SUPPLEMENTARY INFORMATION:

Background and Purpose

On March 22, 2013, the Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** (78 FR 17781), in which we proposed to require owners and operators of certain vessels and facilities regulated by the Coast Guard to use electronic readers designed to work with the Transportation Worker Identification Credential (TWIC) as an access control measure. The NPRM also proposed additional requirements associated with electronic TWIC readers, including recordkeeping requirements for those owners and operators required to use an electronic TWIC reader, and security plan amendments to incorporate TWIC reader requirements. The TWIC program, including the TWIC reader requirements proposed in the NPRM, is an important component of the Coast Guard's multi-layered system of access control requirements and other measures designed to enhance maritime security.

As authorized by the Maritime Transportation Security Act of 2002 [1] (MTSA), the Transportation Security Administration (TSA) established the TWIC program to address identity management shortcomings and vulnerabilities identified in the nation's transportation system and to comply with the MTSA statutory requirements. On January 25, 2007, the Department of Homeland Security (DHS), through the Coast Guard and TSA, promulgated regulations that require mariners and other individuals granted unescorted access to secure areas of MTSA-regulated vessels or facilities to undergo a security threat assessment by TSA and obtain a TWIC.[2]

This NPRM that is the subject of this public meeting, which would require owners and operators of certain types of vessels and facilities to use electronic TWIC readers, would advance the goals of the TWIC program. In crafting the proposals in the NPRM, the Coast Guard conducted a risk-based analysis of MTSA-regulated vessels and facilities to categorize them into one of three risk groups, labeled A, B, and C. Risk Group A is comprised of vessels and facilities that present the highest risk of being involved in a transportation security incident (TSI).[3] The NPRM proposes TWIC reader requirements for vessels and facilities in Risk Group A. Under the NPRM, vessels and facilities in Risk Groups B and C present progressively lower risks, and would continue to follow existing regulatory requirements for visual TWIC inspection.

The Coast Guard believes that in addition to receiving written comments on the NPRM, a public meeting would benefit the impacted community by providing another forum to raise relevant issues. Also, the Security and Accountability For Every (SAFE) Port Act of 2006 [4] requires the Coast Guard to hold at least one public hearing before promulgating final TWIC reader regulations (*see* 46 U.S.C. 70105(k)(3)). This public meeting will further enable the Coast Guard to craft policy informed by the public.

We may hold one or more additional public meetings regarding the proposals in the NPRM on TWIC reader requirements. We will notify the public of the date(s), time(s), location(s), and other details of any such meeting(s) by publishing a separate notice in the **Federal Register** as soon as we have information available.

You may view the NPRM, written comments, and supporting documents in the online docket by going to *http://www.regulations.gov* and using ''USCG–2007–28915'' as your search term. Locate the NPRM among the search results and use the filters on the left side of the page to search for specific types of documents. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Coast Guard has an agreement with the Department of Transportation to use its Docket Management Facility.

We encourage you to participate by submitting comments either orally at the meeting or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be submitted to our online public docket. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LCDR Gregory Callaghan at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice of public meeting.

Public Meeting

The Coast Guard will hold a public meeting regarding the ''Transportation Worker Identification Credential (TWIC)—Reader Requirements'' NPRM (78 FR 17781) on Thursday, April 18, 2013 from 1:00 p.m. to 5:00 p.m., at the Crystal City Marriott at Reagan National Airport, 1999 Jefferson Davis Highway, Arlington, Virginia 22202. The building is accessible by taxi, public transit, and privately-owned conveyance. Please note that the session may adjourn early if all business, concerns, and questions are addressed. We will post a written summary of the meeting and oral comments in the docket.

Authority

This notice of public meeting is issued under the authority of 46 U.S.C. 70105(k)(3) and 5 U.S.C. 552(a).

Dated: March 21, 2013.

A.E. Tucci,

Captain, U.S. Coast Guard, Chief, Office of Port and Facility Compliance (CG–FAC).

[FR Doc. 2013–07173 Filed 3–25–13; 4:15 pm]

BILLING CODE 9110–04–P

[1] Public Law 107–295, 116 Stat. 2064 (Nov. 2, 2002).

[2] Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License, 72 FR 3492 (Jan. 25, 2007).

[3] A transportation security incident is a security incident resulting in a significant loss of life, environmental damage, transportation system disruption, or economic disruption in a particular area, as defined in 46 U.S.C. 70101 (49 CFR 1572.103).

[4] Public Law 109–347, 120 Stat. 1884 (Oct. 13, 2006).

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: Notice of Proposed Rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to revise 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 proposed rule is designed to update the regulations.

DATES: HHS invites comments on this proposed rule from interested parties. Comments must be received by May 28, 2013.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or *http://www.cdc.gov/niosh/docket/review/docket216/default.html.*

FOR FURTHER INFORMATION CONTACT: David Book, NIOSH National Personal Protective Technology Laboratory (NPPTL), 626 Cochrans Mill Road, Pittsburgh, PA 15236; (412) 386–6691 or (412) 386–5200 (these are not a toll-free number).

SUPPLEMENTARY INFORMATION: This proposed 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 product sites and quality systems; (8) verifying quality system performance through 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 are invited to participate in this rulemaking by submitting written views, recommendations, and data. In addition, HHS invites comments specifically on the following recommendations proposed in this notice of proposed rulemaking:

(1) To delay the implementation of the approval maintenance fee specified in ''Respirator Certification Fee Schedule A —Administrative Fees'' [1] 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 invites 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.

Comments submitted by mail should be addressed to the ''NIOSH Docket Officer,'' titled ''Amendments to Respirator Certification Fees, NIOSH Docket #216,'' and should identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted electronically to *http://www.regulations.gov.* Printed comments can be sent to the NIOSH Docket Office at the address above. All communications received on or before the closing date for comments will be fully considered by HHS.

All comments submitted will be available for examination in the rule docket (a publicly available repository of the documents associated with the rulemaking) both before and after the closing date for comments. A complete electronic docket containing all comments submitted will be available on *http://www.regulations.gov.* Comments will be available in writing by request. NIOSH includes all relevant comments received without change in the docket, including any personal information provided.

II. Background

A. Introduction

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 conducting the examination, inspection and testing of such respirators which is necessary to grant the required approval. This proposed rule is designed to assure that all approval activities are covered by appropriate fees, to update the fees charged, and to create a mechanism for routinely updating fees in the future.

B. Background and Significance

The current fees and fee structure for certifying respirators were codified by HHS in 42 CFR part 84, which was published in June of 1995. The fees and

[1] ''Respirator Certification Fee Schedule A—Administrative Fees'' and ''Respirator Certification Fee Schedule B—Testing Fees'' are available in the docket for this rulemaking. The proposed fee schedules will not take effect until after publication of the final rule.

fee structure were carried over from 30 CFR Part 11 [2] without any significant changes, and had not been amended since their initial publication in March 1972. Although the existing fees and fee structure have not been updated in 4 decades, since that time, the cost to NIOSH of respirator examination, inspection, and testing has risen significantly.

C. Need for Rulemaking

Office of Management and Budget (OMB) Circular A–25 Revised (Circular) and the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701) establish Federal policy regarding fees assessed for Government services, and provide guidance to agencies on the implementation of charges. Among other things, a government agency will: (1) Collect fees for services provided to specific recipients in order for such services to remain self-sustaining; and (2) establish charges for special benefits provided to specific recipients that are at least as great as costs to the agency of providing such benefits. An example of a special benefit from a government agency is a license to carry on a specific activity or business.

Currently, NIOSH spends approximately $2,500,000 annually for creating and modifying certificates of approval, verifying conformance to 42 CFR Part 84, and conducting certification testing. Because the fee structure reflects the 1972 economy, NIOSH currently charges applicants only $240,000 to $500,000 annually. This annual disparity of between $2,000,000 and $2,500,000 does not allow the respirator certification program to be self-sustaining, as required by OMB. Under the Consolidated Appropriations Act of 2012 (Pub. L. 112–74), NIOSH is authorized to retain collected user fees. Therefore, it is vital that NIOSH update the fees it charges to applicants to fully recover the actual costs of respirator certification.

Under 42 CFR Part 84, a NIOSH certificate of approval is equivalent to a license providing a specific recipient, a respirator manufacturer, the ability to sell its NIOSH-approved respirators to U.S. businesses or industries that require the use of respirators by their employees. In accordance with the Circular, NIOSH will charge the recipient for the special benefit of examination, inspection, and testing that comprise the approval. Additionally, NIOSH is required to recover the costs of maintaining approvals, which include maintenance of certification records, verification of continued applicant compliance with approved quality systems and procedures, and verification of actual commercial product performance.

Accordingly, HHS proposes to update the fee schedule for the inspection, approval, and certification of manufacturers' (specific recipients) respirators to cover NIOSH's costs in conducting these processes. HHS proposes to establish a process of periodically updating these fees as necessary to maintain current with changes to costs arising from inflation, new certification requirements, and/or technological changes.

D. Public Meetings for Discussion and for Comment

NIOSH will convene a public meeting to provide stakeholders an opportunity to comment orally on this rulemaking during the comment period. The meeting will be held in the Pittsburgh, Pennsylvania, metro area, and will be announced in a separate notice in the **Federal Register**. This meeting will also be available through remote access capabilities.

III. Summary of Proposed Rule

This proposed rule would amend several sections in 42 CFR Part 84 and replace Subpart C—Fees in its entirety. The proposed provisions would establish a new fee structure designed to enable NIOSH to fully recover the cost to the agency of certification examination, testing, and inspection. Unlike the existing fee structure, the proposed fee structure would take 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 proposed fee structure would charge applicants for the costs of issuing, modifying, and maintaining certificates of approval, production facility inspection (site qualification fee), and for verification of on-going quality system compliance and commercial product performance.

The first proposed fee schedules are not included in the proposed regulatory text but are offered as supporting material in NIOSH Docket #216 and on *www.regulations.gov* Docket CDC–2013–0004 for this rulemaking. After the public comment period, the new fee schedules will be published in a **Federal Register** notice after publication of the final rule. The fees will be effective at that time or as otherwise specified in the final rule. Subsequent fee schedules will be updated periodically through notices in the **Federal Register**, according to the proposed provisions in § 84.23, discussed below.

The following is a section-by-section summary which describes and explains the provisions of the proposed rule. The public is invited to provide comment on any aspect of this rule.

84.2 Definitions

This existing section, under subpart A, establishes definitions of terms found in the Part 84 regulations. The proposed amendment to this section would simply add a definition for the NIOSH National Personal Protective Technology Laboratory (NPPTL), which is the NIOSH unit that conducts respirator certification testing.

84.10 Application Procedures

This existing section, under subpart B, establishes procedures for submitting applications to NIOSH for respirator approval. Under this section, paragraphs (a) and (e) will remain unchanged. Respectively, these paragraphs require that applicants submit to NIOSH a written application and that respirators with electrical or electronic components will be tested in accordance with 30 CFR Part 18.

The proposed amendment to paragraph § 84.10(b) would remove all references to checks or money orders being submitted as part of the application. Instead, NIOSH would bill the applicant under the provisions of proposed § 84.22. The mailing address would be updated to reflect the current address in Pittsburgh, Pennsylvania. Changes to paragraphs (c) and (d) would identify NPPTL as the entity that will conduct the respirator testing.

84.12 Delivery of Respirators and Components by Applicant; Requirements

Paragraph (b) of this existing section would be revised to identify NPPTL as the entity to which applicants must deliver respirator units for certification testing.

84.19 Applicability

HHS proposes that the final rule will take effect 30 days after publication in the **Federal Register**. HHS understands that fees for maintaining existing approvals may cause some approval holders to modify their current business practices (e.g., some manufacturers maintain approvals for products that are not commercially available). Therefore, HHS proposes to delay the implementation of the approval

[2] 30 CFR part 11, replaced by 42 CFR part 84 in 1995, formerly prescribed approval procedures, established fees, and consolidated and extended requirements for obtaining joint approval of respirators by the Bureau of Mines within the Department of the Interior, and NIOSH.

maintenance fee specified in ''Respirator Certification Fee Schedule A—Administrative Fees'' (included in the docket for this rulemaking) 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. HHS believes that 4 months is sufficient time for manufacturers to request rescission of approvals for items not in production. However, public comments on this timeframe are welcomed.

Paragraph (c) would specify that fees for site audits would be assessed beginning in the October that falls more than 4 months after publication of the final rule.

84.20 Establishment of Fees

Proposed § 84.20 would replace existing § 84.20 in its entirety. Proposed paragraph (a) would establish the fee structure for the examination, testing and inspection required to issue, maintain, and modify certificates of approval.

Proposed paragraph (b) would specify the activities for which NIOSH would charge fees. Such activities would include: (1) Application and approval processing, including the review of documents, analysis of drawings, technical evaluation and testing of respirators; (2) approval maintenance, including records management, product audits, and site audits to verify the maintenance of approved quality systems; and (3) the qualification of new respirator production sites. Direct and indirect costs associated with those activities would include: (1) Clerical services, computer tracking, status reporting, control of records and document preparation; (2) management and overhead costs (for further discussion, see Section IV.A., below); and (3) the purchase, maintenance, and replacement of the facilities and equipment required to test and evaluate respirators. As discussed below in the Executive Order 12866 economic analysis, the fee structure proposed in this notice is intended to recover the full cost of providing respirator certification services to manufacturers.

Finally, proposed paragraph (c) would specify the activities for which NIOSH does not intend to charge fees. Such activities would include: (1) Technical assistance not associated with applications for approval; (2) research and surveillance activities conducted by other NIOSH branches; (3) respirator research; and (4) regulatory review activities, and the development of standards and regulations.

84.21 Fees Calculation

Proposed § 84.21 would specify how fees would be calculated and administered. Paragraph (a) would specify that the fees charged would reflect the actual costs incurred by the government for the requested services.

Paragraph (b) would specify the procedure by which NIOSH would estimate the fee for an applicant, including deriving the estimate using a published fee schedule. The paragraph would require that NIOSH provide the estimate to the applicant and receive authorization before beginning the technical evaluation. The testing requirements for the various classes of respirators that NIOSH evaluates under 42 CFR Part 84 are well defined. NIOSH has extensive experience with processing applications for respirator approval, and therefore expects that most applications will be of a routine nature and the final charges within the original fee estimate. Application and certification fees are generally standard for each type of respirator, although some charges, such as quality assurance audits, will be dependent on the number of approvals and manufacturing sites maintained by the manufacturer seeking approval. As described in § 84.24, occasionally, unusual or undisclosed features or characteristics of the design under investigation require more evaluation time or additional tests that were not anticipated in the initial fee estimate. Accordingly, NIOSH will notify applicants what the maximum additional cost would be for such tests. NIOSH will require advance authorization from applicants for the additional costs associated with this testing.

Proposed paragraph (c) would establish that, in the event that NIOSH determines that actual costs exceed the estimate provided to applicants, NIOSH would revise the fee estimate. The applicant will have the option of either withdrawing the application and paying for NIOSH services already performed or authorizing payment of the revised estimate, in which case NIOSH will continue the application review and related testing.

Proposed paragraph (d) would require that NIOSH charge no more than the actual costs of respirator application processing, including the review of documents, analysis of drawings, technical evaluation, and testing of respirators. (See section IV.A., below, for a thorough discussion of these costs.)

Proposed paragraph (e) would describe how the applicant may withdraw an application before NIOSH has completed its review, and the costs for which the applicant would remain liable. Such costs would include any work that NIOSH has already performed when the request to withdraw an application is received by NIOSH. Examples include any administrative work, any technical evaluations of drawings and designs, and any testing which has been set up or performed.

84.22 Fee Administration

Section 84.22 would establish the procedure NIOSH would use to bill applicants. Proposed paragraph (a) would explain that applicants will be billed for all fees assessed upon completion of NIOSH testing, rather than be asked to submit an estimated fee with the application, as is currently done. Payment instructions will be provided in the invoice. Applicants will be advised of payment options, including procedures for submitting payments electronically through the Federal Web site *https://pay.gov.*

Proposed paragraph (b) would address billing for maintenance fees, which have not previously been charged by NIOSH.

Proposed (c) would establish that NIOSH may impose sanctions in the event that a manufacturer fails to remit payment for a service performed by the agency. Such sanctions may include, but would not be limited to, NIOSH taking the following actions: (1) Refusing to accept future applications for approval, except for applications for extensions of approval needed to address respirator recall and retrofit matters that are associated with health and safety issues for workers; (2) imposing a stop-sale order for all approved products; or (3) engaging appropriate Federal government authorities to initiate debt collection procedures for the unpaid fees. Sanctions will be determined on a case-by-case basis; considerations will include an assessment of the manufacturer's particular circumstances and other stakeholders' needs. Flexibility in meeting these needs cannot be achieved without the ability to choose and impose appropriate sanctions on manufacturers who may miss one or several payments.

84.23 Fee Revision

Proposed § 84.23 would establish the fee schedules for NIOSH's respirator certification activities. Proposed paragraph (a) would require fee schedules to remain in effect for at least 1 year and to be revised at least every 5 years. NIOSH chose 1 year as the minimum amount of time for the fees to remain in effect to give manufacturers an opportunity to plan for application submissions. Five years was chosen as

a maximum amount of time for the fees to remain in effect to ensure that NIOSH is reimbursed for the actual costs of respirator approval, in the event that costs to the program increase. HHS welcomes public comment on whether a 1-year minimum is adequate for manufacturers to plan their submissions.

Proposed paragraph (b) would specify that notification of changes in schedules would be published in the **Federal Register**.

Proposed paragraph (c) would establish that the current fee schedules would remain in effect until new schedules are published.

84.24 Authorization for Additional Tests and Fees

Proposed § 84.24 would allow NIOSH the discretion to conduct special or additional examinations 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. This authority would be retained without substantive change, as currently specified under existing § 84.22(b).

84.66 Withdrawal of Applications

Existing § 84.66 of subpart G establishes procedures for the withdrawal of respirator certification applications. Existing paragraph § 84.66(a), which establishes an applicant's right to withdraw an application, will be retained in its entirety.

Paragraph (b) would be amended to specify that NIOSH would bill the applicant for costs incurred during the incomplete processing of the application until and including its withdrawal, as provided under § 84.21(e). NIOSH would bill the applicant upon receipt of the written withdrawal notice. More information about billing procedures will be available in the guidance document, ''Standard Application Procedure for the Certification of Respirators Under 42 CFR 84.'' [3]

84.258 Fees

HHS proposes to remove existing § 84.258 from subpart N, which contains a special respirator fee schedule for vinyl chloride respirators. The fees that would be established by this proposed rule under § 84.21 would apply to this group of respirators.

84.1102 Fees

HHS proposes to remove existing § 84.1102 from subpart KK, which contains a special respirator fee schedule for a series of respirators, including powered air purifying respirators. The fees that would be established by this proposed rule under § 84.21 would apply to this group of respirators.

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 proposed rule is not being treated as a ''significant regulatory action'' within the meaning of E.O. 12866. The proposed 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 (ie., ''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.[4] 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

[3] The 2005 version of the Standard Application Procedure is available at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf.* This document does not reflect the changes proposed in this rulemaking and will be updated prior to publication of this final rule.

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

TABLE 1—INDUSTRY OVERVIEW—Continued

Respirator type	Market share 2007 (%)	Revenues 2007 (millions $)
Airline	5.8	106.1

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

As discussed above, 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. HHS proposes to set 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 proposed rule, and NIOSH believes there has been minimal inflation affecting the NIOSH costs in the past 2 years. NIOSH will update the fee schedules and related analyses using the most current available data in the final rule.

All of the proposed 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 proposed 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)	3.96	1.12	5.08
Prorated 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 administrative fees (including site qualification, new applications, new approvals, modification, records maintenance, quality assurance maintenance [site audits], product performance maintenance [product audits], facility maintenance, and testing capacity maintenance [test equipment depreciation]), and testing fees (including all laboratory tests conducted on air-supplied and air-purifying respirators, and respirators certified for use against chemical, biological, radiological, and nuclear agents). To view the full proposed fee schedules, see ''Respirator Certification Fee Schedule A—Administrative Fees'' and ''Respirator Certification Fee Schedule B—Testing Fees,'' which are available in the docket for this rulemaking. HHS offers the following explanation for the fee structure proposed 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 proposed 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 new approvals are estimated to require 2 hours each above the base application fee, the proposed fee is set at $100. In 2009, NIOSH granted 700 approvals [5] 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 approvals are estimated to require 1 hour each above the base application fee. Thus, the proposed modification fee is set at $50. In 2009, NIOSH granted 820 modifications of approval [6] and would have received payments in the amount of $41,000.

Records Maintenance: Each existing approval is estimated to require 1 hour of records maintenance time per year. The proposed maintenance fee is set at $50. Manufacturers held a total of 6,800 current approvals in 2009 and would have remitted maintenance payments in the amount of $340,000.

Quality Assurance Maintenance: The quality assurance maintenance fee will cover the costs of the quality auditing program. The cost to NIOSH for conducting facility audits depends on many variables, including the number of

[5] 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.

[6] 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.

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. NIOSH finds it appropriate to divide the overall cost to the agency among all existing approvals, as the quality systems for all approvals need to be verified. Therefore, quality audits will be charged annually per approval. The proposed quality assurance maintenance fee is set at $85 per existing approval. Manufacturers held a total of 6,800 current approvals in 2009 and would have made payments in the amount of $578,000 to cover in full the costs of quality audits at the sites.

Product Performance Maintenance: The product performance maintenance fee will cover the costs of the product audit program. Product audits are conducted on approved respirators and these respirators are, typically, obtained through normal commercial purchases. A decision logic is used to determine which respirators to purchase and test; one of the central factors in this decision is whether significant modifications have been made from the original, approved design. Accordingly, a fee for product performance audits will be added to each modification of approval requested. The proposed product performance maintenance fee is set at $150. A manufacturer that does not modify an approval will not be subject to a product performance maintenance fee. In 2009, NIOSH granted 820 modifications of approval and would have received payments in the amount of $123,000 to cover in full the costs of product audits.

Site qualification: The site qualification fee provides for a one-time inspection of new production facilities. The fee would include travel expenses for personnel (including travel to sites outside the United States) as well as hourly charges.[7] 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 x $50/hour); travel expenses are estimated at $3000 for each site qualification inspection ($3000 is the average cost of travel for staff conducting site audits). Thus, the proposed site qualification fee is set at $5,000. In 2009, NIOSH performed six site qualifications and would have received 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. 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 approval. In 2009, the facility operating costs specific to respirator certification were $233,156 and manufacturers held 6,800 current approvals. A fee of $34.00 per approval would have returned $231,200 to the program.

Testing Capacity Maintenance: 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. The testing capacity maintenance fee will be assessed annually per 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 approval would have returned $244,800 to the program.

Testing: The proposed fees for each individual test are specified in ''Respirator Certification Fee Schedule B—Testing Fees,'' posted in NIOSH Docket #216 and on *www.regulations.gov* in Docket CDC–2013–0004. 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. 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 proposed 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
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

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

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
Proposed Fee	231,200	Proposed 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 NPPTL 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 proposed 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 proposed rule would 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 believes that it can certify this rule under the RFA, but has prepared an Initial Regulatory Flexibility Analysis because it lacks information about the revenues of small entities that would be impacted. Therefore, HHS requests comments from manufacturers on this matter as the financial operations of these small entities are not publicly available to be directly analyzed.

This rule would update 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 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. above). NIOSH's objective is to recover all of these costs. The proposed schedules (included in NIOSH Docket #216 and *www.regulations.gov* Docket CDC–2013–0004 for this rulemaking) will 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 proposed 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 proposed rule would have 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 proposed regulation. Many of these small companies are privately owned and, therefore, do not release public financial statements. However, as discussed below, we believe it is unlikely that the proposed regulation will 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

TABLE 6—COMPANIES GROUPED BASED ON SIZE—Continued

Group ID	Group type	Number of employees	Number of companies
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.[8]

The current fee structure specifies a single fee for each type of respirator approval (See 42 CFR 84.20–84.22). This type of fee structure tends to favor those companies who demand extensive services and disadvantage companies who have fairly simple, easily executed requests. In order to better balance actual fees charged with actual services requested, the proposed 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 proposed 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 approvals granted/modified, small companies would not pay for potential services that they do not use. Likewise, small companies typically have a limited number of existing approvals, so maintenance fees based on the number of 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 manufactures 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 ($5000) has not been incorporated into those figures.

TABLE 7—CURRENT STATISTICS FOR APPROVAL HOLDERS

	Group 1	Group 2	Group 3	Group 4
Avg. number 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

TABLE 8—STATISTICS FOR APPROVAL HOLDERS IF PROPOSED 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 PROPOSED FEES

	Group 1	Group 2	Group 3	Group 4
Avg. current fees per year per company ($)	850	2,050	4,150	8,100
Avg. proposed fees per year per company ($)	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

[8] 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 the proposed revision to fees.

TABLE 9—COMPARISON OF CURRENT AND PROPOSED FEES—Continued

	Group 1	Group 2	Group 3	Group 4
Percentage of proposed fees paid per group (%)	1.5	5	8	85.5

According to Table 10, below, a site qualification fee would be triggered very infrequently. The types of events that would trigger a site audit include: The company becomes an approval holder for the first time (Event 1); the company moves to or adds a new production site (Event 2); or the company is sold and production moves to a new site (Event 3). Based on the 2005–2009 NIOSH data, an existing small approval holder would require a site qualification about once every 14 years [(5 years) × (25 companies) ÷ (9 events) = 13.9 years between events]. Existing large approval holders would require a site qualification about once every 5 years [(5 years) × (10 companies) ÷ (11 events) = 4.5 years between events]. While NIOSH cannot predict the type or number of events that might trigger a site audit in the future, the number of events that triggered such audits in the past is used here to provide a realistic estimate of future site qualification fees.

The site qualification fee would 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 would 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 would be very small 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 would be very small compared to the cost of buying a company and relocating it.

TABLE 10—STATISTICS FOR APPROVAL HOLDERS IF PROPOSED SITE QUALIFICATION FEE WERE IN PLACE DURING 2005–2009 [1]

	Group 1	Group 2	Group 3	Group 4
Event 1 (New) [2]	1	1	.....	1
Event 2 (Adds) [3]	2	1	2	10
Event 3 (Sold) [4]	3	.....	1	.....
Total Events	6	2	3	11
Total cost ($)	30,000	10,000	15,000	55,000
Avg. cost per company per year [5] ($)	600	250	430	1,100

[1] Example Group 1 has 10 companies and total cost is calculated over 5 years. Avg cost/company/year = $30000/(10 co)(5 yr).
[2] Event 1—Company becomes an approval holder for the first time.
[3] Event 2—Company moves to or adds a new production site.
[4] Event 3—Company is sold and production moves to a new site.
[5] Reflects occurrence of events within each group in NIOSH's internal certification data.

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 their staff. Staffing levels were placed at the smallest likely levels for each size group.

As can be seen in Table 11, below, even using the limited estimator of salaries as a surrogate for total revenues, the cost of the proposed rule does not, on average, reach the HHS threshold of more than 3 percent of revenues for the proposed rule to be considered significant for any of the groups of companies.

TABLE 11—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	1/2 (3 total)	18/33 (51 total)	92/159 (251 total)
Total salaries/company	$132,000	$2,160,000	$13,400,000
Total proposed fees (ref. Tables 7 and 9)	$2,940	$9,595	$18,740

TABLE 11—ECONOMIC IMPACT: FEES AS PERCENTAGE OF REVENUE—Continued

	Group 1	Group 2	Group 3
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 proposed rule could, sporadically, have a significant impact on individual companies. We request input from the regulated manufacturers on the accuracy of our estimates and ask that they provide data regarding the economic impact of this proposed rule.

The RFA requires that the initial regulatory flexibility analysis describe significant alternatives to the rule proposed in this document. HHS has identified two alternatives in addition to the proposed increase in 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 continue 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 has chosen not to pursue this alternative.

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

HHS could maintain the current fee structure but increase 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 has chosen not to pursue this alternative.

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

As proposed here, HHS could 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 proposed rule would also allow NIOSH to fully recover its costs associated with respirator testing and certification, as required by the Circular. Therefore, HHS has chosen to pursue this alternative.

Based on the analysis provided above, HHS believes that the proposed rule would 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, expiration date August 31, 2014), which covers all information collected under 42 CFR Part 84. The information NIOSH would collect under this rule does not differ substantially from the information presently collected from respirator manufacturers who obtain NIOSH certification of their products; nor would 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 would report to Congress the promulgation of a final rule, once it is developed, prior to its taking effect. The report would 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 proposed 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 2011, the inflation adjusted threshold is $136 million.

F. Executive Order 12988 (Civil Justice)

This proposed 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 would apply uniformly to all applicants. This proposed rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The proposed 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 proposed rule on children. HHS has determined that the proposed rule would 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 proposed 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 proposed 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 proposed 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 proposed rule consistent with the Federal Plain Writing Act guidelines.

Proposed 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 proposes to amend 42 CFR Part 84 as follows:

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

■ 1. The authority citation for part 84 is amended 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, and add in alphabetical order a definition for ''National Personal Protective Technology Laboratory'' to read as follows:

§ 84.2 Definitions.

* * * * *

National Personal Protective Technology Laboratory means the National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, P.O. Box 18070, 626 Cochrans Mill Road, Pittsburgh, PA 15236.

* * * * *

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 shall be submitted 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 shall 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 shall be made for such consultation and no written report shall 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 shall deliver, at his or her own expense, the number of completely assembled respirators and component parts required for testing, to the National Personal Protective Technology Laboratory.

* * * * *

■ 5. Revise subpart C as follows:

Subpart C—Fees

Sec.

Subpart C—Fees

§ 84.19 Applicability.

(a) For respirator manufacturers that intend to apply for a respirator certificate of approval under part 84, the provisions of Part 84 subpart C are applicable on [DATE 30 DAYS AFTER FINAL RULE PUBLICATION IN THE **Federal Register**.]

(b) For current approval holders, the records maintenance fee specified in ''Respirator Certification Fee Schedule A—Administrative Fees'' is applicable on [DATE 4 MONTHS AFTER FINAL RULE PUBLICATION IN THE **Federal Register**.]

(c) Fees for site audits are effective [DATE OF FIRST OCTOBER 1 THAT OCCURS MORE THAN 4 MONTHS AFTER FINAL RULE PUBLICATION IN THE **Federal Register**.]

§ 84.20 Establishment of fees.

(a) This section establishes a system under which NIOSH charges a fee for services provided to applicants under 42 CFR part 84. This section specifies the purposes for which fees shall be assessed and the cost factors for such assessments.

(b) Fees will be charged for:

(1) 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;

(2) A proportionate share of management, administration and operation of the NIOSH organizational unit that conducts application processing;

(3) Amortization of facility improvements and depreciation of buildings and equipment used for testing and evaluation or otherwise directly associated with application processing;

(4) Initial review and approval, as specified under 42 CFR part 84 subpart E—Quality Control of this Part, of manufacturing facilities that may be used to manufacturer respirators;

(5) Quality site audits to verify conformance to the requirements of 42 CFR 84.33, 84.40, 84.41, 84.42, 84.43.; and

(6) 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 processing an approval application;

(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 provides the direct and indirect costs of NIOSH's services.

(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 of this part, and will provide that estimate, with payment details, to the applicant. NIOSH will begin the technical evaluation once the applicant accepts the terms of the fee estimate and authorizes payment. The fee estimate will be derived using the current schedules of fees published by NIOSH in the **Federal Register** and on the NIOSH Web site at *http://www.cdc.gov/niosh/npptl/default.html.*

(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 to the applicant a revised fee estimate for completing the application review. The applicant will have the option of either withdrawing the application and paying for NIOSH services already performed or authorizing payment of the revised estimate, in which case NIOSH will continue the application review and related 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 shall pay for services already performed by NIOSH for the application review. Such services shall include any administrative work (including any administrative work to process the withdrawal), and any examinations, inspections, or tests performed pursuant to such application. Withdrawal of an application shall be effective on the first business day following the date NIOSH receives a withdrawal notice from the applicant in writing. Withdrawal notices shall be submitted to NIOSH only at the application address specified under § 84.10 of this part.

§ 84.22 Fee administration.

(a) Applicants will be billed for all application fees when processing of the application is completed or the application is withdrawn. Invoices will contain specific payment instructions, including the address to mail payments and authorized methods of payment.

(b) Applicants who hold active certificates of approval will be billed by NIOSH annually or as appropriate for any applicable maintenance fees. Such maintenance fees, where applicable, are specified in the current schedule of fees published by NIOSH in the **Federal Register** and on the NIOSH Web site at *http://www.cdc.gov/niosh/npptl/default.html.*

(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 shall remain in effect for at least 1 year and shall be revised at least once every 5 years.

(b) Updated fee schedules shall be published in the **Federal Register** and posted on the NIOSH Web site at *http://www.cdc.gov/niosh/npptl/default.html.*

(c) The current fee schedules shall remain in effect until NIOSH publishes new fee schedules in the **Federal Register** as specified under paragraph (b) of this section.

§ 84.24 Authorization for additional tests and fees.

NIOSH shall conduct any examination, inspection, or test 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 shall be paid by the applicant prior to issuance of a certificate of approval for the subject respirator.

Subpart G—General Construction and Performance Requirements

■ 7. In § 84.66, revise 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 shall bill the applicant based on the fee calculated, as specified under § 84.21(e) of this part.

Subpart N—Special Use Respirators

§ 84.258 [Removed]

■ 8. 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]

■ 9. Remove § 84.1102.

Dated: March 20, 2013.

Kathleen Sebelius

Secretary, Department of Health and Human Services.

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3900, 3920, and 3930

[LLWO–3200000 L13100000.PP0000 L.X.EMOSHL000.241A]

RIN 1004–AE28

Oil Shale Management—General

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Land Management (BLM) is proposing to amend the BLM's commercial oil shale regulations by revising these regulations in order to address concerns about the royalty system in the existing regulations and to provide more detail to the environmental protection requirements.

DATES: Send your comments to reach the BLM on or before May 28, 2013. The BLM will not necessarily consider any comments received after the above date in making its decision on the final rule.

ADDRESSES: Mail: Director (630) Bureau of Land Management, U.S. Department of the Interior, Mail Stop 2143LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004–AE28. Personal or messenger delivery: U.S. Department of the Interior, Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. Federal eRulemaking Portal: *http://*