reconstruction cannot be completed and encourage them to submit the petition. NIOSH expects most petitioners for whom Form B would be appropriate will also use the form, since it provides a simple, organized format for addressing the informational requirements of a petition.

NIOSH will use the information obtained through the petition for the following purposes: (a) identify the petitioner(s), obtain their contact information, and establish that the petitioner(s) is qualified and intends to petition HHS; (b) establish an initial definition of the class of employees being proposed to be considered for addition to the Cohort; (c) determine whether there is justification to require HHS to evaluate whether or not to designate the proposed class as an addition to the Cohort (such an evaluation involves potentially extensive data collection, analysis, and related deliberations by NIOSH, the Board, and HHS); and (d) target an evaluation by HHS to examine relevant potential limitations of radiation monitoring and/or dosimetry-relevant records and to examine the potential for related radiation exposures that might have endangered the health of members of the class.

Finally, under the rule, petitioners may contest the proposed decision of the Secretary to add or deny adding classes of employees to the cohort by submitting evidence that the proposed decision relies on a record of either factual or procedural errors in the implementation of these procedures. NIOSH estimates that the average time to prepare and submit such a challenge is five hours. Because of the uniqueness of this submission, NIOSH is not providing a form. The submission will typically be in the form of a letter to the Secretary.

CDC requests OMB approval for an estimated 43 annual burden hours. There are no costs to respondents other than their time to participate, unless a respondent/petitioner chooses to purchase the services of an expert in dose reconstruction, an option provided for under the rule.

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.)
Petitioners	Form A: 42 CFR 83.9	2	1	3/60	1
	Form B: 42 CFR 83.9	5	1	5	25
Petitioners using a submission format other than Form B (as permitted by rule).	42 CFR 83.9	1	1	6	6
Petitioners Appealing final HHS decision (no specific form is required).	42 CFR 83.18	2	1	5	10
Claimant authorizing a party to submit petition on his/her behalf.	Authorization Form: 42 CFR 83.7	3	1	3/60	1
Total					43

Jeffrey M. Zirger,

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

[FR Doc. 2022–16563 Filed 8–2–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–22–22HO; Docket No. CDC–2022–0091]

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 information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction. This project is designed to evaluate oil and gas extraction workers' sleep, fatigue, and other related factors, and their relationship to risks associated with the industry.

DATES: CDC must receive written comments on or before October 3, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0091 by either of the following methods:

- *Federal eRulemaking Portal: www.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 H21–8, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (www.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 H21–8, Atlanta, Georgia 30329; Telephone: 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;

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; and

5. Assess information collection costs.

Proposed Project

Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction Industry—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Oil and gas extraction (OGE) workers play an important role in supporting the United States economy and help fulfill the energy needs of Americans and American businesses. OGE workers have significant risks for a variety of exposures at oil and gas well sites. There has been no significant fatigue research in the United States onshore upstream OGE sector. This proposed project will characterize relationships between sleep, fatigue, fatigue management, and related factors, within the onshore OGE industry.

Primary data will be collected using three approaches. First, researchers will collect direct measurements of sleep and alertness among OGE workers. Second, researchers will use questionnaires to collect information on OGE worker demographics, occupation, general heath, normal working hours, commute times, home life, physical sleeping environment, and typical sleep quality. Third, researchers will collect qualitative information through interviews with workers, front-line supervisors, health and safety leaders, as well as subject matter experts, to understand challenges and opportunities related to fatigue management in the OGE industry.

CDC requests OMB approval for an estimated 305 annual burden hours. There is no cost to respondents other than their time to participate.

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)
Land-based OGE workers	Baseline Questionnaire	80	1	12/60	16
Land-based OGE workers	Daily Pre-Shift Questionnaires	80	14	3/60	56
Land-based OGE workers	Daily Post-Shift Questionnaires	80	14	3/60	56
Land-based OGE workers	Psychomotor Vigilance Test (PVT)	80	28	3/60	112
Land-based OGE workers	Worker Interview Guide	30	1	90/60	45
Field-level Supervisors	Manager Interview Guide	10	1	1	10
Health and Safety Leaders	HSE Interview Guide	7	1	1	7
Subject Matter Experts	SME Interview Guide	3	1	1	3
Total					305

Jeffrey M. Zirger,

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

[FR Doc. 2022–16561 Filed 8–2–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by October 3, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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