

monitoring. This information includes an Environmental Public Health Tracking Workplan Template, a Performance Measure Report, a Communication Plan, a Partnership Plan, and a website Analytics Template. Each of these forms are collected annually as documents emailed to the Tracking Program. A public health action (PHA) report is submitted at least once and up to four times a year via email to the Tracking Program as funded SLHD have PHA to report.

Over the past three years, these data were used to identify funded SLHD in

need of additional technical assistance, identify common challenges and successes, improve communication between funded SLHD and CDC, and to monitor funded SLHD compliance with funding requirements.

There are no costs for the respondents other than their time. The total estimated time burden is 21,860 hours. This estimate includes the time it takes to extract the data from the original data source(s), standardize and format the data to match the corresponding Tracking Network data form, and submit the data to the Tracking Network. In

some cases, the data at the source are centralized and easily extracted. In other cases, like for radon data, the data are not. In those cases, the number of hours for extracting and standardizing the data is much greater. Four respondents have been added to the 26 SLHDs the program currently funds to account for the data voluntarily received from unfunded SLHDs and to allow for potential program growth over the next three years.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Avg. burden per response (in hrs.) | Total burden (in hrs.) |
|---------------------------------------|--------------------------------------|-----------------------|------------------------------------|------------------------------------|------------------------|
| State and local health departments .. | Birth defects prevalence | 22 | 1 | 80 | 1760 |
| | Childhood lead blood levels | 18 | 1 | 80 | 1440 |
| | Community drinking water monitoring. | 30 | 1 | 100 | 3000 |
| | Emergency department visits | 30 | 1 | 80 | 2400 |
| | Hospitalizations | 30 | 1 | 80 | 2400 |
| | Radon testing | 18 | 1 | 100 | 1800 |
| | Metadata records | 30 | 6 | 20 | 3600 |
| | EPHT Work Plan | 30 | 1 | 40 | 1200 |
| | Public Health Action Report | 30 | 4 | 20 | 2400 |
| | Performance Measure Report | 30 | 1 | 20 | 600 |
| | Communications plan | 30 | 1 | 20 | 600 |
| | Partnership plan | 30 | 1 | 20 | 600 |
| | Website analytics | 30 | 2 | 1 | 60 |
| Total | | | | | 21,860 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-0260; Docket No. CDC-2020-0008]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal

agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Health Hazard Evaluations/ Technical Assistance and Emerging Problems. This proposed collection, in accordance with mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, allows the National Institute for Occupational Safety and Health (NIOSH) to respond to requests for HHEs to identify chemical, biological or physical hazards in workplaces throughout the United States.

DATES: CDC must receive written comments on or before April 10, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0008 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600

Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register**

concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Health Hazard Evaluations/Technical Assistance and Emerging Problems (OMB Control No. 0920-0260, Exp. 10/31/2020)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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 Evaluation (HHE) to identify chemical, biological or physical hazards in workplaces throughout the United States. Each year, NIOSH receives approximately 250 such requests. Most HHE requests come from workplaces in the following industrial sectors:

Services, manufacturing, health and social services, transportation, and construction.

A printed HHE request form is available in English and in Spanish. The form is also available on the internet and differs from the printed version only in format and in the fact that it can be submitted directly from the website. The request form takes an estimated 12 minutes to complete. The form provides the mechanism for employees, employers, and other authorized representatives to supply the information required by the regulations governing the NIOSH HHE program (42 CFR 85.3-1). NIOSH reviews the HHE request to determine if an on-site evaluation is needed. The primary purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. For 25% of the requests received, NIOSH determines an on-site evaluation is needed.

In about 70% of on-site evaluations, employees are interviewed in an informal manner to help further define concerns. Interviews may take approximately 15 minutes per respondent. The interview questions are specific to each workplace and its suspected diseases and hazards. However, interviews are based on standard medical practices.

In approximately 30% of on-site evaluations questionnaires are distributed to the employees (averaging about 100 employees per site). Questionnaires may require approximately 30 minutes to complete. The survey questions are specific to each workplace and its suspected diseases and hazards, however, items in the questionnaires are derived from standardized or widely used medical and epidemiologic data collection instruments.

About 70% of the on-site evaluations involve employee exposure monitoring in the workplace. Employees participating in on-site evaluations by wearing a sampler or monitoring device to measure personal workplace exposures are offered the opportunity to get notification of their exposure results. To indicate their preference and, if interested, provide contact information, employees complete a contact information post card. Completing the

contact card may take five minutes or less. The number of employees monitored for workplace exposures per on-site evaluation is estimated to be 25 per site.

NIOSH distributes interim and final reports of health hazard evaluations, excluding personal identifiers, to: Requesters, employers, employee representatives; the Department of Labor (Occupational Safety and Health Administration or Mine Safety and Health Administration, as appropriate); state health departments; and, as needed, other state and federal agencies.

NIOSH administers a follow-back program to assess the effectiveness of its HHE program in reducing workplace hazards. This program entails the mailing of follow-back questionnaires to employer and employee representatives at all the workplaces where NIOSH conducted an on-site evaluation. In a small number of instances, a follow-back on-site evaluation may be completed. The first follow-back questionnaire is sent shortly after the first visit for an on-site evaluation and takes about 10 minutes to complete. A second follow-back questionnaire is sent after the final report is completed and requires about 20 minutes to complete. At 12 months, a third follow-back questionnaire is sent which takes about 15 minutes to complete.

For requests where NIOSH does not conduct an on-site evaluation, the requestor receives the first follow-back questionnaire after our response letter is sent and a second one 12 months after our response. The first questionnaire takes about 10 minutes to complete and the second questionnaire takes about 15 minutes to complete.

Because of the number of investigations conducted each year; the need to respond quickly to requests for assistance; the diverse and unpredictable nature of these investigations; and its follow-back program to assess evaluation effectiveness, NIOSH requests a consolidated clearance for data collections performed within the domain of its HHE program. The total estimated burden hours is 1715. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden (in hrs.) |
|-------------------------------------|--|-----------------------|------------------------------------|---------------------------------------|------------------------|
| Employees and Representatives | Health Hazard Evaluation Request Form. | 175 | 1 | 12/60 | 35 |

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden (in hrs.) |
|---|--|-----------------------|------------------------------------|---------------------------------------|------------------------|
| Employers * | Health Hazard Evaluation Request Form. | 75 | 1 | 12/60 | 15 |
| Employees | Health Hazard Evaluation specific interview example. | 1,470 | 1 | 15/60 | 368 |
| Employees | Health Hazard Evaluation specific questionnaire example. | 2,100 | 1 | 30/60 | 1,050 |
| Employees | Contact information post card | 1,225 | 1 | 5/60 | 102 |
| Employees and Representatives; Employers—Year 1 (on-site evaluation). | First follow-back questionnaire | 140 | 1 | 10/60 | 23 |
| Employees and Representatives; Employers—Year 2 (on-site evaluation). | Second follow-back questionnaire | 140 | 1 | 20/60 | 47 |
| Employees and Representatives; Employers—Year 2 (on-site evaluation). | Third follow-back questionnaire | 140 | 1 | 15/60 | 35 |
| Employees and Representatives; Employers—Year 1 (without on-site evaluation). | First follow-back questionnaire | 94 | 1 | 10/60 | 16 |
| Employees and Representatives; Employers—Year 2 (without on-site evaluation). | Second follow-back questionnaire | 94 | 1 | 15/60 | 24 |
| Total | | | | | 1,715 |

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1095]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information voluntarily submitted to the Center for

Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use.

DATES: Submit either electronic or written comments on the collection of information by April 10, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 10, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 10, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-1095 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health." Received comments, those filed in a timely manner (see **ADDRESSES**), will be