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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-0109]

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 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 July 20, 2020 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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. 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 No. 0920-0109, Exp. 10/31/2020) – Revision – National Institute for Occupational Safety and Health (NIOSH), 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.

NIOSH, in accordance with 42 CFR Part 84: (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 applicants for testing and certification, and (5) establishes approval labeling requirements. Information is collected from those who request services under 42 CFR Part 84 in order to properly establish the scope and intent of request.

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 Form for the Approval of Respirators (SAF) (currently Version 9). Respirator

manufacturers are the respondents (estimated to average 140 each year over the years 2020-2023) and upon completion of the SAF their requests for approval are evaluated. A total of 375 applications were submitted in CY2019. To date, 300 applications have been submitted in CY2020. The increased submission rate is due to the publication of a new respirator class, PAPR100, as well certification requests due to COVID 19. No survey was conducted to more thoroughly analyze the reasons for the change in number of respondents. The applications are submitted at will and taking into account both historical conditions and as well as the current situation, our prediction of the number of respondents each year between CY2020 and CY2022 is 140. 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.

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.

42 CFR Part 84 approvals offer corroboration that approved respirators are produced to certain quality standards. Although 42 CFR Part 84 Subpart E prescribes certain quality standards, it is not expected that requiring approved quality standards will impose an additional cost burden over similarly effective quality standards that are not approved under 42 CFR Part 84.

Manufacturers with current approvals are subject to site audits by the Institute or its agents. Audits may occur periodically, typically every second year, or as a result of a reported issue. Sixty-four site audits from 90 respirator approval holders were scheduled for the 2020 fiscal year. There is an average fee of \$12,656 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. It is estimated that the average over the next three years (FY21-FY23) will be seventy. The total estimated burden hours are 129,920.

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 Form for the Approval of Respirators	140	4	229
Business or other for-profit	Audit	70	1	24

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