. The responses from the cards will allow the NIOSH worker notification program staff to determine ways to alleviate any negative impacts of the notification project and enhance any positive impacts on risk communications. The objective of the Reader Response postcard, therefore, is to provide a structured reporting form which will capture recipient responses concerning the effectiveness of the NIOSH notification efforts and their impact on workers and other stakeholders.

A.3. Use of Improved Information Technology and Burden Reduction

The Reader Response postcard will be provided in English, Spanish, and other languages, as determined by the composition of the notified audience. Only the minimum information necessary will be collected on the Reader Response postcard. Many of the potential respondents may not have access to a computer or have the knowledge to use one; therefore, data will be collected on the Reader Response card.

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

Evaluation forms with the specific kind of information useful for improving worker notification activities are not currently available at NIOSH. NIOSH has unique duties regarding notification of workers about their risk and to evaluate the effectiveness of worker notification activities.

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

No small business will be involved with any of the worker notifications.

A.6. Consequences of Collecting the Information Less Frequently

The notification materials received by the recipients and future communication of risk information will be more effective with the use of the proposed evaluation instrument. NIOSH will request only one Reader Response card from each respondent. There are no legal obstacles to reduce the burden.

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

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

<u>A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside</u> <u>the Agency</u>

- A. A notice of the intended information collected was published in the Federal Register on May 24, 2007 (Volume 72, No. 100, pages 29170-29171), as required by 5 CFR 1320.8(d). (Attachment 4). No comments were received.
- B. The Reader Response card was reviewed by the professionals listed below. Carolyn Needleman, Ph.D. (retired) Professor
 Director of Occupational & Environmental Health Program
 Graduate School of Social Work & Social Research
 Bryn Mawr College
 300 Airdale Road
 Bryn Mawr, PA 19010-2899
 610/520-2633
 Dr. Needleman has been a consultant to various NIOSH worker notification evaluation studies in the past.

David P. Brown, MPH Director of Scientific Program Research Development The Constella Group RTP, NC 27709-2233 919-547-0970 David Brown was the Assistant Chief of the NIOSH Industrywide Studies Branch before taking a position at National Institutes for Environmental Health Sciences (NIEHS), and is very familiar with the NIOSH Worker Notification Program since its inception.

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

No payments will be offered to respondents as remuneration for their participation.

A.10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable. No personal identifiers will appear on the data collected from any of the respondents. The completed Reader Response card will be identified only by a number linked to a master list of names kept in a locked file. Care will be taken so that reported data contain no personal information that could compromise the anonymity of individual respondents. The identification numbers will be used only as a means for NIOSH to respond to workers in writing concerning their questions or requests, as noted in the "comments" section of the postcard. The list linking the study ID number with the name will be destroyed as soon as data collection is complete and follow up has been completed with those requesting further information. If a name or address is provided on the postcard, requesting additional information, this information

will be redacted (lined through with black marker) so that the postcards will then be considered anonymous. The Privacy Act system of records this survey card will be collected under is the Occupational Health Epidemiological Studies and EEOICPA Program Records (0920-0147).

The NIOSH Human Subjects Review Board (HSRB) has determined that this is not a research project and therefore does not require HSRB review (Attachment 5).

A.11. Justification for Sensitive Questions

The Reader Response card contains no questions of a sensitive nature. No personal data will be collected from worker respondents. These data will only be used for the evaluation to further develop NIOSH notification activities.

A.12. Estimates of Annualized Burden Hours and Costs

The annual cost to respondents is as follows:

Cost to respondents:

No direct costs will accrue to respondents other than their time to complete the Reader Response card. The average number of letter-type notifications is estimated at about 8,000 per year. Each postcard is estimated to take less than 10 minutes to complete.

| Form Name | Number of | Number of | Average Burden | Total Burden |
|-----------------|-------------|---------------|------------------|--------------|
| | Respondents | Responses per | per Response (in | Hours |
| | | Respondent | Hours) | |
| Reader Response | 8,000 | 1 | 10/60 | 1,333 |
| Card | | | | |

Table A12.B. Estimated Annualized Burden Cost

| Type of | Number of | Number of | Average | Total | Hourly | Total |
|-------------|-------------|------------|------------|--------|---------|------------|
| Respondents | Respondents | Responses | Burden per | Burden | Wage | Respondent |
| | | per | Response | Hours | Rate | Cost |
| | | Respondent | (in hours) | | | |
| Notified | 8000 | 1 | 10/60 | 1,333 | \$10.00 | \$13,333 |
| Workers | | | | | | |

The wage rate of \$10.00 per hour was estimated based on the following information:

• the current minimum wage rate is \$5.85 per hour,

the U.S. Department of Labor, Bureau of Labor Statistics' Occupational Employment,
Statistics for 2006 shows a median hourly wage rate for Office Clerks, General to be \$10.16,
some former workers are retired and probably no longer earning a wage,

 \cdot some current workers will undoubtedly be earning more than the minimum wage and

• the certainty that wage rates of current industrial workers are higher than \$5.85 per hour.

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

There are no capital or maintenance costs to respondents.

A.14. Annualized Cost to the Federal Government

The conduct of this task will involve in-house personnel expenses and Reader Response postcard mailing costs. The costs for a 12-month period are estimated as follows:

A. Cost to Federal Government: (Includes a 3% personnel cost of living salary increase per year.)

| <u>Costs</u> | 2007 | <u>2008</u> | 2009 |
|---|-----------------------|-----------------------|-----------------------|
| Clerical Assistants Notification Officer | \$1600.08 \$622.58 | \$1648.08 \$549.33 | \$1697.52 \$660.50 |
| Supplies | \$ 200.00 | \$ 200.00 | \$ 200.00 |
| * Total Annual Costs | \$2422.66 | \$2489.34 | \$2558.02 |

* Total costs are based upon the following estimates: 10% of the estimated 8,000 postcards mailed will be returned by workers = 800 postcards. In the first year of the project, a Clerical Assistant will process the postcards at an average 5 minutes per postcard or 12 per hour (800 / 12 = 66.67 hours) x \$24.00 per hour wage rate = \$1600.88. The Notification Officer will review the returned postcards (approximately 10%) and will respond via phone calls or in writing to workers who require a response. It is estimated that the average time spent for review and response per each postcard will be approximately 10 minutes, for a total of 800 minutes or 13.33 hours. At a wage rate of \$46.78 per hour, the total cost would be \$622.58 for the first year. These cost estimates for each successive year include an annual 3% salary increase for the Clerical Assistant and the Notification Officer. The total annualized cost is \$2490.

A.15. Explanation for Program Changes or Adjustments

This is a reinstatement to a previously approved package. There is no change in burden hours.

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

Project Time Schedule:

The use of the Reader Response card will be ongoing for all individual letter worker notifications. The approval period requested is for three years. Data collection will begin immediately following OMB clearance and end 36 months thereafter, followed by a request to continue use of the evaluation tool. During this time, all collected data will be assessed and the results used to further develop and refine the NIOSH worker notification process.

A.16.1-1 Project Time Schedule

A projected time schedule for the project from the time of OMB approval is described below. A typical letter-type notification will take about six months and will be repeated for each successive notification.

| <u>Time Schedule</u> | Activity |
|----------------------------|--|
| 1 month after approval | Obtain OMB approval Mail notification materials with Reader Response postcard |
| 2-4 months after approval | Reader Response postcards returned to NIOSH |
| | NIOSH responds to comments |
| 5 months after approval | Analyses of results |
| 6 months after approval | Report results |
| 7–36 months after approval | Repeat the above activities as needed. |

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

Display of the expiration date for the OMB approval of the information collection is appropriate for this project.

<u>A.18. Exceptions to Certification for Paperwork Reduction Act Submissions</u> No exceptions are requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods will not be used to select respondents or to analyze responses. In this evaluation, data from the Reader Response card from workers will be tallied and reported in terms of simple frequencies of answers to questions, along with a discussion of any important comments that are entered on the Reader Response postcard. Responses will be used to understand how notification procedures can be improved.

B.1. Respondent Universe and Sampling Methods

Sampling methods will not be used. All living and locatable workers from each of the cohorts who received a notification letter and relevant enclosures will be sent a Reader Response postcard. Although only a self-selected proportion of the cohort will complete and return the card, NIOSH researchers wish to provide each notified worker the opportunity to evaluate the notification materials and offer comments. The size of each cohort to be notified varies from study to study, with an average of 8,000 workers notified per year.

B.2. Procedures for the Collection Of Information

The purpose of the evaluation is to assess the effectiveness of current notifications, and to improve the notification process used by NIOSH. Inferential statistics involving issues of statistical power will not be used in this activity. This project will not employ statistical methods other than descriptive statistics to summarize the findings. The Reader Response card contains 10 questions and a space for written comments from respondents. The assessment of routinely conducted worker notifications is aimed at monitoring effectiveness of worker notification materials, with minimal burden to respondents and minimal additional resource requirements.

B.3. Methods to Maximize Response Rates and Deal with Non-response

Notified workers will be encouraged in the notification letter to complete and return the Reader Response card to NIOSH, in the interest of advancing good public health and improving worker notification materials and methods. We estimate, however, that only approximately 10% of the respondents will return the card. This is based upon the fact that this activity is not a formal survey, but merely a mailing to notify subjects of the results of a health study in which they or their records have been included. No follow-up to non-respondents is conducted. To encourage a better response rate, the notification cover letter will contain the statement, "data will be treated in a secure manner unless required otherwise by law. The data will be used for statistical and research purposes only and in such a manner that no one will be personally identified. The information you supply is voluntary and there is no penalty for not providing it."

To further maximize the response rate, if the notification materials are returned from the post office as undeliverable, subjects will be traced to the extent possible and the notification packages will be re-mailed in cases where updated addresses have been found.

B.4. Tests of Procedures or Methods to be Undertaken

A pre-test was completed with a sample of 6-8 workers at the last time of the notification mailing (2001). Respondents completed the evaluation in 10 minutes. This study has been previously approved by OMB in 2001 and expired in 2004.

<u>B.5.</u> Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The persons responsible for collecting and evaluating the Reader Response card data will be: Frank Stern, M.S. Epidemiologist Industrywide Studies Branch Division of Surveillance, Hazard Evaluations, and Field Studies; NIOSH (513) 841-4519 Email FStern@cdc.gov