accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective March 27, 2015, unless objections to this authorization are received.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: January 13, 2015.

Heather McTeer Toney,

Regional Administrator Region 4.

[FR Doc. 2015–01040 Filed 1–23–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket No. CDC–2013–0004; NIOSH–216]

RIN 0920–AA42

Respirator Certification Fees

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is revising the fee structure currently used by the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), to charge respirator manufacturers for the examination, inspection, and testing of respirators which are submitted to NIOSH for the purpose of creating or modifying a certificate of approval. Existing regulations reflect prices for respirator testing and approval that were promulgated in 1972, and have not kept pace with the actual costs of providing these services that benefit respirator manufacturers. This final rule is designed to update the regulations.

DATES: This final rule is effective on May 26, 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave., MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION: This final rule is designed to establish fees for the following: (1) Reviewing applications submitted to NIOSH; (2) issuing a certificate of approval; (3) modifying a certificate of approval; (4) maintaining a certificate of approval; (5) performing specific, standard laboratory tests which are requested by applicants; (6) developing and/or performing novel tests which are required to evaluate respirator performance; (7) qualifying applicant respirator production sites and quality systems; (8) verifying quality system performance through manufacturing site quality audits; (9) verifying commercially available respirator performance through product quality audits; (10) replacing testing equipment; and (11) providing and maintaining laboratories and office space.

The preamble is organized as follows:

I. Public Participation

Interested persons or organizations were invited to participate in this rulemaking by submitting written views, recommendations, and data. In addition, HHS invited comments specifically on the following:

(1) To delay the implementation of the approval [1] maintenance fee specified in ''Respirator Certification Fee Schedule A—Administrative Fees'' [2] until 4 months after the publication date of the final rule to allow current approval holders to adjust their inventory of old, obsolete, or marginally profitable certificates of approval. In particular, HHS invited comments on whether 4 months after publication of the final rule allows for a sufficient amount of time to make such adjustments; and

(2) One year as the minimum amount of time for new fees to remain in effect to provide manufacturers sufficient time to plan for application submissions and to determine which approvals to maintain.

Substantive comments were submitted by 11 interested parties, both to the rulemaking docket and during the public meeting held April 30, 2013. Commenters included respirator manufacturers, trade associations, and a private testing laboratory.

II. Background

Under 42 CFR part 84—Approval of Respiratory Protective Devices, NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres. The Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of respirators. NIOSH currently charges fees for the examination, inspection, and testing of such respirators which is necessary to grant the required approval. This final rule is designed to ensure that all approval activities are covered by appropriate fees, to update the fees charged, and to create a

[1] This fee was improperly referenced as the ''approval'' maintenance fee when HHS was instead requesting input on the records maintenance fee. As discussed below, commenters did offer feedback on the timing of the records maintenance fee.

[2] The final fee schedules have been renamed and slightly reorganized and will be added to 42 CFR part 84 as appendices A and B. The fee schedules appear in full at the end of this document, following the regulatory text.

mechanism for routinely updating fees in the future.

Accordingly, with this rule, and for the reasons discussed in the notice of proposed rulemaking published on March 27, 2013 (78 FR 18535), HHS updates the fee structure for the inspection, approval, and certification of manufacturers' respirators to cover the costs of these processes, and establishes a process to periodically update these fees through rulemaking as necessary to remain current with changes to costs arising from factors such as inflation, new certification requirements, and technological changes.

III. Summary of Final Rule and Response to Public Comments

This final rule amends several sections in 42 CFR part 84 and replaces Subpart C—Fees in its entirety. The revisions establish a new fee structure designed to enable NIOSH to fully recover the costs associated with the examination, inspection, and testing of complete respirator assemblies. Unlike the existing fee structure, the new fee structure takes into account the complexity of the class of respirator and the amount of testing required, as well as the work and resources required to perform the testing. Also, the new fee structure charges applicants for the costs of issuing, modifying, and maintaining certificates of approval, production facility inspection (site qualification fee), and for verification of ongoing quality system compliance and commercial product performance.

The fee schedule is divided into two parts—Fee Schedule A comprises annual (fixed) fees; Fee Schedule B comprises application-based fees, including fees for individual test procedures. The fee schedules are included in new Appendices A and B to the regulatory text in Part 84. The final rule and fee schedules will be effective on May 26, 2015. As described in Appendix A, annual fees, including records maintenance, quality assurance maintenance, maintenance of testing and approval facilities, and maintenance of test equipment, will not be invoiced until 2015. As described in the fee schedule, NIOSH will send invoice previews to manufacturers for maintenance fees in July 2015 and final invoices in September 2015, with payment expected no later than October 30, 2015; all other services will be billed upon completion of the project for which they were conducted. Subsequent fee schedules will be updated periodically by notice and comment rulemaking in the **Federal Register**, according to the provisions in § 84.23, discussed below.

The following summary of public comments and NIOSH responses to the comments is organized by topic and by section, and describes and explains the provisions of the final rule.

Overall Response

Comment: Six commenters express unequivocal support for the fee increases. Of the six, some state that they understand NIOSH's need to raise testing and certification fees, after not having done so in over 40 years. Two suggest that it is reasonable for manufacturers to expect NIOSH to provide improved services as a result of the higher fees.

Two commenters express concern that increased fees would reduce worker safety. Specifically, one commenter is concerned that the fee increase may cause ''manufacturers [to] scale back their research and development.'' Another suggests that higher fees would be ''passed on to the user in the form of higher prices.''

Response: NIOSH recognizes the concerns expressed by the commenters. However, NIOSH does not believe that the fee increases, being relatively minor (as discussed in Section IV.A. of this preamble) could have a negative effect on research and development activities or the appropriate use of respirators. Furthermore, in accordance with OMB Circular No. A–25 Revised (OMB Circular), it is NIOSH's obligation to ''ensure that each service, sale, or use of Government goods or resources provided by an agency to specific recipients be self-sustaining.''

Use of Fee Increases

Comment: Three commenters state that it is imperative that NIOSH does not transfer resources resulting in a reduction in service or an increase in certification processing time. The commenters encourage NIOSH to use the increased fees to add equipment or otherwise improve the certification process. Some commenters further assert that NIOSH should use the revised fees to establish firm certification time requirements or to maintain its current goal of completing respirator approvals within 90 days. Finally, one commenter indicates that some certification agencies offer expedited service for a higher fee and encourages NIOSH to pursue this possibility.

Response: NIOSH has historically used retained fees within the certification program to maintain and improve current operations (*e.g.,* to replace equipment and supplies), and intends to continue using the collected fees to augment certification activities. NIOSH is committed to working with manufacturers to maintain efficient turnaround times and expeditiously process the certification applications. NIOSH is also committed to equitable treatment of applicants without regard to ability or willingness to pay and accordingly will not establish expedited testing services on a supplemental fee basis.

Comment: One commenter suggests that the revised fees should support a higher priority for correlation testing.

Response: The revised fee schedules are not intended to support a higher priority for correlation testing, although NIOSH will continue to provide this service to applicants. NIOSH prioritizes activities that most directly increase, monitor, and ensure the quality of the national inventory of respiratory protective devices.

Number of Approvals

Comment: Several of the annual administrative and maintenance fees in Fee Schedule A are applicable ''per every active approval on file with NIOSH.'' Two commenters request clarification of the meaning of the phrase ''every active approval on file,'' and ask whether ''every active approval'' is intended to indicate every respirator model or every NIOSH testing and certification (TC) number.

Response: ''Every active approval'' means every TC number on file with NIOSH; TC numbers are issued to identify specific respirator approvals. NIOSH recognizes three kinds of approvals: active, obsolete, and revoked/rescinded; the NIOSH Certified Equipment List (CEL) contains all active and obsolete approvals and does not contain revoked/rescinded (delisted) TC numbers. Together, active and obsolete approvals are referred to as ''listed'' approvals.

Active approvals are those under which a manufacturer is currently authorized by NIOSH to produce and offer for sale respirator configurations represented as NIOSH-approved devices.

Obsolete approvals are also considered to be active approvals because the respirator model is still being used in the workplace and the manufacturer can continue to sell spare parts for the fielded units even though the device is no longer being manufactured and there is no plan to resume production. NIOSH retains and actively maintains the records of obsolete approvals.

Delisted approvals have been removed from the CEL product listings

through either NIOSH revocation for cause or the approval holder's request for voluntary rescission of approval. NIOSH archives the records of revoked or rescinded approvals.

Where applicable to both active and obsolete approvals in the fee schedule, NIOSH has replaced the term ''active'' with ''listed.''

Comment: One commenter suggests that NIOSH should determine how a manufacturer can obsolete an approval.

Response: To obsolete an approval, manufacturers should submit a *Standard Application for the Approval of Respirators* to NIOSH and specify in the ''application type'' section of the application that they desire to obsolete the existing approval. The *Standard Application Procedure for the Certification of Respirators under 42 CFR 84* (*Standard Application Procedure*) will be updated to inform manufacturers of the procedures to follow to obsolete an approval.

Comment: Three commenters express concern that the NIOSH Certified Equipment List (CEL) and the manufacturers' internal records of approvals may not agree. They would also like a method for resolving discrepancies and ask that NIOSH provide a list of current active, obsolete, and inactive approvals.

Response: NIOSH considers the information in the Certified Equipment List to be correct and that the CEL is the official location of these records. If an approval holder has a discrepancy they should contact NIOSH for resolution and clarification. As requested, NIOSH will send each manufacturer a list of current approvals.

Assignment of Testing and Certification (TC) Numbers

Comment: Two manufacturers express concerns that the procedures for assigning approval (TC) numbers to respirator configurations are not well-defined or consistent. Commenters argue that NIOSH practice is to issue ''separate approval numbers for variations of a device rather than allowing variations to be included in the umbrella of a single approval,'' and that more approval numbers will result in more fees.

Response: NIOSH determines whether a requested configuration can be evaluated as a modification to an existing approval or requires a new TC number during the application review process. If a change is made to an approved respirator configuration that allows the end-user to be able to build more than one unique configuration that does not visually appear the same or does not provide the same protections as the approved configuration, a new TC number is issued for the modified configuration. If the modification does not substantially change the appearance or performance of the respirator, the modification will be incorporated into the existing TC number. The original configuration will retain the existing TC number.

Revision of Standard Application Form

Comment: One commenter suggests that the *Standard Application for the Approval of Respirators* should be revised to include the standard test procedure (STP) identification numbers to assist in aligning certification activities and expected fees.

Response: NIOSH concurs with the need for improved tools and information for manufacturers to align activities with fees, and accepts the recommendation to link the STPs to certification activities and fees in the *Standard Application Procedure,* which will be revised for this purpose.

Testing by Private Sector Laboratories

Comment: One commenter suggests that NIOSH pursue the use of private sector laboratories to do certification testing rather than establishing fees to cover the current costs of testing by the government.

Response: NIOSH has, at times, used third parties to perform certain specific parts of respirator testing activities. For example, chemical warfare agent tests (conducted to evaluate chemical, biological, radiological, and nuclear protections) are presently performed by the U.S. Army Edgewood Chemical and Biological Center with oversight provided by NIOSH. NIOSH is continuing to assess options for third party testing. However, the matter is outside the scope of this rulemaking. No changes to the final rule are made in response to this comment.

Air-Supplying Respirator Clarification

Comment: One commenter is concerned about the use of the terms ''air-supplying'' and ''air-supplied'' rather than ''atmosphere-supplying'' to specify one of the broad groupings of respirators referenced in the proposed rule preamble and in Fee Schedule B. The commenter's specific concern is whether respirators that supply oxygen by means of chemical oxygen generation or using compressed oxygen will no longer be approved by NIOSH.

Response: Respirators approved by NIOSH fall into two broad categories: ''Air- or atmosphere-supplying'' and ''air- or atmosphere-purifying.'' NIOSH has consistently used the phrases ''air-supplying'' and ''air-supplied'' throughout 42 CFR part 84 and other official NIOSH documents to refer to respirators which supply air to the respirator user from remote air supplies, chemical generation of oxygen, controlled release of compressed oxygen, or other means of supplying air/oxygen. The Occupational Safety and Health Administration uses the term ''atmosphere-supplying respirator'' in 29 CFR 1910.134 to refer to a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units. NIOSH considers the terms ''air-supplying,'' ''air-supplied,'' and ''atmosphere-supplying'' to be equivalent.

NIOSH will continue to use the phrases ''air-supplying'' or ''air-supplied'' to describe this type of respirator. Use of these terms does not reflect any change in policy or regulation about the types of respirators which are referenced or will be approved.

Balance of Fees Between Small and Large Companies

Comment: One commenter expresses concern that NIOSH's plan to base fees on the number of existing approvals will minimize fees to small companies that hold a limited number of approvals but also may give them an unfair advantage by conveying benefits and services which are not fully covered by the fees that they are charged. For example, the commenter points out that because the new fees will be assessed per every active approval on file with NIOSH, manufacturers with few approvals will not be charged for ''services and benefits that they alone receive,'' such as the quality site audit.

Response: NIOSH is committed to ensuring that the fees charged to small and large companies are commensurate with their costs. NIOSH finds that a fee based on the number of approvals held is appropriate for recovering fixed costs. However, because NIOSH does acknowledge this approach may not always recover the full cost of services to companies with a very limited number of approvals, NIOSH is expanding the use of the concept of fixed costs and variable costs to the quality assurance maintenance (site audit), maintenance of product performance (product audit), and site qualification fees (discussed below). Where possible, fixed costs will be broken out and based on the broadest possible base (such as number of approval holders or number of listed approvals held). Likewise, variable costs

will be calculated and fees will be based on one or more measures associated with the work performed. NIOSH has determined that these modifications will more equitably support the actual usage of the various NIOSH services as well as contributing to the costs for maintaining their continued availability.

Section 84.2 Definitions

This existing section establishes definitions of terms found in the Part 84 regulations.

Comment: One commenter indicates that NIOSH must add a definition for NIOSH National Personal Protective Technology Laboratory (NPPTL). Another commenter indicates that the definition of Certification and Quality Assurance Branch (CQAB) should be stricken from 42 CFR 84.2.

Response: The definition of NPPTL was proposed in the notice of proposed rulemaking and is included in 42 CFR 84.2. Further, NIOSH agrees that the definition of ''Certification and Quality Assurance Branch'' is outdated, and is stricken from § 84.2. The term ''Certification and Quality Assurance Branch'' is replaced with ''National Personal Protective Technology Laboratory (NPPTL).'' As discussed below, all references to the ''Certification and Quality Assurance Branch'' are stricken from all of Part 84. Finally, the definition of ''Institute'' is also slightly amended to include the acronym ''NIOSH.''

Section 84.10 Application Procedures

This existing section establishes procedures for submitting applications to NIOSH for respirator approval. Although no comments were received on this section, changes have been made to this section to clarify that applications must be submitted in accordance with the *Standard Application Procedure.* The text has also been changed to acknowledge that the NIOSH National Personal Protective Technology Laboratory may use an independent laboratory to conduct certification testing, at its discretion.

Section 84.12 Delivery of Respirators and Components by Applicant; Requirements

Section 84.12 specifies the requirements for submitting respirators to NIOSH for certification testing. Paragraph (b) of this existing section is revised to identify NPPTL as the entity to which applicants must deliver respirator units for certification testing. Although no comments were received on this section, the text has been changed slightly to clarify our intent.

Section 84.19 Applicability

Proposed § 84.19 was intended to specify the effective dates of various parts of the rule. However, because this section was confusing and NIOSH's intent better communicated by extending the effective date of the rule and clarifying the dates in the fee schedule, this section has been stricken.

Comment: Two commenters suggest alternate phase-in schedules for the new fees, citing a concern that manufacturers will find the 4-month implementation plan to be a hardship. One suggests that NIOSH should phase in the new fee schedule over the course of 3 years; the other was to delay implementation for 18 months for current approval holders.

Response: After consideration of public comments as well as programmatic administrative concerns, NIOSH has found it appropriate to extend the effective date of this final rule to 120 days after publication. Accordingly, the application-based fees in Appendix B, as well as the product audit fee in Appendix A will be effective and applicable beginning on [INSERT DATE 120 DAYS AFTER PUBLICATION IN THE **Federal Register**]. The fixed fees in Appendix A will be determined on a typical annual period. Manufacturers will be sent an invoice preview showing initial fixed (annual) fee assessments for records maintenance, quality assurance maintenance, and maintenance of testing and approval facilities and test equipment in July 2015 and a final invoice in September (with payment expected by the end of October 2015). If an approved respiratory protective product has been selected for evaluation in a product audit as part of the planned quality assurance maintenance activities for the upcoming year, the invoice will include a fee to cover NIOSH purchase of audit product samples. The assessed fee for purchase of audit samples can be reduced or eliminated if test samples are made available to NIOSH without charge.

Section 84.20 Establishment of Fees

Section 84.20 replaces existing § 84.20 in its entirety. Paragraph (a) establishes the fee structure for the examination, inspection, and testing required to issue, maintain, and modify certificates of approval. Paragraph (b) specifies the activities for which NIOSH will charge fees, including (1) application and approval processing; (2) approval maintenance, including records management, product audits, and site audits; and (3) the qualification of new respirator production sites. Finally, paragraph (c) specifies the activities for which NIOSH does not intend to charge fees. HHS received many comments on the specific fees within § 84.20; those comments and the corresponding responses are identified by paragraph, below. Changes have been made to the rule text to better clarify our intent, and changes to the fee schedule have been made in response to public comment. The specific changes are discussed below.

Application Processing [§ 84.20(b)(1)]

Comment: One commenter believes that applications vary in complexity and, therefore, more NIOSH resources will be required for issuing, modifying, and maintaining certificates of approval for more complicated devices as compared to simpler ones. According to the commenter, applications requiring more resources should result in higher fees than ones requiring less information and material.

Response: The commenter correctly points out that the time to process different applications is variable. NIOSH concurs that this variability is not reflected anywhere in the current or updated fees process. The proposed fee was calculated to cover an application time of 4 ± 2 hours, which is the average amount of time it takes NIOSH to complete a review of the application. In NIOSH's experience, very few applications require more than 6 hours to complete. To address variation between application processing times, NIOSH will retain a single basic application fee of $200 per application to be submitted with each application. Because NIOSH has not historically tracked application processing times, we will monitor the application processing times to obtain current information during implementation of the new fee structure. As discussed below, the fee schedules will be reviewed every two years to assure that the fees are being assessed as intended.

Comment: Two commenters observed that modifications of approvals vary in complexity and, therefore, the resources required for processing them vary as well. Applications requiring more resources should cost more than ones requiring less information and material. Another commenter suggests that fees for modification of approvals (*e.g.,* ''adding new cleaning and disinfection procedures to the Instructions for Use, document format changes and any other type of modification to the records that may be currently on file at NIOSH where testing is not required'') should incur lower fees or include only the application fee and not the product modification fee.

Response: The modification of approval fee covers the cost of issuing the modification, which is basically a fee for generating a written letter to approval holders acknowledging the modification of certification. The costs associated with processing approval modifications do not vary significantly. Differences in the complexity of a modification of approval are captured in the same way as applications for new approval with the variable application and testing fees. The application fee is set at $100 for each new approval granted; the approval modification fee is set at $50 for each modification of an existing approval. No changes to the fee schedule have been made in response to this comment.

Records Maintenance [§ 84.20(b)(1)]

Comment: One commenter does not concur with NIOSH's assertion that records maintenance fees are predicated on an analysis of the OMB Circular, which requires agencies to establish charges for special benefits provided to specific recipients. One example of a special benefit is a license to carry on a specific activity. The commenter ''contends that the special recipient is actually the respirator user,'' and not the manufacturer.

Response: As discussed in the notice of proposed rulemaking (78 FR 18535, 18537), NIOSH finds that because manufacturers derive economic benefit from the sale of respirators which would not be possible without NIOSH approval, the approval is a license, and the manufacturer is the special beneficiary. Although the current fee structure and rates have not been adjusted in recent years to cover the actual program costs for the examination, inspection, and testing of complete respirator assemblies, the principle of the government recovering fees from the applicant are traceable to the origins of the standards.

Comment: Eight stakeholders comment on the records maintenance fee. One questions whether the fee implies that NIOSH will review all approvals annually, and recommends that we base the records maintenance fee on the complexity of the device and the number of records associated with the approval. Another asserts that since NIOSH does not maintain samples of approved products, approvals should require very little maintenance, and that there should be no costs to manufacturers. The commenter further states that the records maintenance fee ''appears to be more of a NIOSH imposed manufacturer tax.'' The remaining commenters feel either that records maintenance fees should be the same for all approvals regardless of status, or alternatively that they should not be the same and should instead be based on the approval status (active, obsolete, or revoked/rescinded).

Response: The records maintenance fee pays for the computer database used to hold and access all of the records of listed (active and obsolete) approvals. The fee also pays for NIOSH staff to maintain and modify the database. All active and obsolete approval records must be retained, retrievable, and maintained, even though they may not be routinely used, reviewed, or inspected.

NIOSH has considered basing the fee on the number of approval holders (manufacturers) or, alternatively, on the number of records in the files. Neither of these options would improve the proposed fee structure in terms of equitably distributing costs among approval holders. Therefore, HHS finds it appropriate to establish a flat fee for records maintenance for all listed approvals, based on the number of active and obsolete approvals contained in the NIOSH Certified Equipment List, as presented in the proposed rule.

Maintenance of NIOSH Facilities and Test Equipment [§ 84.20(b)(2)]

Comment: One commenter agrees that the facilities maintenance fee is fixed and independent of certification activity or approval status in any given year. Two commenters suggest that maintenance fees should be based on the activity status of respirator approvals. Two commenters state that any maintenance fee is an economic hardship that could ''ultimately lead to diminished availability of variations and choices to the users.''

Response: Maintenance of facilities is a fixed cost. NIOSH has determined that it is equitable to spread this cost over all approvals. For these purposes, the activity status of an application is not an important cost factor. NIOSH has retained the proposed maintenance of facilities fees.

Comment: One commenter suggests that testing equipment depreciation be spread out over the life of the equipment. One manufacturer comments that the testing fees should be modified to capture the depreciation cost associated with maintaining testing capacity.

Response: Maintenance of test equipment is a fixed cost. NIOSH can neither predict which applications will be submitted by manufacturers, nor which pieces of equipment will be required to support these applications. Therefore, we cannot estimate the use of each piece of equipment and incorporate that into the testing fees schedule. However, NIOSH recognizes that listed approvals identified as obsolete are not expected to require the use of test equipment. Accordingly, NIOSH has determined that it is equitable to spread this cost over all listed active approvals and to exempt facilities maintenance fees for listed obsolete approvals, and has so amended Fee Schedule A.

Site Qualification [§ 84.20(b)(3)]

Comment: One commenter asks if the site qualification fee is intended for new manufacturers who do not yet have NIOSH approvals or if it is intended for the routine ongoing factory quality system audits. Four commenters state that the $5000 fixed cost for a new site qualification should be reconsidered in favor of charging direct and true costs.

Response: The site qualification fee is different from the quality assurance maintenance (site audit) fee: The former provides for a one-time inspection of new production facilities; the latter for the ongoing manufacturing quality system audits NIOSH requires of approval holders. As discussed in the notice of proposed rulemaking (78 FR 18535, 18544), the site qualification program is designed to cover three groups of manufacturers. The first group consists of manufacturers with no approvals who want to receive a 3-letter manufacturer's code. This is the first step in submitting a respirator for NIOSH approval. The code is issued after receipt of an application if NIOSH is satisfied that the potential approval holder has the capabilities and documented system required to manufacture a quality product; the site qualification inspection is a tool to provide that assurance. The manufacturers in this group are basically unknown to NIOSH, and will have a site visit to determine their manufacturing abilities and credibility to become an approved respirator manufacturer.

The second group consists of manufacturers that have one or more listed NIOSH-approved respirators and that are in the process of opening a new manufacturing site for the production of respirators. These manufacturers will require a document review to determine their manufacturing capabilities to produce approved respirators at the new site.

The third group consists of NIOSH approval holders that have been acquired by another entity and the manufacturing site for the production of approved respirators is relocated to a new site. These manufacturers will also require a document review to determine

their manufacturing capabilities to produce approved respirators at the new site.

In response to public comments, NIOSH has reconsidered the site qualification fee, which will now distinguish between the cost of a paper-based review for the new manufacturing site of an existing approval holder and the actual cost of a one-time site visit for manufacturers with no existing approvals. Flat fees will be established for the inspection of domestic and foreign manufacturing sites, respectively. Fee Schedule B has been amended accordingly.

Quality Assurance Maintenance (Site Audits) [§ 84.20(b)(4)]

Comment: Six commenters express concern about using the number of approvals as the basis for calculating the quality site audit fee. All six commenters suggest that the fees should be tied to the actual (or average) cost to perform each site audit. One commenter asks for clarification of the intent of this fee, and claims that the quality assurance maintenance fee and the maintenance of product performance fee (discussed below) will result in economic hardship to manufacturers, which in turn will impact the U.S. workforce and the ''overall safety of the working public.''

Response: The fees for the site audit program are divided between management of the site audit program (largely fixed costs) and individual quality audits and associated expenses (variable costs). NIOSH has modified the site audit fee in response to the commenters' request that the fee be more equitably allocated. Accordingly, the quality assurance maintenance (site audit) fee will be a combination of fixed and variable costs. Beginning in 2015, manufacturers will be charged annually a flat fee per every manufacturing site registered with NIOSH (those sites that exclusively conduct design activities are exempt from this annual fixed fee). Variable fees will be billed within the fiscal year during which the site audit is conducted, and are established based on the duration of the audit (either 1 or 2 days) and whether the site is domestic or outside the United States. Any site that is not scheduled to be audited within a fiscal year will not be billed the variable fee for that year. The variable cost fee also applies to sites that only do design. Fee Schedule A has been amended accordingly.

Maintenance of Product Performance (Product Audits) [§ 84.20(b)(5)]

Comment: One commenter stated that NIOSH should not be billing manufacturers for product audits because manufacturers have no input in determining which products NIOSH will select for audit. One commenter feels that, ''[s]ince NIOSH does not typically maintain samples of approved products there should be no reason to charge the Manufacturers a fee for the maintenance.'' If a change of the product or design of any type is requested by the manufacturer, it will be submitted to NIOSH as an Extension of Approval at which time the submittal fee is charged.'' Another commenter states that NIOSH should charge each approval holder directly for the cost of product audits, rather than add the fee to a modification request. One commenter further supports the use of a respirator selection audit logic to establish an audit schedule for the upcoming year, allowing NIOSH time to notify manufacturers that a charge is forthcoming.

Response: The maintenance of product performance fee allows NIOSH to purchase and test commercially available respirators for audit. The purpose of the NIOSH product audit program is to select respirators for sale in the marketplace and test them in the laboratory to verify that approved manufacturing systems are meeting NIOSH quality standards. Participating in the product audit program is an obligation of all approval holders, and all listed approvals are subject to audit.

NIOSH has a process in place to identify and help prioritize the identification of respirator configurations for audit activities. NIOSH introduced the ''Default to Test'' procedures in 2009 to support the product audit program. These procedures were implemented to help locate and procure samples of product for testing, and were developed to work within funding limitations that constrained the number and types of respirator configurations as well as how many products NIOSH could accommodate for testing and evaluation. NIOSH is exploring approaches to be able to efficiently, effectively, and economically obtain candidate respirators for product audit without placing undue burden on the manufacturers of those products. The increased fees recovered for product audits will enable NIOSH to redesign the product audit program, to make its scope and content more consistent with the wide variety of products being marketed under the NIOSH approval label.

Manufacturers can defray the audit costs by providing sample units rather than providing funds to NIOSH to purchase the samples. Respirators selected for audit may be obtained from distributors and other typically available market outlets, or directly from the manufacturer during production runs.

In response to comments, NIOSH agrees to de-couple the maintenance of product performance (product audit) fee from the fee for approval modification. The product audit fee is segmented into an annual fixed cost fee and a variable cost fee that is assessed based on the respirators chosen to be tested each year. The fixed cost portion of the fee is designed to cover the cost of staff associated with product audit program management. The variable fee is designed to cover the cost to NIOSH of obtaining sample respirators and performing the audit tests. This variable fee will be collected for the same fiscal year in which the product audit is scheduled to occur. The fee schedules have been changed accordingly.

Comment: One commenter inquires whether the closed-circuit escape respirators sampled in the Long-Term Field Evaluation (LTFE) program will be billed to the approval holder as a component of the product audit sampling program.

Response: Although the LTFE program is a component of the product audit program, respirators used in the LTFE program are currently not billed to the approval holder. Approval holders will, however, be billed for closed-circuit escape respirators chosen for routine audit sampling.

Section 84.21 Fees Calculation

Section 84.21 specifies how fees will be calculated and administered. Although no comments were received on this section, the rule text is changed to better clarify our intent.

Section 84.22 Fee Administration

Section 84.22 establishes the procedure NIOSH will use to invoice applicants. Although there are no changes made to this section as a result of public comment, HHS is making slight adjustments to the rule text in paragraphs (a) and (b) to clarify our intent.

Comment: Four commenters ask that the fee system be as simple as possible and that manufacturers receive a single, consolidated maintenance invoice at the same time each year. One commenter asks whether manufacturers will be invoiced on a calendar year or on the U.S. Government fiscal year basis. They also requested that online billing be available so that manufacturers can ''view and update their records without an overabundance of paperwork.''

Response: NIOSH intends to send a single consolidated invoice for annual maintenance fee assessments in the month of September, with payment expected in October. *Pay.gov* will be available for online fee collection, and we expect it to become the preferred means for the collection of fees in the future.

Comment: One manufacturer concurs that NIOSH should have the ability to impose sanctions on manufacturers who may miss one or several payments, but requests clarification regarding what constitutes a missed payment. The commenter proposes that a minimum period of 120 days from the date of the invoice be allowed before the payment is considered to be ''missed.''

Response: Standard government contracts are written in terms of ''net 60 days.'' This implies a standard payment period of 60 days. Late payment notices are typically sent at 60 and 90 days. Missed payment activity would typically start at 120 days. Accordingly, NIOSH will send late payment notices at 60 and 90 days and missed payment activity will start at 120 days.

Section 84.23 Fee Revision

Section 84.23 establishes the fee schedules for NIOSH's respirator certification activities.

Comment: Three commenters ask that NIOSH provide a formal mechanism for public comment prior to any future revisions to the fee schedules.

Response: NIOSH agrees to propose future fee schedule revisions in the **Federal Register**, subject to public comment. Accordingly, the fee schedules are added to 42 CFR part 84 in a new Appendix A (annual fees) and a new Appendix B (application-based fees).

Comment: One commenter suggests that a 1-year period between revisions of fees schedules will not allow sufficient time for companies to plan. The commenter proposes a fixed 5-year interval for fee revisions with no revisions outside of the 5-year cycle.

Response: HHS agrees that the proposed 1-year interval between revisions of the fee schedules may not provide sufficient time for planning; however the 5-year minimum suggested by the commenter will be inadequate to keep fees reasonably updated. Variables such as inflation and other factors that might affect the cost of testing supplies will be taken into account as NIOSH updates the fee schedules. Accordingly, in response to public comment and in accordance with the OMB Circular, the rule text is changed to establish a 2-year minimum interval for fee schedule revisions. The text is further changed to indicate that the fee schedules will not be revised at least once every 5 years, as proposed, and instead will be revised as needed based on the biennial reviews.

Section 84.24 Authorization for Additional Tests and Fees

Section 84.24 allows NIOSH the discretion to conduct special or additional examinations, inspections, or tests, apart from those specified for a particular respirator class under this Part, as might be necessary due to unusual characteristics of the respirator design, manufacturing information, or product samples. The text has been changed to acknowledge that the NIOSH National Personal Protective Technology Laboratory may use an independent laboratory to conduct certification testing, at its discretion. No comments were received on this section.

Section 84.36 Delivery of Changed or Modified Approved Respirator

Section 84.36 informs manufacturers that respirators for which a formal certificate of modification has been issued should be delivered to the National Personal Protective Technology Laboratory, rather than the Certification and Quality Assurance Branch.

Section 84.41 Quality Control Plans; Contents and 84.43 Quality Control Records; Review by the Institute; Revocation of Approval

Existing §§ 84.41 and 84.43 establish requirements for quality control plans and records. These sections are amended to replace reference to the ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.66 Withdrawal of Applications

Existing § 84.66 establishes procedures for the withdrawal of respirator certification applications. Paragraph (b) directs stakeholders to the fee calculation procedures in § 84.21(e) for the withdrawal of applications, where NIOSH has already performed some administrative and/or testing services. There are no changes made to this section as a result of public comment.

Comment: In response to NIOSH's statement in the preamble to the proposed rule that more information about billing will be available in the guidance document *Standard Application Procedure,* one commenter says that the current edition of the *Standard Application Procedure* does not address billing under the new rule and that the new billing procedures were not made available for public comment.

Response: NIOSH respirator certification fee estimates will be calculated according to the procedures established in § 84.21. Paragraph (e) of that section concerns those applications for which a manufacturer opts to withdraw an application but NIOSH has already begun application review and testing. In that case, according to § 84.21(e), the applicant will be invoiced for services already performed by NIOSH.

Although HHS provided an opportunity to comment on the proposed withdrawal billing procedures in § 84.21(e), no comments were received.

Section 84.76 Facepieces; Eyepieces; Minimum Requirements

Existing § 84.76 establishes minimum requirements for facepieces and eyepieces for self-contained breathing apparatus. The text in paragraph (b) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.79 Breathing Gas; Minimum Requirements

Existing § 84.79 establishes minimum requirements for breathing gas. The text in paragraphs (c) and (d) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.81 Compressed Breathing Gas and Liquefied Breathing Gas Containers; Minimum Requirements

Existing § 84.81 establishes minimum requirements for compressed breathing gas and liquefied breathing gas. The text in paragraph (d) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.97 Test for Carbon Dioxide in Inspired Gas; Open- and Closed-Circuit Apparatus; Maximum Allowable Limits

Existing § 84.97 establishes the method NIOSH uses to measure the concentration of carbon dioxide in inspired gas in open- and closed-circuit respirators. The text in paragraph (a) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.110 Gas Masks; Description

Existing § 84.110 includes descriptions of different types of gas masks. The text in paragraph (c) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.113 Canisters and Cartridges; Color and Markings; Requirements

Existing § 84.113 establishes requirements for the color and markings of canisters and cartridges or labels. The text is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.119 Facepieces, Eyepieces; Minimum Requirements

Existing § 84.119 establishes the minimum requirements for facepieces and eyepieces for gas masks. The text in paragraph (b) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.136 Facepieces, Hoods, and Helmets; Eyepieces; Minimum Requirements

Existing § 84.136 establishes the minimum requirements for facepieces, hoods, and helmets for gas masks. The text in paragraph (b) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.141 Breathing Gas; Minimum Requirements

Existing § 84.141 establishes the minimum requirements for breathing gas for supplied-air respirators. The text in paragraphs (b) and (c) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.193 Cartridges; Color and Markings; Requirements

Existing § 84.193 establishes requirements for the color and markings of all cartridges or labels. The text is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.258 Fees

Existing § 84.258 is removed from subpart N. This section contains a special respirator fee schedule for vinyl chloride respirators. The fees established by this final rule under § 84.21 apply to this group of respirators. No comments were received on this section.

Section 84.1102 Fees

Existing § 84.1102 is removed from subpart KK. This section contains a special respirator fee schedule for a series of respirators, including powered air purifying respirators. The fees that are established by this final rule under § 84.21 apply to this group of respirators. No comments were received on this section.

Section 84.1136 Facepieces, Hoods, and Helmets; Eyepieces; Minimum Requirements

Existing § 84.1136 establishes the minimum requirements for facepieces, hoods, and helmets for dust, fume, mist, pesticide, paint spray, and powered air-purifying high efficiency respirators and combination gas masks. The text in paragraph (b) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.1154 Canister and Cartridge Requirements

Existing § 84.1154 establishes requirements for two or more canisters and for color and markings of canisters or cartridges and labels for facepieces, hoods, and helmets for dust, fume, mist, pesticide, paint spray, and powered air-purifying high efficiency respirators and combination gas masks. The text in paragraph (b) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Section 84.1157 Chemical Cartridge Respirators With Particulate Filters; Performance Requirements; General.

Existing § 84.1157 establishes minimum requirements for the performance and protection of chemical cartridge respirators with particulate filters. The text in paragraphs (d)(5) and (e)(5) is amended to replace ''Certification and Quality Assurance Branch'' with ''National Personal Protective Technology Laboratory.''

Appendix A and Appendix B

Appendix A is added to Part 84 to establish the fee schedule for annual (fixed) respirator certification fees. Appendix B is added to Part 84 to establish the fee schedule for application-based respirator certification fees.

IV. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Order 12866 and Executive Order 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

This final rule is not being treated as a ''significant regulatory action'' within the meaning of E.O. 12866. The final rule is not considered economically significant, as defined in section 3(f)(1) of the executive order, and does not raise novel policy issues or have any of the other effects specified in section 3(f)(2)–(4). Thus, this rule has not been reviewed by the Office of Management and Budget (OMB).

NIOSH approves two categories of respirators: air-purifying respirators (APR), which filter contaminants in the environment (ambient air); and air-supplying respirators (ASR), which provide the user with clean breathing air (from a supply separate from the ambient air). APR includes particulate respirators, like the disposable N95 commonly used in healthcare settings; the elastomeric respirator with replaceable filters (*i.e.,* ''gas mask''); and the powered air-purifying respirator (PAPR), which employs a battery-powered blower to move breathing air through the filters.

ASR includes respirators that deliver breathing air to the wearer, using either compressed or chemical breathing air or a remote source. The respirator types in this category include the self-contained breathing apparatus (SCBA) commonly worn by members of the fire service; the closed-circuit escape respirator (CCER) used for emergency escape in underground coal mining and on-board ships; and the airline (air hose) respirator used for industrial chemical and paint applications and hazardous materials management.

Of the U.S. respirator market of products approved by NIOSH, approximately 35 percent of approval holders are U.S. companies and 65 percent are foreign. The foreign component of this distribution has nearly doubled since 2000, and is largely represented by manufacturers producing low-cost filtering facepiece respirators. The North American respiratory protection market generated revenues around $1,830 million in 2007,

the most recent data available.[3] A summary of market segmentation, by respirator type, is offered in Table 1, below.

TABLE 1—INDUSTRY OVERVIEW

Respirator type	Market share 2007 (%)	Revenues 2007 (millions $)
Air-Purifying:		
Elastomeric	28.1	514.2
Particulate	21.1	386.1
Powered air purifying	7.0	115.3
Air-Supplying:		
SCBA (open- and closed-circuit)	35.2	677.1
CCER	2.8	31.1
airline	5.8	106.1

Source: Frost & Sullivan [2008]. North American Respiratory Protective Equipment Market. Report N2E7–39.

As discussed in the notice of proposed rulemaking, OMB Circular A–25 Revised requires that the NIOSH respirator program be self-sustaining, and that the Agency recover the full cost of certification and testing services offered to respirator manufacturers. With this final rule, HHS sets fees for these services based upon costs generated in a typical calendar year, 2009. The data and analyses discussed here were generated at the outset of the drafting of this final rule, and NIOSH believes there has been minimal inflation affecting the NIOSH costs in the years since. All of the fees incorporate direct and indirect costs of providing testing and approval services, including personnel costs, physical overhead, and management and supervisory costs. For the purposes of this final rule, an average hourly cost of $50 per hour (rounded figure from Table 2) was used as a reasonable estimate; in cases where there were special or unique costs (*e.g.* chemicals for testing, travel for site audits), those costs were accounted for over and above the hourly cost.

TABLE 2—HOURLY COSTS

	Salary/hour ($)	Benefits/hour ($)	Total ($)
Certification Staff	36.66	9.55	46.21
Management Overhead (OD) Prorated	3.96	1.12	5.08
Total	40.62	10.67	51.29

Fixed costs are approximately $500,000 per year. These are the costs required to ensure the continued availability of a testing laboratory and are reasonably independent of the number of respirators tested or reviewed at any given time. These costs are broken down in Table 3, below.

TABLE 3—FIXED COSTS

Facilities	
Total cost	$5,161,860.
Total square feet used by NIOSH	474,000.
Cost per square foot	$9.93.
Square feet used for certification and approval activities	23,480.
Annual cost for certification and approval activities	$233,156.
Test Equipment	
Total cost	$2,510,000.
Amortization period	10 years.
Annual cost of test equipment	$251,000.

The fee schedules that are the basis for the analysis below are broken down into annual (fixed) fees (including product performance maintenance [product audits], records maintenance, quality assurance maintenance [site audits], facility maintenance, and testing capacity maintenance [test equipment depreciation]), and approval-based fees (including application, approval, approval modification, and site qualification fees, as well as all

[3] Frost & Sullivan [2008]. North American Respiratory Protective Equipment Market. Report N2E7–39 at 1–1.

laboratory tests conducted on air-supplied and air-purifying respirators, and respirators certified for use against chemical, biological, radiological, and nuclear agents). HHS offers the following explanation for the fee structure established in this rulemaking:

Application: The application fee allows NIOSH to process the paperwork associated with a new application request. New applications were estimated at 4 hours of processing time with no other expenses. Thus, the new application processing fee is set at $200. In 2009, NIOSH processed 435 applications and would have received payments in the amount of $87,000.

Approval: A fee is charged for each new approval granted an applicant. Because the issuance of new approvals is estimated to require 2 hours each above the base application fee, the fee is set at $100. In 2009, NIOSH granted 700 approvals [4] and would have received payments in the amount of $70,000.

Approval Modification: An approval-holder may apply to NIOSH for the modification of an existing approval. Requests to obsolete a certificate of approval are considered to be modifications of an existing approval. Modified approval activities are estimated to require 1 hour each above the base application fee. Thus, the modification fee is set at $50. In 2009, NIOSH granted 820 modifications of approval [5] and would have received payments in the amount of $41,000.

Records Maintenance: The proposed fee schedule is changed to clarify that this fee applies to all active and obsolete, or listed, approvals. Each listed approval is estimated to require 1 hour of records maintenance time per year. The maintenance fee is set at $50. Manufacturers held a total of 6,800 current approvals (active and obsolete) in 2009 and would have remitted maintenance payments in the amount of $340,000.

Quality Assurance Maintenance (site audit): The quality assurance maintenance fee will cover the costs of the quality auditing program. As discussed above, the proposed fee schedule is amended in response to commenters who suggested that the site audit fee reflect the actual cost to perform each audit. Accordingly, the fee is changed from the proposal to base the fee on each active approval on file with NIOSH. The cost to NIOSH for conducting facility audits depends on many variables, including the number of manufacturing sites, the size of the manufacturing sites, the quality performance of the manufacturing sites, the location of the sites, and whether the respirators are used for mining. Therefore, a fixed fee for quality audits will be charged annually per every manufacturing site registered with NIOSH, which is set at $3,000 per every manufacturing site registered with NIOSH. Sites which do only design, but not production, are excluded from this fixed fee. In addition to the fixed annual fee, NIOSH will also bill for the average cost of a site audit based on audit duration and geographic location (domestic or foreign), during the same fiscal year in which the audit occurs. Sites which do only design, but not production, will be charged the variable fee during the same fiscal year in which the audit occurs.

The initial schedule for these variable fees is:

VARIABLE SITE AUDIT FEES

U.S. site	1-day audit	$ 2,500
U.S. site	2-day or longer audit	5,000
International site	1-day audit	7,500
International site	2-day or longer audit	10,000

In the draft ''Respirator Certification Fee Schedule A—Administrative Fees,'' included in the docket for the notice of proposed rulemaking published in March 2013, NIOSH proposed a site audit fee of $85 per approval, which would have generated $578,000 during the 2009 evaluation period. The billing structure established in this final rule results in the same recovery to NIOSH, for the 2009 basis period, as the original proposal.

REVISED BILLING STRUCTURE

	Fee	Total
Fixed site audit fee production sites		
101	$3,000	$303,000
Variable site audit fee audit sites		
7 U.S. sites	2,500	17,500
11 U.S. sites	5,000	55,000
15 non-U.S.	7,500	112,500
9 non-U.S.	10,000	90,000
Total recovery		578,000

Maintenance of Product Performance (product audit): The product performance maintenance fee will cover the costs of the product audit program. As discussed above, the proposed fee schedule is changed in response to public comments to charge each approval holder directly for the cost of product audits, rather than link the fee to modification requests. Product audits are conducted on approved respirators and these respirators are, typically, obtained through normal commercial purchases. One of the central factors in determining which respirators to purchase and test is whether significant modifications have been made from the original, approved design. Accordingly,

[4] Note: One application may result in multiple approvals, so it is not unusual for the number of new approvals to exceed the number of applications.

[5] Note: One application may result in multiple modifications of approval, so it is not unusual for the number of modifications of approval to exceed the number of applications.

a fee for product performance audits will be added to each modification of approval requested. The product performance maintenance fee is set at $761 per approval holder ($53,300 staffing/70 approval holders). The variable cost portion of the fee is designed to cover the cost of obtaining respirators and performing the testing. This cost will be billed directly to the approval holder in the October billing for testing to be performed within the next 12 months. In 2009, NIOSH conducted 42 product audits; the variable portion of the fee would have been $70,000.

Site qualification: The site qualification fee provides for a one-time inspection of new production facilities. As discussed above, the proposed fee schedule is changed in response to public comments to charge each approval holder directly for the cost of site qualification inspections. A flat fee is established for existing approval holders, who will undergo a paper review only: $400 per each request. Non-approval holders will be charged $2,500 for inspection of a domestic facility, and $7,500 for an international site visit. The fee for non-approval holders includes travel expenses for personnel (including travel to sites outside the United States) as well as hourly charges.[6] Each site qualification is estimated to take 4 hours of preparation time, 16 hours in travel time, 16 hours on-site, and 4 hours of document/report time for a total of $2000 in staff costs (40 hours × $50/hour). In 2009, NIOSH performed 12 paper reviews for existing approval holders (12 × 400 = 4,800), and 4 domestic (4 × 2,500 = 10,000) and 2 foreign (2 × 7,500 = 15,000) site qualification audits, which would have resulted in payments in the amount of $30,000.

Maintenance of Testing and Approval Facilities: The facility maintenance fee will cover the costs of the respirator certification facilities located at the HHS-owned site in Pittsburgh, Pennsylvania. The costs for utilities, security, maintenance, maintenance equipment, maintenance staff and facilities management staff are included in this fee. The proposed fee schedule is changed to clarify that this fee applies to all active and obsolete, or listed, approvals. Facility maintenance is considered to be a fixed cost and independent of the certification activity in any given year. Accordingly, this fee will be assessed annually per listed approval. In 2009, the facility operating costs specific to respirator certification were $233,156 and manufacturers held 6,800 current approvals (active and obsolete). A fee of $34.00 per approval would have returned $231,200 to the program.

Maintenance of Test Equipment: The testing capacity maintenance fee is designed to recover the depreciation of testing equipment used for respirator certification. Equipment depreciation is typically considered to be a fixed cost and, therefore, NIOSH has classified it as an administrative (maintenance) fee. In accordance with the comments discussed above, the proposed fee schedule is changed to clarify that this fee applies to all active, and not obsolete, approvals. The fee itself is unchanged because the number of obsolete approvals included in the calculation of the proposed fee was insignificant. The testing capacity maintenance fee will be assessed annually per active approval. In 2009, the total cost of all certification equipment was $2,510,000. A 10 year amortization schedule is consistent with the life expectancy used in the purchasing of this equipment; therefore the annual depreciation of testing equipment is $251,000. In 2009, manufacturers held 6,800 approvals. A fee of $36.00 per each active approval would have returned $244,800 to the program.

Testing: The fees for each individual test are specified in Fee Schedule B. The testing fees include the cost of materials and equipment as well as hourly wages. Testing fees are established by analyzing the time, equipment, chemicals and supplies required for each individual test. The actual tests performed by NIOSH in 2009 generated estimated fees of $717,000 for that year. Unlike other fees charged by NIOSH, fees for testing respirators against chemical, biological, radiological, and nuclear (CBRN) agents have been recently generated and are currently billed according to the actual cost of testing performed by either U.S. military laboratories or by the NIOSH National Personal Protective Technology Laboratory. Accordingly, manufacturers should refer to the U.S. Army Research, Development and Engineering Command Edgewood Chemical Biological Center (ECBC) Web site at *http://www.ecbc.army.mil/* for a list of current testing costs. Costs for tests listed in Fee Schedule B and identified by the symbol ''#'' may not be reflective of current prices charged by ECBC. In 2009, NIOSH performed three CBRN tests and received payments in the amount of $150,000. These CBRN fees have been excluded from Table 4.

In order to use the existing accounting system, the fees have also been grouped into three categories—administrative/evaluation, testing, and audit activities—as summarized in Table 4, below.

TABLE 4—VARIABLE FEE RECOVERY ESTIMATES

Administrative/Evaluation Activities	
2009 Budget	$775,000.
Percentage of activities related to billable fees	75%.
Fees target	$581,000.
Estimated recovery under revised regulation:	
Applications	$87,000.
New approvals	$70,000.
Modifications	$41,000.
Maintenance fee, records	$340,000.
Site qualification	$30,000.
Total fees	$568,000.
Percent recovery	97.1%*
Testing Activities **	
2009 Budget	$840,000.

[6] NIOSH typically employs contractors to conduct site audits, at an average cost of $100 per hour.

TABLE 4—VARIABLE FEE RECOVERY ESTIMATES—Continued

Percentage of activities related to billable fees	85%.
Fees target	$714,000.
Estimated recovery under revised regulation:	
Testing fees	$717,000.
Total fees	$717,000.
Percent recovery	100%.
Audit Activities	
2009 Budget	$708,000.
Percentage of activities related to billable fees	100%.
Fees target	$708,000.
Estimated recovery under revised regulation:	
Product audit fees	$123,000.
Site audit fees	$578,000.
Total audit fees	$701,000.
Percent Recovery	99.0%.

* Given the level of variation in submissions from year to year, projections of 90–100% are considered to be full recovery.
** CBRN fees have been excluded.

In Table 4, above, the administrative/evaluation category includes most of the NPPTL Technology Evaluation Branch overhead in addition to the certification activities. HHS estimates that 75 percent of this category provided services that were directly related to billable certification activities. The testing category targets maintenance of certification equipment, laboratory supplies, and testing. HHS estimates that 85 percent of this category provides services directly related to billable certification testing activities. The audit category includes both the site audit and product audit activities. HHS estimates that 100 percent of this category provides services directly related to billable audit activities.

TABLE 5—FIXED FEE RECOVERY ESTIMATES

Facility maintenance		Test equipment depreciation	
2009 Actual Cost	$233,156	2009 Depreciation	$251,000.
New Fee	$231,200	New Fee	$249,600.
Percent Recovery	99.2%	Percent Recovery	99.4%.

The fixed fee categories are recoverable operating expenses of the respirator certification activity. However, they have not historically been part of the NIOSH National Personal Protective Technology Laboratory budget process and, therefore, they are broken out here separately. The facilities maintenance costs have been appropriated through NIOSH appropriation requests. Equipment replacement has been handled as either (a) a special one-time request related to special circumstances or special needs; or (b) as a distribution from retained user fees provided by manufacturers for certification activities.

This final rule is designed to recover the costs associated with providing services for the examination, inspection, and testing of respirators for the purposes of issuing, modifying, and maintaining certificates of approval. The current annual cost for this program is $2,500,000. NIOSH currently recovers approximately 10 to 20 percent of these costs under an outdated fee schedule that has remained in effect since 1972. NIOSH estimates that the total additional cost of this rulemaking to the 70 manufacturers of NIOSH-approved respirators would be between $2,000,000 and $2,500,000 annually, approximately 0.125 percent of the almost $2 billion industry, and less than 2.5 percent of the $100 million significance threshold.

The final rule will not interfere with state, local, and tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. HHS certifies this rule under the RFA, but prepared an Initial Regulatory Flexibility Analysis in order to solicit feedback regarding the impact of this rulemaking on revenues of small entities.

This rule updates the user fee structure for the certification of respiratory protective devices. The current fee structure, in place since 1972, has limited the Agency's ability to recover the majority of costs for respirator testing and certification. The current fee structure charges a set fee for the examination, inspection, and testing of eight broad groups of respirators. A single fixed fee is specified for each type of respirator without regard to the complexity of the respirator or the number of specific tests which are required. For example, the examination, inspection, and testing of a self-contained breathing apparatus for entry and escape, 1 hour or more costs $3,500; for a single hazard gas mask, the cost is $1,100; a supplied-air respirator will cost $750 for examination, inspection, and testing (42 CFR 84.20). As a result, NIOSH currently recovers only about 10 to 20 percent of the costs to provide initial certification and testing activities.

The OMB Circular requires that the NIOSH respirator certification program be self-sustaining, and that the Agency recover the full cost of certification, maintenance and testing (see Section II.C. in the notice of proposed rulemaking published on March 27, 2013 (78 FR 18535)). NIOSH's objective is to recover all of these costs. The fee

schedules include fees for each individual test required to grant a new approval or modification of an approval; processing the paperwork associated with any application request; granting a new approval or modifying an existing approval; maintaining each approval held during the year; and inspecting new production facilities.

This final rule applies only to those companies that hold NIOSH approvals for certified respirators, or wish to apply for such approvals. It does not duplicate, overlap, or conflict with other rules.

There are 70 respirator manufacturers that hold NIOSH approvals. Of this group, 10 manufacturers are considered large companies; 35 are approval-holders based outside of the United States; and 25 are classified as small businesses as defined under the Small Business Act for this industry sector (NAICS 339113—Surgical Appliance and Supplies Manufacturing), employing fewer than 500 employees. Accordingly, HHS has given consideration to the potential impact of this rule on these 25 companies.

HHS must establish whether the final rule has a significant economic impact on a substantial number of small businesses. According to HHS guidance, 5 percent or more of affected small businesses within an industry is considered a substantial number of businesses; an average annual impact on small businesses of 3–5 percent or more is considered a significant economic impact. Given that 25 of 70 regulated companies that comprise the respirator industry are small businesses, HHS considers a significant number to be affected by this final regulation. Many of these small companies are privately owned and, therefore, do not release public financial statements. However, as discussed below, the final rule does not exceed the HHS threshold for economic significance. For the purposes of this analysis, HHS has further categorized the small companies into three groups, as presented in Table 6 below.

TABLE 6—COMPANIES GROUPED BASED ON SIZE

Group ID	Group type	Number of employees	Number of companies
Group 1	Small	<50	10
Group 2	Small	51–250	8
Group 3	Small	251–500	7
Group 4	Large	>500	10

In order to predict the effects of the new fee structure, the existing fees submitted to NIOSH for approval activities were examined for the years 2005 through 2009 inclusive. This 5-year period was considered to be representative of typical approval activities. The recent past is the best model that NIOSH has to predict likely application behavior in the near future.[7]

The current fee structure specifies a single fee for each type of respirator approval. This type of fee structure tends to favor those companies that demand extensive services and disadvantage companies that have fairly simple, easily executed requests. In order to better balance actual fees charged with actual services requested, the fees have been reallocated to be proportionate to the extent of services required.

HHS is committed to ensuring that the regulatory burden does not disproportionately impact small businesses. Accordingly, the fee structure takes into account the complexity of the testing required to approve a respirator model. Typically, small companies have simple approval requests with few testing requirements. By designing a fee structure which would charge for the actual testing performed and individual fees which would be based on the number of active and obsolete approvals held, small companies would not pay for potential services that they do not use. Likewise, small companies typically have a limited number of listed approvals, so maintenance fees based on the number of listed approvals would minimize the fees charged to small companies versus large companies. Simply increasing the fees under the existing fee structure would impose a competitive disadvantage on small companies, because any fixed increase in fees would represent a greater percentage of revenue for small companies than for large companies. This is particularly relevant for the respirator manufacturers since the smallest companies have 1–10 employees while the largest significantly exceed 1,000 employees.

Tables 7, 8, and 9, below, address the costs for existing approval holders. The site qualification fee has not been incorporated into those figures.

TABLE 7—CURRENT STATISTICS FOR APPROVAL HOLDERS

	Group 1	Group 2	Group 3	Group 4
Avg. number listed approvals held per company	3	30	31	566
Avg. new approval applications per year per company	0.6	0.8	1.8	3.5
Avg. number modification applications per year per company	0.4	0.9	2.6	6.6
Avg. fees paid per year per company ($)	850	2,050	4,150	8,100
Total fees for 2005–2009 ($)	42,200	81,820	145,450	403,965

[7] Fees for the certification of respirators that provide protection from chemical, biological, radiological, and nuclear (CBRN) agents processed during the 2005–2009 time period were not included in the comparison for the following reasons: Only one small company holds any current CBRN approvals; CBRN approvals tend to be very expensive (~$100,000) and would skew all of the statistics; CBRN fees were set fairly recently (2002) and are based on actual testing costs; and CBRN fees will not change significantly as a result of this rulemaking.

TABLE 8—STATISTICS FOR APPROVAL HOLDERS IF NEW FEES HAD BEEN IN PLACE DURING 2005–2009

[$]

Average cost per company per year	Group 1	Group 2	Group 3	Group 4
Testing fees	1,400	2,730	10,600	15,680
New approvals	185	255	575	2,490
Modified approvals	95	225	525	1,740
Records maintenance	150	1,500	1,570	28,310
Product audits	60	135	390	990
Site audits	255	2,550	2,640	48,100
Facilities maintenance fee	100	990	1,020	18,680
Test equipment depreciation	95	960	990	18,110
Total fees	2,340	9,345	18,310	134,100

TABLE 9—COMPARISON OF CURRENT AND NEW FEES

	Group 1	Group 2	Group 3	Group 4
Avg. current fees per year per company ($)	850	2,050	4,150	8,100
Avg. new fees per year per company ($)	2,340	9,345	18,310	134,100
Avg. increase in cost per company ($)	1,490	7,295	14,160	126,000
Avg. percentage increase per company (%)	175	356	341	1,556
Percentage of current fees paid per group (%)	6	12	22	60
Percentage of new fees paid per group (%)	1.5	5	8	85.5

A site qualification fee will likely be triggered very infrequently. The types of events that will trigger a site audit include: The company becomes an approval holder for the first time (Event 1); the approval holder moves to or adds a new production site (Event 2); or the approval holder is sold and production moves to a new site (Event 3). The site qualification fee (covering costs for inspection of either a domestic or foreign manufacturing site) will apply to all new approval holders, since their facilities will not have been previously qualified. NIOSH does not believe that this fee represents a significant entry cost, in relation to the costs required to newly manufacture NIOSH-certified respirators. In any event, these do not represent new costs imposed on existing small businesses in respirator manufacturing impacted by this rulemaking.

For both small and large companies, the most common reason that a site qualification fee will be required is Event 2. That is, a company either adds a new production site or moves the existing production site to a new facility. The cost of qualifying a new production site will be very small ($400) compared to the costs of acquiring, designing, staffing, and beginning production at a new site.

Small companies often experience type 3 events. They are often sold and then relocated by the acquiring company. Again, the cost of qualifying a production site will be very small compared to the cost of buying a company and relocating it.

As discussed above, financial information from the small respirator manufacturers is difficult to discover, as many of these companies are privately held and are not required to file public financial statements. The only component of total revenues that is publically available is salary data. Attempts to determine the other production costs and/or the levels of profits for these companies did not generate reliable or consistent data. In order to estimate the revenues of these companies, statistics from the 2007 Economic Census for NAICS code 339113 were used. As a base for the revenues, it was assumed that the company needed, at a minimum, to cover the cost of its staff. Staffing levels were placed at the smallest likely levels for each size group.

As can be seen in Table 10, below, even using the limited estimator of salaries as a surrogate for total revenues, the cost of the final rule does not, on average, reach the HHS threshold of more than 3 percent of revenues for the final rule to be considered significant for any of the groups of companies.

TABLE 10—ECONOMIC IMPACT: FEES AS PERCENTAGE OF REVENUE

	Group 1	Group 2	Group 3
Number of employees	1–50	51–250	251–500.
Econ. Census Table	5–9 employees	50–99 employees	250–499 employees.
Management salary/year	$70,000	$64,200	$72,800.
Production wages/year	$31,000	$30,400	$41,900.
Management percent of employees	35.7%	35.2%	36.5%.
Number of management staff/number of production employees.	½ (3 total)	18/33 (51 total)	92/159 (251 total).
Total salaries/company	$132,000	$2,160,000	$13,400,000.
Total new fees (ref. Tables 7 and 9)	$2,940	$9,595	$18,740.
Fees as percentage of revenues	2.2	0.44	0.14.

However, because the usage of NIOSH services varies markedly from company to company, and even from year to year for any specific company, it is difficult to determine whether or not the final rule could, sporadically, have a significant impact on individual companies. Although we requested input from the regulated manufacturers on the accuracy of our estimates and asked that they provide data regarding the economic impact of this rule, HHS did not receive any public comments on this matter.

The RFA requires that the initial regulatory flexibility analysis describe significant alternatives to this final rule. HHS has identified two alternatives in addition to the final rule, which increases respirator fees on a test-by-test basis: (1) Retain the current fee and fee structure; or (2) increase the fees themselves.

Alternative 1: Retain the Current Fees and Fee Structure

HHS could have continued to use the current fees and fee structure. However, those fees have been in effect since 1972 and return only 10 to 20 percent of the annual costs associated with providing initial certification and testing activities. This does not meet the cost needs of the NIOSH certification and testing programs, and does not meet the specifications of the OMB Circular which requires NIOSH to recover all of these costs. Hence, HHS chose not to pursue this alternative.

Alternative 2: Retain the Current Fee Structure and Increase the Fees

HHS could have maintained the current fee structure but increased the fees to cover current NIOSH costs. Typically, small companies have simple approval requests with few testing requirements. Likewise, small companies typically have a limited number of existing approvals requiring certification maintenance activities by NIOSH (see Table 6, above). The current fee structure distributes the cost burden equally across applicants despite the higher level of service provided to large companies with higher numbers of applications and approvals. The effect of the current fee structure is that small companies receive fewer tests and maintain fewer approvals for the same fixed application fee than do the large companies. This puts small companies at a disadvantage. HHS chose not to pursue this alternative.

Final Rule: Modify Both the Fees and the Fee Structure To Reflect Actual Usage of NIOSH Services

As established in this final rule, HHS chose to break up the fees into assignable services which reflect actual testing, certification and maintenance costs for respirator approvals. These fees are discussed in detail above and include fees for: (1) Testing; (2) application requests; (3) approvals; (4) modifications; (5) maintenance; and (6) site qualification. This alternative increases fees to all business groups, but does so in a graduated way which minimizes the burden on the small companies. Projected fees increase by 175 percent, 355 percent and 340 percent, respectively, for the smallest to largest groups of small companies. Projected fees increase by 1560 percent for the group of large companies. The final rule also allows NIOSH to fully recover its costs associated with respirator testing and certification, as required by the OMB Circular. Therefore, HHS has chosen to pursue this alternative.

Based on the analysis provided above, HHS believes that this final rule will not have a significant economic impact on a substantial number of small businesses.

C. Paperwork Reduction Act of 1995

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* requires an agency to invite public comment on and to obtain OMB approval of any regulation that requires 10 or more people to report information to the agency or to keep certain records.

NIOSH has obtained approval from OMB to collect information from respirator manufacturers under ''Information Collection Provisions in 42 CFR part 84—Tests and Requirements for Certification and Approval of Respiratory Protective Devices'' (OMB Control No. 0920–0109, exp. November 30, 2017), which covers all information collected under 42 CFR part 84. The information NIOSH will collect under this rule does not differ substantially from the information presently collected from respirator manufacturers who obtain NIOSH certification of their products; nor will there be an increase in the reporting burden on respirator manufacturers.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), HHS will report to Congress the promulgation of a final rule, prior to its taking effect. The report will state that HHS has concluded that the rule is not a ''major rule'' because it is not likely to result in an annual effect on the economy of $100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this final rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million by state, local or tribal governments in the aggregate, or by the private sector, adjusted annually for inflation. For 2014, the inflation-adjusted threshold is $152 million.

F. Executive Order 12988 (Civil Justice)

This final rule has been drafted and reviewed in accordance with Executive Order 12988, Civil Justice Reform and will not unduly burden the federal court system. NIOSH has provided a fee structure that will apply uniformly to all applicants. This final rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The final rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this final rule on children. HHS has determined that the final rule will have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this final rule on energy supply, distribution, or use because it applies to

the underground coal mining sector since coal mine operators are consumers of respirators. The final rule is unlikely to affect the cost of respirators used in coal mines and hence is not likely to have ''a significant adverse effect on the supply, distribution, or use of energy.'' Accordingly, this final rule does not constitute a ''significant energy action'' under E.O. 13211 and requires no further Agency action or analysis.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the final rule consistent with the Federal Plain Writing Act guidelines.

Final Rule

List of Subjects in 42 CFR Part 84

Fees, Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 84 as follows:

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

■ 1. The authority citation for part 84 is revised to read as follows:

Authority: 29 U.S.C. 651 *et seq.;* 30 U.S.C. 3, 5, 7, 811, 842(h), 844; 31 U.S.C. 9701.

Subpart A—General Provisions

■ 2. In § 84.2, remove the alphabetical paragraph designations, arrange definitions in alphabetical order, remove the definitions of ''Certification and Quality Assurance Branch'' and ''Institute'', and add in alphabetical order definitions for ''Institute or NIOSH'' and ''National Personal Protective Technology Laboratory'' to read as follows:

§ 84.2 Definitions.

* * * * *

Institute or NIOSH means the National Institute for Occupational Safety and Health, Department of Health and Human Services.

* * * * *

National Personal Protective Technology Laboratory (NPPTL) means the National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236. NPPTL administers the NIOSH conformity assessment program for respiratory protective devices, replacing the former Certification and Quality Assurance Branch within the Division of Safety Research, Appalachian Laboratory for Occupational Safety and Health, NIOSH.

* * * * *

Subpart B—Application for Approval

■ 3. In § 84.10, revise paragraphs (b), (c), and (d) to read as follows:

§ 84.10 Application procedures.

* * * * *

(b) Applications must be submitted in accordance with the *Standard Application Procedure for the Certification of Respirators under 42 CFR 84,* (*Standard Application Procedure*) available on the NPPTL Web site, to Records Room, National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

(c) Except as provided in § 84.64, the examination, inspection, and testing of all respirators will be conducted or caused to be conducted by the National Personal Protective Technology Laboratory.

(d) Applicants, manufacturers, or their representatives may visit or communicate with the National Personal Protective Technology Laboratory in order to discuss the requirements for approval of any respirator or the proposed designs thereof. No charge will be made for such consultation and no written report will be issued to applicants, manufacturers, or their representatives by the Institute as a result of such consultation.

* * * * *

■ 4. In § 84.12, revise paragraph (b) to read as follows:

§ 84.12 Delivery of respirators and components by applicant; requirements.

* * * * *

(b) The applicant will deliver, at his or her own expense, the number of completely assembled respirators and component parts required for their examination, inspection, and testing, to the National Personal Protective Technology Laboratory.

* * * * *

■ 5. Revise subpart C to read as follows:

Subpart C—Fees

Sec.

Subpart C—Fees

§ 84.20 Establishment of fees.

(a) This section establishes a system under which NIOSH charges a fee for services provided to applicants for conformity assessment activities conducted by NIOSH for respiratory protective devices under 42 CFR part 84. This section specifies the purposes for which fees will be assessed and the cost factors for such assessments.

(b) Fees will be charged for:

(1) *Respirator certification application, approval, approval modification, records maintenance, and testing.* Application processing under this Part by engineers, technicians and other specialists, including administrative review of applications, analysis of drawings, technical evaluation, testing, test set up and tear down, and consultation on applications, clerical services, computer tracking and status reporting, records control and security, and document preparation directly supporting application processing. This fee also contributes to a proportionate share of management, administration and operation of the NIOSH National Personal Protective Technology Laboratory;

(2) *Maintenance of testing and approval facilities and test equipment.* Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing;

(3) *Site qualification.* Initial review and approval, as specified under 42 CFR part 84 subpart E—Quality Control, of manufacturing facilities that may be used to manufacture respirators, principal components, and/or subassemblies;

(4) *Quality assurance maintenance.* Quality site audits to verify conformance to the requirements of §§ 84.33, 84.40, 84.41, 84.42, 84.43; and

(5) *Maintenance of product performance.* Product audits to verify the performance of commercially available respirators which have been granted a NIOSH certificate of approval.

(c) Fees will not be charged for:

(1) Technical assistance not related to application processing;

(2) Technical programs including development of new technology programs;

(3) Participation in research; and

(4) Regulatory review activities, including participation in the development of health and safety standards, regulations, and legislation.

§ 84.21 Fee calculation.

(a) This section explains the process NIOSH uses to calculate estimates of the direct and indirect costs of services provided in the course of application processing.

(b) Upon completion of an initial administrative review of the application, NIOSH will calculate a fee estimate for each application, including the maximum cost of conducting additional tests under § 84.24, and will provide that estimate, with payment details, to the applicant. The fee estimate will be derived using the current schedules of fees published by NIOSH in Part 84. NIOSH will begin the technical evaluation once the applicant accepts the terms of the fee estimate and authorizes payment.

(c) If NIOSH determines that actual costs for application processing and related testing will exceed the fee estimate provided to the applicant, NIOSH will provide a revised fee estimate for completing the application review before exceeding the previously-authorized fees. The applicant will have the option of either withdrawing the application and paying for services already performed or authorizing payment of the revised estimate, in which case NIOSH will continue the application review and testing.

(d) If the actual cost of processing the application is less than the fee estimate NIOSH provided to the applicant, NIOSH will charge the actual cost.

(e) If the applicant withdraws an application, the applicant will be invoiced for services already performed by NIOSH. Withdrawal of an application will be effective on the first business day following the date NIOSH receives a withdrawal notice from the applicant in writing. Withdrawal notices will be submitted to NIOSH in accordance with the *Standard Application Procedure* using the address specified in § 84.10.

§ 84.22 Fee administration.

(a) Applicants will be invoiced for all fees incurred in the processing of an application when all required reviews, analyses, evaluations, and tests are completed or the application is withdrawn. Invoices will contain specific payment instructions and identify authorized methods of payment.

(b) Applicants who hold active and/or obsolete certificates of approval will be invoiced by NIOSH annually for applicable maintenance fees, in accordance with the fee schedule published in Appendix A of this part.

(c) NIOSH reserves the right to impose sanctions for any missed payment, and will administer such penalties after assessing the circumstances of the manufacturer and the needs of other stakeholders. Sanctions may include but are not limited to:

(1) Refusal to accept future applications for approval;

(2) Stop-sale of all approved product; and

(3) Engaging appropriate government authorities to initiate debt collection procedures for the unpaid fees.

§ 84.23 Fee revision.

(a) Each fee schedule will remain in effect for at least 2 years and will be revised as needed to reflect cost increases identified in biennial reviews.

(b) Fee schedule updates will be proposed in a notice of proposed rulemaking published in the **Federal Register**.

(c) The current fee schedules will be published in Appendix A and Appendix B of this part and will remain in effect until the effective date of the new fee schedules published in the **Federal Register**.

§ 84.24 Authorization for additional examinations, inspections, tests, and fees.

NIOSH will conduct or cause to be conducted any additional examinations, inspections, or tests it deems necessary to determine the quality and effectiveness of any respirator submitted to NIOSH for the purposes of seeking a certificate of approval. The costs of such examinations, inspections, or tests will be paid by the applicant prior to issuance of a certificate of approval for the subject respirator.

Subpart D—Approval and Disapproval

§ 84.36 [Amended]

■ 6. In § 84.36, remove ''Certification and Quality Assurance Branch'' and add in its place ''National Personal Protective Technology Laboratory''.

Subpart E—Quality Control

§§ 84.41 and 84.43 [Amended]

■ 7. In Subpart E, remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236'' wherever it appears in the following places:

■ a. § 84.41(b); and

■ b. § 84.43(a)

Subpart G—General Construction and Performance Requirements

■ 8. In § 84.66, revise the section heading and paragraph (b) to read as follows:

§ 84.66 Withdrawal of applications.

* * * * *

(b) Upon the receipt of a written request from the applicant for the withdrawal of an application, NIOSH will invoice the applicant based on the fee calculated, as specified under § 84.21(e).

Subpart H—Self-Contained Breathing Apparatus

§§ 84.76, 84.79, 84.81, and 84.97 [Amended]

■ 9. In Subpart H, remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236'' in the following places:

■ a. § 84.76(b)

■ b. § 84.79(c) and (d)

■ c. § 84.81(d)

■ d. § 84.97(a)

Subpart I—Gas Masks

§ 84.110 [Amended]

■ 10. In § 84.110(c), remove ''Certification and Quality Assurance Branch'' and add in its place ''National Personal Protective Technology Laboratory''.

§§ 84.113 and 84.119 [Amended]

■ 11. Remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236'' in the following places:

■ a. § 84.113

■ b. § 84.119(b)

Subpart J—Supplied-Air Respirators

§§ 84.136 and 84.141 [Amended]

■ 12. In Subpart J, remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236'' in the following places:

■ a. § 84.136(b)

■ b. § 84.141(b) and (c)

Subpart L—Chemical Cartridge Respirators

§ 84.193 [Amended]

■ 13. In § 84.193, remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236''.

Subpart N—Special Use Respirators

§ 84.258 [Removed]

■ 14. Remove § 84.258.

Subpart KK—Dust, Fume, and Mist; Pesticide; Paint Spray; Powered Air-Purifying High Efficiency Respirators and Combination Gas Masks

§ 84.1102 [Removed]

■ 15. Remove § 84.1102.

§§ 84.1136, 84.1154 and 84.1157 [Amended]

■ 16. Remove ''Certification and Quality Assurance Branch, 1095 Willowdale Road, Morgantown, WV 26505–2888'' and add in its place ''National Personal Protective Technology Laboratory, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236'' in the following places:

■ a. § 84.1136(b)

■ b. § 84.1154(b)

■ c. § 84.1157(d)(5) and (e)(5)

■ 17. Add Appendix A to Part 84 to read as follows:

Appendix A to Part 84—Annual (Fixed) Respirator Certification Fees

RESPIRATOR CERTIFICATION FEE SCHEDULE A—ANNUAL (FIXED) FEES

[Implemented on May 26, 2015]

Fee type	Legal citation	Amount	Due date
Maintenance of Product Performance (product audit).	42 CFR 84.20(b)(5)	• Annual fee: $761 per each approval holder • Variable fee: As billed by NIOSH based on the respirators chosen to be tested each year.	• Upon billing from NIOSH.[1] • October.
Records Maintenance	42 CFR 84.20(b)(1)	$50 for all listed[2] approvals on file with NIOSH on July 1st of each year.	• Upon billing from NIOSH.[1] • October (beginning in 2015).
Quality Assurance Maintenance (site audit).	42 CFR 84.20(b)(4)	• Annual fee: $3,000 per every manufacturing site registered with NIOSH. • Variable fee:[3] ..... ▪ 1 day domestic audit—$2,500 per site ▪ 2 day domestic audit—$5,000 per site ▪ 1 day international audit—$7,500 per site. ▪ 2 day international audit—$10,000 per site.	• Upon billing from NIOSH.[1] • October (beginning in 2015).
Maintenance of Testing and Approval Facilities.	42 CFR 84.20(b)(2)	$34 per every listed[2] approval on file with NIOSH on July 1st of each applicable year.	• Upon billing from NIOSH.[1] • October (beginning in 2015).
Maintenance of Test Equipment.	42 CFR 84.20(b)(2)	$36 per every active[4] approval on file with NIOSH on July 1st of each applicable year.	• Upon billing from NIOSH.[1] • October (beginning in 2015).

[1] For the first year that annual fees are in effect, NIOSH will provide manufacturers with a pre-invoice/advanced billing/invoice preview no later than July 1, 2015. The actual invoice will be sent in September 2015.

[2] ''Listed'' approvals include all active and obsolete approvals. The Certified Equipment List (CEL) reflects the current listed approvals maintained by NIOSH. See *http://www.cdc.gov/niosh/npptl/topics/respirators/CEL/default.html.*

[3] Applies to design as well as manufacturing sites.

[4] Does not include obsolete approvals.

■ 18. Add Appendix B to Part 84 to read as follows:

Appendix B to Part 84—Application-Based Respirator Certification Fees

RESPIRATOR CERTIFICATION FEE SCHEDULE B—APPLICATION-BASED FEES

[Implemented on May 26, 2015]

Fee type	Legal citation	Amount	Due date
Application	42 CFR 84.20(b)(1)	$200 per application submitted	Upon receipt of any application request.
Approval	42 CFR 84.20(b)(1)	$100 per each certificate of approval issued	Upon completion of the application and granting of an approval number.
Approval Modification ..	42 CFR 84.20(b)(1)	$50 per each certificate of approval modified	Upon completion of the application and issuing a modified approval.
Site Qualification	42 CFR 84.20(b)(3)	• Existing approval holder, paper review: $400 per each request to inspect new production facility. • Non-approval holders: ..... ▪ Domestic site visit—$2,500 ..... ▪ International site visit—$7,500	Upon agreement on the date of the site qualification examination.

Standard Test Procedure	Fee ($)
Testing Fees	
Descriptor:	For testing respirators.
Amount:	See below.
Basis:	Per each test.
Due date:	Upon initiation of testing.
Air-Purifying Respirators	
TEB–APR–STP–0001 Determination of particulate filter penetration (PAPR)	150
RCT–APR–STP–0003—Determination of exhalation resistance	150
TEB–APR–STP–0004—Determination of exhalation valve leakage	300
TEB–APR–STP–0005—Determination of qualitative isoamyl acetate (IAA) facepiece fit test	1,800
TEB–APR–STP–0005A—Determination of qualitative isoamyl acetate (IAA) facepiece fit test	1,800
TEB–APR–STP–0006—Determination of qualitative isoamyl acetate (IAA) facepiece fit test	1,800
TEB–APR–STP–0007—Determination of inhalation resistance	150
RCT–APR–STP–0012—Determination of air flow for powered air-purifying respirators	150
RCT–APR–STP–0014—Determination of leakage of drinking tube and accessories for respirator facepieces	300
RCT–APR–STP–0025—Determination of silica dust loading test for powered air-purifying respirator filters	1,200
RCT–APR–STP–0030—Determination of noise level test, powered air-purifying respirator with hoods or helmets	450
TEB–APR–STP–0033A—Determination of ammonia service-life test, air-purifying respirators with cartridges	750
TEB–APR–STP–0033B—Determination of ammonia service-life test, air-purifying respirators with canisters	750
TEB–APR–STP–0033C—Determination of ammonia service-life test, powered air-purifying respirators with cartridges	750
TEB–APR–STP–0033D—Determination of ammonia service-life test, tight-fitting powered air-purifying respirators with gas mask canister(s).	750
RCT–APR–STP–0034—Carbon monoxide service life	750
RCT–APR–STP–0035—Determination of chlorine service life	750
RCT–APR–STP–0036—Determination of chlorine dioxide service life	750
RCT–APR–STP–0037—Determination of a-chloroacetophenone (CN) service life	2,400
RCT–APR–STP–0038—Determination of ethylene oxide service life	450
TEB–APR–STP–0039A—Determination of formaldehyde service-life test, air-purifying respirators with cartridges	750
TEB–APR–STP–0039B—Determination of formaldehyde service-life test, air-purifying respirators with canisters	750
TEB–APR–STP–0039C—Determination of formaldehyde service-life test, powered air-purifying respirators with cartridges	750
RCT–APR–STP–0040—Determination of hydrogen chloride service life	500
RCT–APR–STP–0041—Determination of hydrogen cyanide service life	1,800
RCT–APR–STP–0042—Determination of hydrogen fluoride service life	750
TEB–APR–STP–0043A—Determination of hydrogen sulfide service-life test, air-purifying respirators with cartridges	750
TEB–APR–STP–0043B—Determination of hydrogen sulfide service-life test, air-purifying respirators with canisters	750
TEB–APR–STP–0043C—Determination of hydrogen sulfide service-life test, powered air-purifying respirators with cartridges	750
RCT–APR–STP–0044—Determination of mercury vapor service life	2,400
TEB–APR–STP–0045A—Determination of methylamine service-life test, air-purifying respirators with cartridges	450
TEB–APR–STP–0045B—Determination of methylamine service-life test, air-purifying respirators with canisters	450
TEB–APR–STP–0045C—Determination of methylamine service-life test, powered air-purifying respirators with cartridges	450
TEB–APR–STP–0045D—Determination of methylamine service-life test, tight-fitting powered air-purifying respirators with gas mask canister(s).	450
TEB–APR–STP–0046A—Determination of organic vapor (carbon tetrachloride) service-life test, air-purifying respirators with cartridges.	450
TEB–APR–STP–0046B—Determination of organic vapor (carbon tetrachloride) service-life test, air-purifying respirators with cartridges.	450
TEB–APR–STP–0046C—Determination of organic vapor (carbon tetrachloride) service-life test, powered air-purifying respirators with cartridges.	450
TEB–APR–STP–0046D—Determination of organic vapor (carbon tetrachloride) service-life test, tight-fitting powered air-purifying respirators with gas mask canister(s).	450
RCT–APR–STP–0047—Determination of phosphine service life	750
TEB–APR–STP–0048A—Determination of sulfur dioxide service-life test, air-purifying respirators with cartridges	450
TEB–APR–STP–0048B—Determination of sulfur dioxide service-life test, air-purifying respirators with canisters	450
TEB–APR–STP–0048C—Determination of sulfur dioxide service-life test, powered air-purifying respirators with cartridges	450
TEB–APR–STP–0048D—Determination of sulfur dioxide service-life test, tight-fitting powered air-purifying respirators with gas mask canisters.	450
RCT–APR–STP–0050—Determination of O-chlorobenzylidene malononitrile (CS) service life	2,400
TEB–APR–STP–0051—Determination of particulate filter efficiency level for P100 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0052—Determination of particulate filter efficiency level for P99 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0053—Determination of particulate filter efficiency level for P95 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0054—Determination of particulate filter efficiency level for R100 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200

Standard Test Procedure	Fee ($)
TEB–APR–STP–0055—Determination of particulate filter efficiency level for R99 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0056—Determination of particulate filter efficiency level for R95 series filters against liquid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0057—Determination of particulate filter efficiency level for N100 series filters against solid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0058—Determination of particulate filter efficiency level for N99 series filters against solid particulates for non-powered, air-purifying respirators.	1,200
TEB–APR–STP–0059—Determination of particulate filter efficiency level for N95 series filters against solid particulates for non-powered, air-purifying respirators.	1,200
RCT–APR–STP–0060—Determination of end-of-service-life indicator drop	300
RCT–APR–STP–0061—Determination of end-of-service-life indicator visibility	300
RCT–APR–STP–0062—Determination of nitrogen dioxide service life	750
RCT–APR–STP–0063—Determination of facepiece carbon dioxide and oxygen concentration levels—tight fitting, powered air-purifying respirators, with the blower unit running.	300
RCT–APR–STP–0064—Determination of facepiece carbon dioxide and oxygen concentration levels, tight fitting, powered air-purifying respirators, with the blower unit off.	300
RCT–APR–STP–0065—Determination of air flow resistance, breath responsive, powered air-purifying respirators	300
RCT–APR–STP–0066—Determination of end-of-service-life indicator (ESLI)	300
RCT–APR–STP–0067—Particulate respirator qualitative fit test utilizing saccharin or bitrex solutions	1800
Air-Supplied Respirators	
RCT–ASR–STP–0100—Determination of strength of hoses and couplings, type C and CE supplied-air respirators	150
RCT–ASR–STP–0101—Determination of tightness of hoses and couplings, type C and CE supplied-air respirators	150
RCT–ASR–STP–0102—Determination of nonkinkability of hoses, type C and CE supplied-air respirators	150
RCT–ASR–STP–0103—Determination of gasoline permeation of hoses and couplings, type C and CE supplied-air respirators	450
RCT–ASR–STP–0104—Determination of air-regulating valve 100,000 cycles performance, demand and pressure-demand type C and CE supplied-air respirators.	3,000
RCT–ASR–STP–0105—Determination of airflow, continuous flow type C and CE supplied-air respirators	300
RCT–ASR–STP–0105A—Determination of airflow, demand and pressure-demand type C and CE supplied-air respirators	300
RCT–ASR–STP–0106—Determination of inhalation airflow resistance, pressure-demand type C and CE supplied-air respirators	150
RCT–ASR–STP–0107—Determination of exhalation airflow resistance, pressure-demand type C and CE supplied-air respirators	150
RCT–ASR–STP–0108—Determination of inhalation airflow resistance, demand type C and CE supplied-air respirators	150
RCT–ASR–STP–0109—Determination of exhalation airflow resistance, demand type C and CE supplied-air respirators	150
RCT–ASR–STP–0110—Determination of gas-tightness test, isoamyl acetate (IAA), type C and CE supplied-air respirators	450
RCT–ASR–STP–0111—Determination of air velocity and noise levels—sound level, type C and CE supplied-air respirators	450
RCT–ASR–STP–0112—Determination of the level of protection provided by abrasive blast, type CE supplied-air respirators using a challenge aerosol of NaCl (sodium chloride) or corn oil.	450
RCT–ASR–STP–0113—Determination of airflow resistance—continuous-flow, type C and CE supplied-air respirators	150
RCT–ASR–STP–0114—Determination of sound-level measurement—escape, open-circuit self-contained breathing apparatus using hoods or helmets.	450
RCT–ASR–STP–0115—Determination of rated service time—constant-flow, escape, open-circuit self-contained breathing apparatus.	150
RCT–ASR–STP–0116—Determination of airflow resistance—continuous-flow, escape, open-circuit self-contained breathing apparatus with hoods.	150
RCT–ASR–STP–0117—Determination of positive pressure—closed-circuit, pressure-demand, self-contained breathing apparatus	150
RCT–ASR–STP–0118—Determination of low temperature operation—minimum temperature per applicant, open-circuit self-contained breathing apparatus.	1,200
RCT–ASR–STP–0119—Determination of low-temperature operation—minimum temperature per applicant, combination open-circuit self-contained breathing apparatus and type C and CE supplied-air respirators.	1,200
RCT–ASR–STP–0120—Determination of positive pressure—open-circuit, pressure-demand self-contained breathing apparatus	75
RCT–ASR–STP–0121—Determination of rated service time—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	75
RCT–ASR–STP–0121A—Determination of rated service time—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	75
RCT–ASR–STP–0122—Determination of exhalation breathing resistance—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0123—Determination of gas flow measurements—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0124—Determination of remaining service-life indicator—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0124A—Determination of alarm pressure—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0125—Determination of gas tightness—isoamyl acetate (IAA)—self-contained breathing apparatus with facepieces and mouthpieces.	750
RCT–ASR–STP–0125A—Determination of gas tightness—isoamyl acetate (IAA)—self-contained breathing apparatus with hoods or helmets.	750
RCT–ASR–STP–0126—Determination of by-pass valve flow—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0127—Determination of by-pass valve flow—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0128—Determination of accuracy of gauge—self-contained breathing apparatus	150

Standard Test Procedure	Fee ($)
RCT–ASR–STP–0132—Determination of inhalation breathing resistance—open-circuit, demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0133—Determination of exhalation breathing resistance—open-circuit, pressure-demand, self-contained breathing apparatus using two second stage regulators.	150
RCT–ASR–STP–0134—Determination of gasoline permeation test on breathing bags—closed-circuit, self-contained breathing apparatus.	750
RCT–ASR–STP–0135—Determination of inhalation and exhalation breathing resistance—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0136—Determination of demand gas flow—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0137—Determination of continuous gas flow on constant flow with demand flow—closed-circuit, self-contained breathing apparatus.	450
RCT–ASR–STP–0138—Determination of safety relief valve operation—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0139—Determination of facepiece carbon dioxide concentrations—self-contained breathing apparatus	450
RCT–ASR–STP–0140—Man tests—self-contained breathing apparatus	3,000
RCT–ASR–STP–0141—Man test number 5—closed-circuit, self-contained breathing apparatus	150
RCT–ASR–STP–0142—Determination of vibration (Ro-Tap test) for man test number 1—escape, closed-circuit, demand, self-contained breathing apparatus.	750
RCT–ASR–STP–0143—Determination of low-temperature operation—minimum per manufacturer—closed-circuit, self-contained breathing apparatus.	1,200
RCT–ASR–STP–0144—Determination of continuous gas flow on constant flow—closed-circuit, self-contained breathing apparatus.	300
RCT–ASR–STP–0145—Determination of sound level measurements for remaining service-life indicators—self-contained breathing apparatus.	750
RCT–ASR–STP–0146—Determination of diaphragm over-pressurization—open-circuit, self-contained breathing apparatus with belt mounted regulators and breathing tubes.	300
RCT–ASR–STP–0147—Determination of mode transfer test—combination, open-circuit self-contained breathing apparatus and supplied-air respirators (SCBA/SAR).	150
RCT–ASR–STP–0148—Determination of remote gauge leak-flow test—open-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0148A—Determination of remote gauge leak-flow test—closed-circuit, demand and pressure-demand, self-contained breathing apparatus.	150
RCT–ASR–STP–0155—Man test number 6—self-contained breathing apparatus using liquefied gas	2,400
Chemical, Biological, Radiologic, Nuclear (CBRN) Air-Purifying and Air-Supplied Respirators	
NIOSH/NPPTL administrative support for all CBRN projects	1,300
# *RCT–CBRN–STP–0200, 0201*—Determination of open-circuit self-contained breathing apparatus (SCBA) performance during dynamic testing against chemical agents of sarin (GB) vapor and distilled sulfur mustard (HD) vapor and liquid—*GB live agent testing*.	6,000
# *RCT–CBRN–STP–0200, 0201*—Determination of open-circuit self-contained breathing apparatus (SCBA) performance during dynamic testing against chemical agents sarin (GB) vapor and of distilled sulfur mustard (HD) vapor and liquid—*HD live agent testing*.	6,000
# *RCT–CBRN–STP–0200, 0201—aerosol process TDA–99M only*	600
CET–APRS–STP–CBRN–0301—Determination of CBRN organic vapor (cyclohexane) service-life test	1,000
CET–APRS–STP–CBRN–0302—Determination of CBRN acid gases (cyanogen chloride) service-life test	2,400
CET–APRS–STP–CBRN–0303—Determination of CBRN acid gases (hydrogen cyanide) service-life test	2,400
CET–APRS–STP–CBRN–0304—Determination of CBRN acid gases (phosgene) service-life test	1,400
CET–APS–STP–CBRN–0305—Determination of CBRN acid gases (hydrogen sulfide) service-life test	800
CET–APRS–STP–CBRN–0306—Determination of CBRN acid gases (sulfur dioxide) service-life test	800
CET–APRS–STP–CBRN–0307—Determination of CBRN acid gases (ammonia) service-life test	1,000
CET–APRS–STP–CBRN–0308—Determination of CBRN nitrogen oxide gases (nitrogen dioxide) service-life test	1,200
CET–APRS–STP–CBRN–0309—Determination of CBRN hydride gases (phosphine) service-life test	1,000
CET–APRS–STP–CBRN–0310—Determination of CBRN formaldehyde service-life test, air-purifying respirators	1,000
CET–APRS–STP–CBRN–0311—Laboratory durability conditioning process for environmental, transportation and rough handling use conditions on chemical, biological, radiological, and nuclear (CBRN) respiratory protective devices (RPD) standard conditioning procedure (SCP)—*US Army Research Development and Engineering Command (RDECOM) environmental conditioning*.	20,000
CET–APRS–STP–CBRN–0311—NPPTL environmental conditioning	16,000
CET–APRS–STP–CBRN–0311—RDECOM modified environmental conditioning—minus 125 canisters	16,000
CET–APRS–STP–CBRN–0311—NPPTL modified environmental conditioning—minus 125 canisters	8,000
CET–APRS–STP–CBRN–0312—Determination of field of view for full facepiece chemical biological radiological nuclear (CBRN) respiratory protective devices (RPD).	1,000
TEB–CBRN–APR–STP–0313—Determination of communication performance test for speech conveyance and intelligibility of chemical biological radiological and nuclear (CBRN) full-facepiece air-purifying respirator.	5,000
CET–APRS–STP–CBRN–0314—Determination of lens fogging on full facepiece chemical biological radiological nuclear (CBRN) air-purifying respirator.	3,000
CET–APRS–STP–CBRN–0316—Determination of haze, luminous-transmittance, and abrasion-resistance properties of the primary lens system material for full-facepiece respiratory protective devices (RPD).	2,000
# *RCT–CBRN–APR–STP–0350*—Determination of full facepiece, tight-fitting, negative-pressure, air-purifying respirator (APR) performance during dynamic testing against the chemical agent vapor sarin (GB)—*qualifier live agent testing (QLAT) only*.	7,000
# *RCT–CBRN–APR–STP–0350—remainder live agent testing (RLAT)*	6,000

Standard Test Procedure	Fee ($)
# *RCT–CBRN–APR–STP–0351*—Determination of full-facepiece, tight-fitting, negative-pressure, air-purifying respirator (APR) performance during dynamic testing against chemical agent distilled sulfur mustard (HD) vapor and liquid CBRN—*qualifier live agent testing (QLAT) only*.	7,000
# *RCT–CBRN–APR–STP–0351—remainder live agent testing (RLAT)*	6,000
# *RCT–CBRN–APR–STP–0350 and RCT–CBRN–APR–STP–0351—aerosol process TDA–99M*	600
TEB–CBRN–APR–STP–0352—Determination of laboratory respirator protection level (LRPL) values for CBRN self-contained breathing apparatus (SCBA) facepieces or CBRN air-purifying respirator (APR)—*LRPL*.	20,000
TEB–CBRN–APR–STP–0352—partial laboratory respirator protection level (LRPL) (in cases where failure occurs with less than 50% of subjects tested).	16,000
* *TEB–CBRN–APR–STP–0353*—Weight and diameter	200
CET–APRS–STP–CBRN–0401—Determination of CBRN organic vapor (cyclohexane) service-life test, air-purifying escape respirators.	1,000
CET–APRS–STP–CBRN–0402—Determination of CBRN acid gases (cyanogen chloride) service-life test, air-purifying escape respirators.	2,400
CET–APRS–STP–CBRN–0403—Determination of CBRN acid gases (hydrogen cyanide) service-life test, air-purifying escape respirators.	2,400
CET–APRS–STP–CBRN–0404—Determination of CBRN acid gases (phosgene) service-life test, air-purifying escape respirators	1,400
CET–APRS–STP–CBRN–0405—Determination of CBRN acid gases (hydrogen sulfide) service-life test, air-purifying escape respirators.	800
CET–APRS–STP–CBRN–0406—Determination of CBRN acid gases (sulfur dioxide) service-life test, air-purifying escape respirators.	800
CET–APRS–STP–CBRN–0407—Determination of CBRN base gases (ammonia) service-life test, air-purifying escape respirators	1,000
CET–APRS–STP–CBRN–0408—Determination of CBRN nitrogen oxide gases (nitrogen dioxide) service-life test, air-purifying escape respirators.	1,200
CET–APRS–STP–CBRN–0409—Determination of CBRN hydride gases (phosphine) service-life test, air-purifying escape respirators.	1,000
CET–APRS–STP–CBRN–0410—Determination of CBRN formaldehyde service-life test, air-purifying escape respirators	1,000
CET–APRS–STP–CBRN–0411—Laboratory durability conditioning process for environmental, transportation and rough handling use conditions on chemical, biological, radiological and nuclear (CBRN) (air-purifying or self-contained) escape respirator—*RDECOM environmental conditioning.*	22,000
CET–APRS–STP–CBRN–0411—NPPTL environmental conditioning	20,000
* *CET–APRS–STP–CBRN–0414*—Fogging	4,000
* *CET–APRS–STP–CBRN–0417*—Flammability, heat resistance	14,000
# *CET–APRS–STP–CBRN–0450*—Determination of chemical agent permeation and penetration resistance performance against sarin (GB) vapor of chemical, biological, radiological, and nuclear (CBRN) air-purifying escape respirator—*qualifier live agent testing (QLAT) only*.	7,000
# *CET–APRS–STP–CBRN–0450—remainder live agent testing (RLAT)*	6,000
# *CET–APRS–STP–CBRN–0451*—Determination of chemical agent permeation and penetration resistance performance against sulfur mustard (HD) liquid and vapor of the chemical, biological, radiological, and nuclear (CBRN) air-purifying escape respirator—*qualifier live agent testing (QLAT) only*.	7,000
# *CET–APRS–STP–CBRN–0451—remainder live agent testing (RLAT)*	6,000
# *CET–APRS–STP–CBRN–0450 and CET–APRS–STP–CBRN–0451—aerosol process TDA–99M*	600
TEB–CBRN–APR–STP–0452—Determination of laboratory respirator protection level (LRPL) values for CBRN air-purifying escape respirator—*LRPL*.	20,000
TEB–CBRN–APR–STP–0452—partial LRPL	16,000
CET–APRS–STP–CBRN–0454—Determination of human subject breathing gas (HSBG) concentrations (carbon dioxide and oxygen) for chemical, biological, radiological and nuclear (CBRN) air-purifying escape respirator.	3,500
* *CET–APRS–STP–CBRN–0455*—Human subject breathing gas test	6,000
CET–APRS–STP–CBRN–0456—Determination of practical performance level for chemical, biological, radiological and nuclear (CBRN) (air-purifying or self-contained) escape respirator.	(1)
CET–APRS–STP–CBRN–0499—Determination of donning effectiveness of chemical, biological, radiological and nuclear (CBRN) (air-purifying or self-contained) escape respirator.	(1)
TEB–CBRN–STP–0501—Determination of CBRN organic vapor (cyclohexane) service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,000
TEB–CBRN–STP–0502—Determination of CBRN acid gases (cyanogen chloride) service-life test, tight-fitting powered air-purifying respirators (PAPR).	2,400
TEB–CBRN–STP–0503—Determination of CBRN acid gases (hydrogen cyanide) service-life test, tight-fitting powered air-purifying respirators (PAPR).	2,400
TEB–CBRN–STP–0504—Determination of CBRN acid gases (phosgene) service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,400
TEB–CBRN–STP–0505—Determination of CBRN acid gases (hydrogen sulfide) service-life test, tight-fitting powered air-purifying respirators (PAPR).	800
TEB–CBRN–STP–0506—Determination of CBRN acid gases (sulfur dioxide) service-life test, tight-fitting powered air-purifying respirators (PAPR).	800
TEB–CBRN–STP–0507—Determination of CBRN base gases (ammonia) service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,000
TEB–CBRN–STP–0508—Determination of CBRN nitrogen oxide gases (nitrogen dioxide) service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,200
TEB–CBRN–STP–0509—Determination of CBRN hydride gases (phosphine) service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,000
TEB–CBRN–STP–0510—Determination of CBRN formaldehyde service-life test, tight-fitting powered air-purifying respirators (PAPR).	1,000

Standard Test Procedure	Fee ($)
TEB–APR–STP–0511–CBRN—Determination of CBRN organic vapor (cyclohexane) service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,000
TEB–APR–STP–0512–CBRN—Determination of CBRN acid gases (cyanogen chloride) service-life test, loose-fitting powered air-purifying respirators (PAPR).	2,400
TEB–APR–STP–0513–CBRN—Determination of CBRN acid gases (hydrogen cyanide) service-life test, loose-fitting powered air-purifying respirators (PAPR).	2,400
TEB–APR–STP–0514–CBRN—Determination of CBRN acid gases (phosgene) service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,400
TEB–APR–0515–CBRN—Determination of CBRN acid gases (hydrogen sulfide) service-life test, loose-fitting powered air-purifying respirators (PAPR).	800
TEB–APR–STP–0516–CBRN—Determination of CBRN acid gases (sulfur dioxide) service-life test, loose-fitting powered air-purifying respirators (PAPR).	800
TEB–APR–STP–0517–CBRN—Determination of CBRN base gases (ammonia) service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,000
TEB–APR–STP–0518–CBRN—Determination of CBRN nitrogen oxide gases (nitrogen dioxide) service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,200
TEB–APR–STP–0519–CBRN—Determination of CBRN hydride gases (phosphine) service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,000
TEB–APR–STP–0520–CBRN—Determination of CBRN formaldehyde service-life test, loose-fitting powered air-purifying respirators (PAPR).	1,000
NPPTL–STP–CBRN–PAPR–0550—Determination of CBRN powered air-purifying respirator (PAPR) performance during dynamic testing against the chemical agent vapor sarin (GB) chemical, biological, radiological and nuclear (CBRN) standard testing procedure (STP).	7,000
NPPTL–STP–CBRN–PAPR–0551—Determination of CBRN, powered air-purifying respirator (PAPR) performance during dynamic testing against chemical agent distilled sulfur mustard (HD) vapor and distilled sulfur mustard (HD) liquid chemical, biological, radiological, and nuclear (CBRN) standard testing procedure (STP).	7,000
TEB–CBRN–APR–STP–0552—Determination of laboratory respirator protection level (LRPL) values for CBRN tight-fitting powered air-purifying respirator (PAPR).	20,000
TEB–CBRN–APR–STP–0553—Determination of laboratory respiratory protection level (LRPL) values for CBRN loose-fitting powered air-purifying respirator (PAPR).	20,000
New and Unspecified Tests	
This category is to be used for new, on-going, tests which are developed between revisions of the test fee schedule or for special, one-time tests which are required for respirators with unique features (per 42 CFR 84.63).	(2)

* Draft test procedure in place, but final STP has not been published.
# Test is conducted by U.S. Army Research, Development and Engineering Command Edgewood Chemical Biological Center (ECBC).
1 No Fee, done as part of LRPL (TEB–CBRN–APR–STP–0452).
2 $500/day + the actual cost of non-NPPTL staff (typically medical staff and test subjects).

Dated: January 14, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–01046 Filed 1–23–15; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 79

[MB Docket Nos. 12–108, 12–107; FCC 13–138]

Accessibility of User Interfaces, and Video Programming Guides and Menus

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with the Commission's *Report and Order* implementing provisions of the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA) related to accessible user interfaces and video programming guides and menus. This document is consistent with the *Report and Order*, which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the requirements.

DATES: 47 CFR 79.107(c), 79.108(a)(5), 79.108(c) through (e), and 79.110 published at 78 FR 77210, December 20, 2013 are effective on January 26, 2015.

FOR FURTHER INFORMATION CONTACT: For additional information contact Cathy Williams, *Cathy.Williams@fcc.gov*, (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on October 1, 2014, OMB approved the information collection requirements contained in the Commission's *Report and Order,* FCC 13–138, published at 78 FR 77210, December 20, 2013. The OMB Control Number is 3060–1203. The Commission publishes this document as an announcement of the effective date of the requirements. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–1203, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it