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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0109]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Respiratory Protective Devices—42 CFR part 84—Regulation to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on October 20, 2017 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) 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;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) 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 submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Respiratory Protective Devices—42 CFR part 84—Regulation (OMB Control Number 0920-0109, expiration November 30, 2017) - Reinstatement with Change - National Institute for Occupational

Safety and Health, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 et seq., and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844). These regulations have, as their basis, the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters.

Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH-approved respirators. These regulations also establish methods for respirator manufacturers to submit respirators for testing under the regulation and have them certified as NIOSH-approved if they meet the criteria given in the above regulation. This data collection was formerly named Respiratory Protective Devices 30 CFR part 11, but in 1995, the respirator standard was moved to 42 CFR part 84.

In accordance with 42 CFR part 84, NIOSH performs the following activities: (1) Issues certificates of approval for

respirators which have met specified construction, performance, and protection requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged to applicants for testing and certification, and (5) establishes approval labeling requirements. To establish the scope and intent of request, NIOSH collects information from those who request services under 42 CFR part 84.

Information collected from requests for respirator approval functions includes contact information and information about factors likely to affect respirator performance and use. Such information includes, but is not necessarily limited to, respirator design, manufacturing methods and materials, quality assurance plans and procedures, and user instruction and draft labels, as specified in the regulation.

The main instrument for data collection for respirator approval functions is the Standard Application for the Approval of Respirators (SAF), currently Version 9.

Respirator manufacturers are the respondents (estimated to average 73 each year over the years 2017-2020). Upon submission of the SAF, NIOSH evaluates their applications for approval.

Respirator manufacturers submit applications according to their business needs, which depends upon market conditions, technical advances, and other factors that are not easy to forecast. The best estimate for the annual number of respondents is the number from the most recent year for which data exists, 73 in 2016, an increase from 63 in 2014. Those 73 applicants submitted 542 applications in 2016, providing the current best estimate. A \$200 fee is required for each application. Respondents requesting respirator approval or certain extensions of approval are required to submit additional fees for necessary testing and evaluation as specified in 42 CFR parts 84.20-22, 84.66, 84.258 and 84.1102. In 2016, \$2,662,329.00 was accepted.

Applicants are required to provide test data that shows that the manufacturer is capable of ensuring that the respirator is capable of meeting the specified requirements in 42 CFR part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer, and is not required to follow the relevant NIOSH Standard Test Procedures. As additional testing is not required, providing proof that an adequate test has been performed is limited to providing existing paperwork.

Manufacturers with current approvals are subject to site audits by the Institute or its agents. Audits may occur periodically, typically every second year, or because of a

reported issue. NIOSH completed 59 site audits from 92 respirator approval holders for the 2016 fiscal year. There is an average fee of \$8,833 for each audit to align with fee collection provisions of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701), and OMB Circular A-25 Revised. There is no cost to respondents other than the time to participate. The total estimated burden hours are 118,435. Burden hours have increased due to a moderate increase in the estimated number of annual responses per respondent.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Business or other for-profit	Standard Application for the Approval of Respirators	73	7	229
Business or other for-profit	Audit	59	1	24

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Information Collection Review Office,
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