styrene has also been associated with cases of non-malignant respiratory disease (NMRD), including COPD and obliterative bronchiolitis. However, little is understood about the long-term respiratory effects on styrene-exposed workers.

The goal of this project is to understand the prevalence of long-term respiratory morbidity in styrene-exposed workers. The objectives of the proposed study are: (1) To characterize work exposures by acquiring job histories and comparing with historical exposure levels obtained from a past industrial hygiene survey, (2) to examine prevalence of respiratory morbidity by duration and level of styrene exposure and other characteristics, (3) to apply research biomarkers of lung injury to a styrene-exposed workforce, and (4) to describe the prevalence of color vision impairment with the presence of respiratory morbidity. Our hypothesis is that workers previously exposed to high concentrations of styrene (≥5 ppm), even those with short tenure (<1 year), will have a higher prevalence of respiratory symptoms and lung function abnormalities compared with workers exposed to low concentration of styrene (<5ppm).

We will conduct face-to-face interviews with members of a cohort of workers from two reinforced plastic boatbuilding plants that closed in 1989 and 1993. The purpose of the interviews is to collect demographic information, detailed job history during and after the worker's tenure at the boatbuilding plant, upper and lower respiratory symptoms, physician diagnoses of respiratory diseases, cigarette smoking history, and medication use. A NIOSH employee will conduct the interviews.

We will also conduct several lung function tests including: Exhaled nitric oxide, impulse oscillometry, multiple-breath washout, spirometry, and bronchodilator reversibility testing.

The purpose of the lung function testing is to identify small and large airway abnormalities that are consistent with NMRD. NIOSH technicians will perform the lung function testing. We will collect blood to analyze for biomarkers associated with lung injury caused by obliterative bronchiolitis. A NIOSH phlebotomist will collect the blood samples. Finally, we will assess cohort members for color vision abnormalities using the Lanthony D–15 Color Test. Color vision assessment will be completed by a NIOSH technician.

The only cost to boatbuilder cohort members is local travel to the medical survey site and their time. The total estimated burden hours are 712.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Boatbuilder Cohort Members	Questionnaire and medical survey consent form.	676	1	15/60
Boatbuilder Cohort Members	Questionnaire	676	1	45/60
Boatbuilder Cohort Members	Exhaled Nitric Oxide—no form	676	1	5/60
Boatbuilder Cohort Members	Impulse Oscillometry—no form	676	1	10/60
Boatbuilder Cohort Members	Spirometry—no form	676	1	10/60
Boatbuilder Cohort Members	Bronchodilator Test—no form	50	1	20/60
Boatbuilder Cohort Members	Multiple-Breath Washout—no form	676	1	30/60
Boatbuilder Cohort Members	Color vision test—no form	676	1	5/60
Boatbuilder Cohort Members	Blood test—no form	676	1	5/60

Jeffrey M. Zirger,

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

[FR Doc. 2020–21735 Filed 9–30–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20–1278; Docket No. CDC–2020–0101]

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 ''Online training for law enforcement to reduce risks associated with shift work and long work hours.'' This study will develop and pilot test a new, online, interactive training program tailored for the law enforcement community that relays the health and safety risks associated with shift work, long work hours, and related workplace sleep issues, and presents strategies for managers and officers to reduce these risks.

DATES: CDC must receive written comments on or before November 30, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0101 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

Online training for law enforcement to reduce risks associated with shift work and long work hours (OMB Control No. 0920–1278, Exp. 12/30/2020)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Police often work during the evening, at night, and sometimes irregular and long hours. Shift work and long work hours are linked to many health and safety risks due to disturbances to sleep and circadian rhythms. These work schedules also lead to difficulties with personal relationships due to having less time with family and friends, poor mood from sleep deprivation, and problems balancing work and personal responsibilities. These work schedules and inadequate sleep likely contribute to health problems seen in police: shorter life spans, high occupational injury rates, and burden of chronic illnesses. One strategy to reduce these risks is training programs to inform employers and law enforcement officers about the risks and strategies to reduce their risks.

An extension is being requested due to delays recruiting participants and initiating data collection activities. The delays resulted from the COVID–19 pandemic and the civil unrest after George Floyd's death on May 25, 2020. Law enforcement leaders requested that the data collection be delayed until the end of June 2020. As a result, NIOSH is requesting a one-year extension for an extension of the data collection end date to May 31, 2021. This pilot study is part of a project awarded National Occupational Research Agenda (NORA) funding. The National Institute for Occupational Safety and Health is authorized to carry out this data collection through Occupational Safety and Health Act of 1970.

The purpose of this project is to develop a training program to relay the risks linked to shift work and long work hours and give workplace strategies for employers and personal strategies for the officers to reduce the risks. Once finalized, the training will be available on the NIOSH website. The training will be pilot tested with 30 recent graduates of a police academy and 30 experienced officers. The study will recruit 60 law enforcement officers during a 30-minute phone call. All respondents will work full-time on fixed night shifts. The pilot test will use a pre-test—post-test design to examine sleep (both duration and quality), worktime sleepiness, and knowledge retained. Pre-test measures will be collected two weeks before the training. Post-test measures will be collected the week of the training (week three of the study), one week after the training (week four) and at eight and nine weeks after the training (weeks 11 and 12 of the study). Additional post-test measures will include feedback about the training and if specific behaviors changed.

Before starting the pretest, the respondent will sign an informed consent form. The pilot pre-test will start with the respondent filling out a 10-minute online survey that includes four short surveys: (1) Demographic information and work experience; (2) the Epworth Sleepiness Scale; (3) the Pittsburgh Sleep Quality Index; and (4) a knowledge test. The respondent will be fitted with a wrist actigraph, which will record activity and estimate the times of sleep. The respondents will keep an online sleep activity diary and wear the actigraph continuously during weeks one to four of the study. The online sleep activity diary takes approximately two minutes a day to complete. The sleep diary and actigraph are being used together to obtain a more accurate timing of respondent's sleep and activity.

During the third week of the study, the respondent will take the 2.5 hour online training program. Immediately after completing the training, the respondent will take the post-test knowledge test and will provide feedback about the training including barriers to using the training information and what influential people in their life would want them to do with the training information. At the end of week four, the respondent will return the actigraph. No data collection will occur during weeks five to 10 of the study.

The second post-test period will be weeks 11 and 12 of the study to gather longer-term outcomes. At the beginning of week 11, the respondents will be fitted with an actigraph. The respondent will wear the actigraph and complete the sleep activity diary for the next 14 days. At the end of week 12 of the study, the respondent will complete the Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, and Changes in Behaviors After Training. The combined response time is five minutes.

The burden table lists three 10-minute meetings during the post-test period when they will return the actigraph at the end of week four, be fitted with an actigraph at the beginning of week 11 and return it at the end of week 12. The respondents will complete the sleep activity diary for 42 days total (two minutes each day). The total burden hours for the diary is 84.

Study staff will use the findings from the pilot test to make improvements to the training program. The research team will reinforce or expand training content that showed less than desired results on the pilot test. Potential impacts of this project include improvements in management practices such as the design of work schedules and improvements in officers' personal behaviors for coping with the demands of shift work and long work hours. The total estimated annualized burden hours is 334. There are no costs 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 hours)	Total burden (in hours)
Law enforcement officers	phone call for recruitment & informed consent.	60	1	30/60	30
Law enforcement officers	Initial meeting	60	1	15/60	15
Law enforcement officers	Knowledge survey	60	2	5/60	10
Law enforcement officers	Epworth Sleepiness Scale	60	2	1/60	2
Law enforcement officers	Pittsburgh Sleep Quality Index	60	2	2/60	4
Law enforcement officers	Demographics and work experience	60	1	2/60	2
Law enforcement officers	Sleep diary	60	42	2/60	84
Law enforcement officers	Online training	60	1	150/60	150
Law enforcement officers	Feedback about Training, Barriers, and Influential People.	60	1	5/60	5
Law enforcement officers	Changes in Behaviors after Training	60	1	2/60	2
Law enforcement officers	Actigraph fitting and return	60	3	10/60	30
Total					334

Jeffrey M. Zirger,

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

[FR Doc. 2020–21731 Filed 9–30–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3386–CN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of its Home Infusion Therapy Accreditation Program; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice; correction.

SUMMARY: This document corrects a technical error that appeared in the final notice published in the **Federal Register** on September 28, 2020 entitled ''Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program.''

DATES: This correction is effective September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786–2441. Shannon Freeland, (410) 786–4348. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020–21260 of September 28, 2020 (85 FR 60799–60800), there was a technical error that is identified and corrected in this correcting document. The provision in this correction document is effective as if it had been included in the document published September 28, 2020. Accordingly, the correction is effective September 28, 2020.

II. Summary of Error

On page 60799, in the **DATES** section of the notice, the phrase ''takes effect October 1, 2020 through October 1, 2024'' should be replaced with the phrase ''September 28, 2020-September 28, 2024.''

III. Correction of Error

In the **Federal Register** of September 28, 2020, in FR Doc. 2020–21260, on page 60799, in the 2nd column, in the **DATES** section, the phrase ''takes effect October 1, 2020 through October 1, 2024'' is corrected to read ''September 28, 2020-September 28, 2024.''

Dated: September 28, 2020.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2020–21766 Filed 9–28–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1517]

The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.'' This guidance provides general recommendations regarding the development, evaluation, and use of physiologically based pharmacokinetic (PBPK) analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. The guidance covers how to develop, evaluate, and apply PBPK models for biopharmaceutics-related uses, such as establishing clinically relevant dissolution specifications and quality risk assessment for postapproval manufacturing changes.