Registration will also assist NIOSH in locating deployed units to periodically evaluate whether this respirator is remaining effective under field conditions of storage and use.''

Editorial Note: This document was received at the Office of the Federal Register on December 5, 2008.

Dated: July 23, 2008.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920–AA04

Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking

AGENCY: Centers for Disease Control and Prevention.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to update existing quality assurance requirements under 42 CFR Part 84 for the manufacture of all respirators approved by the National Institute for Occupational Safety and Health (''NIOSH'') of Centers for Disease Control and Prevetion (CDC), HHS. The proposed new requirements would require respirator manufacturers to be compliant with a widely adopted voluntary consensus standard for quality management systems, would update technical requirements particular to quality assurance for manufacturing of NIOSH-approved respirators, and would establish requirements governing the related quality assurance oversight activities of NIOSH.

DATES: CDC invites comments on this proposed rule from interested parties. Comments must be received by February 9, 2009.

ADDRESSES: You may submit comments, identified by RIN: 0920–AA04, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: niocindocket@cdc.gov*. Include ''RIN: 0920–AA04'' and ''42 CFR pt. 84'' in the subject line of the message.
- *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 Regulatory Information Number (RIN) for this rulemaking, RIN: 0920-AA04. All comments received will be posted without change to *http://www.cdc.gov/niosh/docket*, 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.cdc.gov/niosh/docket*.

FOR FURTHER INFORMATION CONTACT: William Newcomb, NIOSH National Personal Protective Technology Laboratory (''NPPTL''), Pittsburgh, PA, (412) 386–4034 (this is not a toll-free number). Information requests can also be submitted by e-mail to *niocindocket@cdc.gov*.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this proposal.

Comments submitted by e-mail or mail should be addressed to the ''NIOSH Docket Officer'' , titled ''NIOSH Docket #109'', and should identify the author(s), return address, and a phone number, in case clarification is needed. Comments can be submitted by e-mail to: *niocindocket@cdc.gov*. E-mail comments can be provided as e-mail text or as a Word or Word Perfect file attachment. 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 CDC.

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 the NIOSH Web page at *http://www.cdc.gov/niosh/docket*, and comments will be available in writing by request. NIOSH includes all 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'' (''Part 84'') 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. In addition, MSHA co-approves with NIOSH all respirators used in mine emergencies and mine rescue.

As provided under Subpart E of Part 84, NIOSH presently requires, as a condition of approval, that the manufacturer of a NIOSH-approved respirator maintain a quality control plan designed to ensure that the products manufactured are of adequate quality and perform to the specifications under which they were approved by NIOSH. To provide quality assurance oversight, NIOSH conducts audits of manufacturing facilities (site audits) and of finished products (product audits). Additionally, NIOSH investigates complaints from employers and users concerning the performance of approved respirators in their workplaces. These audits and investigations can result in a variety of compliance actions by NIOSH, including requesting product recalls, stop-sale orders, retrofits, advisories, and various remedial quality control actions.

B. Background and Significance

Employers rely upon NIOSH-approved respirators to protect their employees from airborne toxic contaminants and oxygen-deficient environments. More than 3.3 million private sector employees in the United States wear respirators for certain work tasks. The most effective and reliable means of protecting workers from airborne contaminants is to prevent the workplace air from substantial contamination in the first place through enclosed processes and ventilation engineering. Similarly, the most effective and reliable means of protecting workers from oxygen-deficient environments is to prevent their causes or entry into them by workers. However, it is not technologically or economically feasible in all workplaces and operations to reduce airborne concentrations of

contaminants to safe levels and to prevent exposure to oxygen-deficient environments. In such cases, workers depend on respirators to protect them from asphyxiation or airborne contaminants that are known or suspected to cause acute and chronic health effects, such as heavy metal poisoning, acid burns, chronic obstructive pulmonary disease, silicosis, neurological disorders, and cancer.

As immediate protection, respirators must not only be certified as safe, functional, and effective; they must also be manufactured to perform reliably. This is exceptionally important because in many circumstances, particularly involving chronic health effects that develop gradually or after a long latent period, the worker has no way of knowing if a respirator is failing to provide the protection for which it was certified. Occupational cancers, for example, typically become symptomatic decades following the toxic exposures. Even for acute health effects, the worker many not be able to detect defective performance of the respirator prior to the toxic exposure, upon which it might be too late to avoid serious injury or death.

Respirator manufacturers and NIOSH have critical roles in assuring employers, other purchasers of respirators, and workers that their respirators will provide the protection that is implied by their NIOSH certification. This rulemaking, which has been identified as a priority among the policymaking needs of the NIOSH respirator certification program by respirator manufacturers, employers, and other stakeholders of the program, [1] is intended to strengthen this assurance.

C. Need for Rulemaking

The current requirements of Part 84 for a quality control plan (Subpart E) were established in 1972. Since that time, the quality management practices employed in manufacturing and other industries have developed substantially and have become more effective. Quality management systems have developed and become widely diffused. These systems direct the work of an organization regarding the quality of its products and services through a highly focused system of processes, documentation, resources, and monitoring. Central to this progress, particularly in manufacturing industries, are quality assurance methods that have improved through the increasing application of statistical process control methods (monitoring methods for achieving consistent satisfactory performance of each process involved in the manufacture of a final product). This progress has enabled manufacturers in many industries to reduce levels of product nonconformance with design and performance standards to a diminishingly small fraction of their total product output.

Revising Part 84 to incorporate up-to-date requirements for quality management is a necessary step to facilitate progress in respirator manufacturing that has been achieved in other manufacturing concerns. Although most respirator manufacturers maintain effective quality management systems, more than eight percent of NIOSH audits of manufacturing facilities since 1999 have found nonconformances in product quality requiring a cessation of sales and remedial actions by the approval holder. Approximately 40 percent of NIOSH product audits conducted since 1999 have identified a nonconformance with certification requirements and five percent have resulted in a product recall or retrofit. In addition, of the 40 field problem investigations NIOSH conducts per year, 45 percent require corrective actions, 20 percent result in a recall request, and 2.5 percent result in NIOSH issuing a stop-sale request. The levels of nonconformance indicated by these statistics, although they cover a small number of the 7,100 respirators approved by NIOSH, suggest that some respirator manufacturers can make substantial advances in product quality by instituting improved quality management systems.

In addition to facilitating quality management in respirator manufacturing, this proposed rule provides NIOSH with the opportunity to more efficiently deploy its auditing resources to focus on quality matters that are highly specific to assuring respirator performance. Over the past decade, the number of approved respirators has increased substantially. NIOSH has issued more than 5,100 of the 7,100 active approvals since 1995. In October 2007, there were 87 approval holders operating manufacturing facilities in the United States and foreign countries. The growth of the industry, the diversity of its products, and the globalization of its operations, have strained NIOSH resources applied to providing adequate quality assurance audits and related services.

This proposed rule would incorporate into Part 84 the ISO Q9001:2000 standard: *Quality management systems—Requirements,* 3rd Edition, established by the International Organization for Standardization (ISO),[2] which is a national and international consensus standard widely adopted by leading manufacturers in many industries. All respirator manufacturers holding or seeking a NIOSH approval would have to be compliant with this standard. Presently, approximately 77 percent of approval holders are voluntarily registered as compliant with this standard, having undergone auditing to establish compliance, and most of the remaining approval holders claim also to be compliant.

Incorporation of the ISO standard would elaborate and enhance the existing Part 84 quality control requirements. The existing requirements are general except for those governing the use of product inspection sampling plans. The ISO standard, by contrast, requires the use of a clearly specified, comprehensive, systematic, quality management system, providing specific parameters for quality management system documentation, management responsibilities, resource management, product realization, and measurement, analysis and quality management improvement. Incorporation of the ISO standard would foster better quality management consistently throughout this critical safety product market.

With respect to quality control activities governed by the current provisions of Part 84, the proposed rule would also update the existing requirements governing the inspection sampling plans used by respirator manufacturers (42 CFR 84.41(b)). The existing requirements constrain manufacturers to conducting extensive inspection regardless of the design and sophistication of their quality management systems. The proposed rule would enable manufacturers to establish product inspection approaches suited to their quality management

[1] All Manufacturers Meeting—Application Log-in Time and flowchart of application process; March 22, 2000, NIOSH, Morgantown, WV.

Private Sector Lab meeting to discuss improvement concepts for updating quality assurance and administrative requirements in the regulation (42CFR 84); June 12–13, 2000, ICS Inc., Brunswick, OH.

Stakeholder and Public meeting concerning Quality Assurance and Administrative Requirements for Approval of Respirators, (FR65:129:41472), August 8, 2000, Quality Hotel and Suites, Arlington, VA; August 16, 2000, Embassy Suites, Burlingame, CA.

NIOSH/NPPTL CBRN and Quality Assurance Public Meeting (FR68:107:33494–33495), June 25, 2003, Hilton Garden Inn, Canonsburg, PA.

NIOSH/NPPTL Public Meeting—Quality Assurance Module for Respiratory Protective Equipments (FR 65:180:54458–54459), October 16, 2003, Radisson Hotel, Morgantown, WV.

[2] ISO Q9001:2000 is available from the American National Standards Institute (ANSI), 25 West 43rd St., New York, NY 10036; Web page: *http://www.ansi.org*; phone 212–642–4900.

systems and the degree of process control they achieve. The change would save inspection resources and costs for manufacturers achieving high levels of process control in any elements of their production processes.

D. Public Meetings for Discussion and Comment

NIOSH held public meetings to discuss underlying issues and technical matters addressed in this proposed rule on August 8, 2000, at the Quality Hotel and Suites, Arlington, VA; on August 16, 2000, at the Embassy Suites, Burlingame, CA; June 25, 2003, at the Hilton Garden Inn, Canonsburg, PA; and on October 16, 2003, at the Radisson Hotel, Morgantown, WV.[3] Official transcripts of the meetings are available from the NIOSH Docket Office at the address provided above. Most comments were generally supportive of the need to update the quality assurance and control provisions of Part 84.

NIOSH will convene public meetings to provide to stakeholders an opportunity to comment orally on this rulemaking during the comment period. The meetings will be in the vicinities of Washington DC and Los Angeles, CA and are announced in a separate notice in this issue of the **Federal Register**.

III. Summary of Proposed Rule

This proposed rule would establish new quality assurance and control requirements for manufacturers of respirators approved by NIOSH, or NIOSH and MSHA, under 42 CFR Part 84—Approval of Respiratory Protective Devices. The current provisions of Subpart E would be replaced almost entirely. In addition, some related provisions of several other subparts of Part 84 would be revised, added, or removed. The following is a section-by-section summary which describes and explains the provisions of the rule. The public is invited to provide comment on any aspect of the proposed rule. The complete regulatory text for this proposed rule is provided in the last section of this notice.

Subpart A

Definitions (Section 84.2)

This section provides definitions for Part 84. It would be amended to add definitions of terms included in the proposed revision of Subpart E, to revise definitions related to Subpart E, and to make other clarifications. Definitions requiring explanation are identified in the following discussion.

Under paragraph (a), the definition of ''applicant'' is revised to clarify that the applicant remains an applicant, for the purposes of the regulation, after receiving a product approval from NIOSH. This is necessary because Subpart E uses the term applicant with respect to quality assurance provisions that apply to the applicant during the manufacture of the approved product and subsequently.

Paragraph (d) defines an ''Authorized NIOSH Representative'' to clarify that NIOSH contractors and their employees may serve as authorized representatives, as well as NIOSH employees. This is germane to the planned use of contractor employees by NIOSH in audits of manufacturing facilities.

Paragraph (w) defines ''manufacturing facility'' to clarify that the buildings of any supplier whose quality system is a component of the applicant's quality system will be potentially subject to NIOSH facility audits under Subpart E. This is important for NIOSH efforts to oversee quality assurance for the increasing number of respirator manufacturers that are not vertically integrated manufacturing enterprises. While NIOSH does not have legal authority to mandate access and cooperation to conduct such facility audits, NIOSH respirator approvals are contingent on voluntary acceptance of such audits and necessary cooperation with the audits by all facilities involved in the respirator manufacturing process. If a supplier to an applicant whose quality system is integral to that of the applicant were to refuse to allow such an audit or refuse to cooperate sufficiently to permit the completion of such an audit, then NIOSH would either deny the associated application for approval or, if the respirator were already approved, NIOSH would revoke the approval.

Subpart B—Application for Approval

Application Procedures (Section 84.10).

This section specifies procedures for applicants seeking the approval of a respirator under Part 84. It would be amended for administrative reasons, clarifications, and in support of the quality assurance requirements of Subpart E.

Paragraph (b) would be added to notify potential applicants that complete application procedures are available on the NIOSH Web page as indicated.

Paragraph (c) would be added to notify applicants who are holders of prior approvals that non-compliance with the quality assurance requirements of Subpart E would result in the suspension of processing of any new applications the applicant might have submitted. This is expected to provide incentive for the applicant to maintain adequate quality assurance and to remediate quality assurance problems identified by NIOSH in a timely fashion. Moreover, NIOSH believes it is sensible and efficient use of federal technical and administrative resources to require an applicant to remedy existing quality assurance problems prior to considering the approval of additions to the applicant's respirator product line which would extend the quality assurance responsibilities of the applicant.

Paragraph (d) clarifies that NIOSH may use contractors as well as its own employees in its certification and auditing activities under Part 84.

Paragraph (e) is not substantively changed. It would be revised to replace the specification of the ''Certification and Quality Assurance Branch'' with ''NIOSH''.

Contents of Application (Section 84.11)

This section specifies key elements of the Standard Application Package for applicants seeking approval under Part 84. It would be amended to be consistent with new quality assurance provisions under Subpart E, to revise or remove provisions that are outdated, and to reflect current practice.

Paragraphs (a) and (b) are current provisions of Part 84 that have been simplified since NIOSH now provides detailed instructions concerning application elements in the Standard Application Procedure available to applicants from the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html*.

Paragraph (c) would require applicants to include a user instruction manual. Applicants currently include these, which contain information essential to NIOSH for testing to determine that a respirator will perform as certified and that users will have adequate relevant information, such as length of the service life of the respirator.

Paragraphs (d) through (f) would provide for application contents that are consistent with the new quality assurance provisions of Subpart E. See the summary of Subpart E provisions for discussion of these contents.

Paragraph (g) would require the applicant to provide a table that cross-references the certification requirements under this Part applicable to the respirator with the stage or stages in the manufacturing process in which the

[3] Notice of these meetings were published in the **Federal Register** (FR65:129:41472) (FR68:107:33494–33495) (FR 65:180:54458–54459). NIOSH also sent a letter announcing the meetings to known stakeholders and posted it on the NIOSH Web page *http://www.cdc.gov/niosh/npptl*.

particular requirement is addressed by quality assurance and control procedures. This table would serve as a roadmap allowing NIOSH to efficiently evaluate the adequacy of the quality assurance program and would also reduce the time required of the applicant to guide NIOSH through quality assurance reviews during the application review and audits. NIOSH will include an example of such a cross-referencing table in the Standard Application Procedure to illustrate the degree of specificity sought.

Paragraph (h) and (i) are revised but not substantially changed.

Paragraph (j) would direct manufacturers to the information specified in the Standard Application Procedure, which provides instructions at a more detailed level than is appropriate for regulation and provides administrative information subject to periodic clarification and updating. As discussed above, the Standard Application Procedure is available on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html*.

Delivery of Respirators and Components by Applicant; Requirements (Section 84.12)

This section would be revised to direct applicants to the Standard Application Procedure for instructions on where to submit respirators and component parts for testing by NIOSH. The substantive requirements with respect to such submissions would remain without change.

Subpart D—Approval and Disapproval

Revocation of Certificates of Approval (Section 84.34)

This section, which provides NIOSH with authority to revoke certificates of approval for cause, would be revised to be consistent with the new quality assurance provisions of Subpart E by specifying that failure to maintain or cause to be maintained the quality assurance or quality control requirements of the certificate of approval would constitute a valid cause for a revocation. The existing provision is identical except that it specifies solely quality control requirements. The existing provisions of Subpart E are limited to activities termed as quality control activities, whereas the broader nomenclature of ''quality assurance'' would also be applied to the proposed new provisions of Subpart E.

Changes or Modifications of Approved Respirators; Issuance of Modification of Certificate of Approval (Section 84.35)

This section provides a procedure for applicants who seek approval from NIOSH for modifying features of an approved respirator. Paragraph (c) of the current provisions includes requirements for quality control information germane to the modifications. These provisions would be revised to also comprise the new quality assurance requirements proposed for Subpart E.

Changes in Device or Applicant Ownership (Section 84.36)

This section would specify requirements for an applicant acquiring the manufacturing rights to one or more devices (either respirators or specific respirator configurations) that has received NIOSH approval under this Part. Ownership change of NIOSH-approved devices might occur through the sale of a product line from one manufacturer to another or through a merger, buy-out, or other means of corporate acquisition or divestiture. The representative of the new owner must submit an Application for Modification of Certificate of Approval for such devices, pursuant to § 84.36, detailing the change in ownership and the impact on the approved manufacturing and quality processes documented in the respirator certification files at NIOSH. Documentation of the change in ownership status from the original applicant to whom the NIOSH certificates of approval were issued to the new owner must be included by the new owner in the application. The new owner would be required to complete such application submissions and receive a modified certificate of approval from NIOSH for each approved device prior to placing a NIOSH approval label or otherwise representing any respirators produced by the new owner as having been approved by NIOSH. Sales of an approved device that was manufactured by the original applicant prior to the change in ownership can continue after ownership of the device or the applicant has changed.

Ownership turnover in the respirator industry has increased in recent years. This has elevated the importance of ensuring that acquiring applicants provide timely notification to NIOSH of such changes, such that NIOSH can provide timely reviews to verify that required quality assurance activities and resources are maintained under the new ownership. It is in the interest of all parties, including the original applicant and the prospective new owner, to seek approvals from NIOSH as soon as possible once a change of ownership is decided, to avoid any interruption in the manufacture or sales of an approved product pending such approvals.

Changes in Manufacturing Facility or Quality System (Section 84.37)

This section would ensure that applicants obtain approval from NIOSH when they update their quality system, including updates made necessary by the addition of a new manufacturing facility. Approval by NIOSH is necessary to ensure that the quality system remains in compliance with the quality assurance provisions of Subpart E and to ensure that NIOSH has correct information for audits that it conducts pursuant to Subpart E.

Delivery of Changed or Modified Approved Respirator (Section 84.38)

This section authorizes NIOSH to obtain from the applicant, for inspection and retention, a unit of a respirator whose modification had been approved by NIOSH and is being commercially produced. The proposed revision is non-substantive, redesignating the section and replacing the specification of the ''Certification and Quality Assurance Branch'' with ''NIOSH''.

Subpart E—Quality System

Quality System, General Requirements (Section 84.40)

Paragraph (a) of this section would require that each applicant be compliant with the ISO standard for Quality Management Systems [4], which is an international consensus standard widely adopted by leading manufacturers in many industries. All respirator manufacturers holding or seeking a NIOSH approval would have to be compliant with this standard. The standard includes requirements for the following elements of a quality management system:

a. *Quality Policy and Management Responsibility* (management's stated commitment to the development and implementation of the quality management system and its continual improvement and related responsibilities, authorities, and communications)

b. *Organization* (clear assignment of a structure by which management of quality is overseen and implemented)

[4] ISO Q9001:2000 is the International Standard: *Quality management systems—Requirements*, 3rd edition, approved on December 15, 2000, and available from the International Organization for Standardization (ISO) and the American National Standards Institute (ANSI).

c. *Quality Program Documents* (a system governing the creation, control, and maintenance of documents related to quality management)

d. *Resource Management* (a framework for ensuring that physical and human resources required to implement the management of quality are identified and provided)

e. *Customer-related Processes* (procedures to identify and address customer requirements and ensure customer satisfaction)

f. *Design Assurance* (a framework for ensuring that design work involves appropriate planning, controls, inputs, outputs, review processes, and validation of results)

g. *Purchases and Subcontracts* (requirements for ensuring that purchased products conform to specified requirements)

h. *Production and Servicing* (requirements for the control and validation of these processes and for related policies)

i. *Control of Monitoring and Measuring* (requirements and processes for monitoring to assure product conformity with quality specifications, including internal and external audits)

j. *Control of Nonconforming Products* (procedures for the identification and processing of nonconforming products)

k. *Corrective Actions and Improvement* (procedures for identifying, evaluating, and implementing corrective actions to ensure product conformity with requirements and for continually improving the quality management system)

Incorporation of the ISO standard would elaborate the related existing Part 84 quality control requirements substantially. These existing requirements are general, except for the requirements governing the use of product inspection sampling plans.

As discussed under section II–C of this preamble, requiring ISO compliance by all respirator manufacturers would foster better quality management overall without substantial involvement of NIOSH and would promote a higher and more consistent level of quality in this critical safety product market. As manufacturers increasingly become ISO registered, this will also improve the efficiency and coverage of NIOSH manufacturing facility audits. To the extent that ISO registrars are effective in addressing generic quality management issues, NIOSH auditors will be able to focus their efforts on the most technical factors in quality management for assuring the supply of high quality respirators, especially the design and implementation of effective product inspection sampling plans. This increased technical focus would allow NIOSH, over time, to extend the scope of the audit program to achieve more timely audits of manufacturing facilities and coverage of more products.

Subsection (b) of this section would authorize NIOSH to conduct an audit of an applicant who is registered as compliant with the ISO standard or claims to be compliant, to assess or reassess the compliance of the applicant.

The purpose of the NIOSH audit would be to evaluate compliance with the ISO standard as it applies to the requirements of this Part. Such audits would be conducted only when NIOSH has reason to seek assurance of the adequacy of the basis of an applicant's ISO registration or statement of compliance. Past evaluations by NIOSH of ISO-registered manufacturer's quality plans have indicated to NIOSH that some ISO audits have not provided an adequate basis for the resulting ISO registrations.

Subsection (c) of this section would require each applicant and approval holder to submit to NIOSH documentation of compliance with the ISO standard. The applicant can provide either a copy of registration under the ISO standard (or any update to the standard), if the applicant is registered as compliant, or a statement of compliance if the applicant has not undergone an audit for such compliance by an ISO registrar.

Quality Manual Requirements (Section 84.41)

This section would require applicants to submit to NIOSH a copy of their quality manual, which should meet the specifications of the ISO standard and should address all quality assurance elements specified in the Standard Application Procedure. The applicant would submit a copy of the manual with each initial application for approval of a product and upon substantial revisions of the manual or, at minimum, once every four years, and upon a request by NIOSH.

The quality manual is a critical source of information by which NIOSH evaluates the adequacy of the applicant's quality management system. It documents the structure, resources, and policies of the quality management system.

Quality Control Plan Content (Section 84.42)

The current § 84.41 of Part 84 specifies elements that must be established in the applicant's quality control plan, which documents all manufacture, assembly, inspection, testing, and servicing processes applicable to the respirator submitted to NIOSH for approval. The section would be redesignated § 84.42 and revised to eliminate redundancy with information covered in the quality manual (e.g., information on organizational structure), to clarify and generalize the required elements, and to distinguish clearly between those elements that must be submitted to NIOSH and those that must be made available upon request to NIOSH. NIOSH has retained the framework used to classify nonconformances (termed ''defects'' under the current provisions of this section) according to their potential effect with respect to the safety of the user and the usability and performance of the respirator. Most important to this revision, NIOSH would replace the current product inspection sampling requirements of the quality control plan with quality assessment requirements appropriate to the variety of present day quality management approaches and appropriate to a consumer-oriented statistical weighting of ''producer and consumer risks,'' as explained further below.

The proposed quality assessment requirements reflect the range of possible quality management approaches, from the use of more intensive inspection regimens, appropriate when processes are not highly controlled or the degree of control is unknown (paragraph (a)(5)(i) of this section), to the use of statistical process control for highly controlled production processes (paragraph (a)(5)(iii) of this section). The flexibility in sampling plans proposed would progressively reward manufacturers who can achieve high levels of quality management performance by allowing increasing economy in their product quality inspection time and effort.

The three sampling plans specified in this section are statistically equivalent and are moderately more stringent than the current requirements of this section. The sampling requirements under the current § 84.41 were designed to limit producer risk, which is the statistical ''risk'' or probability that the manufacturer would erroneously reject a conforming product as nonconforming. The proposed new sampling requirements would shift the emphasis to limiting consumer risk, the latter being the statistical probability that the manufacturer would fail to reject a nonconforming product. This shift in emphasis results in a greater likelihood that non-conforming products will be identified and rejected by the manufacturer. A more technical analysis

of the proposed sampling plans, their statistical equivalence, and a comparison with the sampling plans covered by the existing requirements of § 84.41, is available from the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html.*

Paragraph (a)(5)(iv) would allow applicants to devise, with NIOSH approval, alternative sampling plans that are statistically equivalent to those specified in this section. Under paragraph (a)(6), applicants would also be allowed to continue to use the inspection plan under which their respirator was approved by NIOSH prior to the effective date of the final rule, with the exception that a more stringent performance requirement would be applied to ''Major A'' nonconformances. NIOSH has proposed a three-year grandfather period for this provision, after which all quality assurance plans would have to comply with the proposed new requirements. Finally, paragraph (a)(7) would continue to allow applicants to use other sampling plans they might devise, with NIOSH approval, for destructive inspection or test sampling.

Proposed Quality Control Plans; Approval by NIOSH (Section 84.43)

This section, currently designated as § 84.42 in Part 84, authorizes NIOSH to review, require modifications, and approve the applicant's quality control plans; requires the applicant to comply with the plans; and makes such compliance a condition of approval. This section further authorizes NIOSH to revoke approvals of the applicant as a consequence of noncompliance. Paragraph (c) would be revised to clarify the possible response by NIOSH to a case of noncompliance and paragraph (d) would be added to provide a procedure for applicants to revise and obtain NIOSH approval of revised quality control plans as necessary.

Respiratory Device Complaints (Section 84.44)

This section would elaborate the requirements of the ISO standard for Quality Management Systems to govern the applicants' management of complaints they receive concerning their NIOSH-approved respirators. Paragraphs (a)(3)(A) and (B) would impose on applicants special requirements for timeliness of response and for the timely reporting of complaints of a particularly serious nature that potentially involve health endangerment. The requirement for reporting of these cases would enable NIOSH to monitor and facilitate investigations of safety and health importance and to involve NIOSH and other federal resources in efforts to notify respirator users and take other actions necessary to remediate an identified hazardous condition involving a NIOSH-approved respirator.

Audit Programs (Section 84.45)

This section would replace and elaborate current provisions of § 84.43 under Part 84, which authorize NIOSH to inspect and evaluate the quality control program of an applicant and, if necessary, to revoke for cause an approval on the basis of such evaluation. Under these current provisions, NIOSH presently conducts audits of manufacturing facilities and of manufactured products, as discussed in section II.C. of this preamble. The proposed new subsection § 84.45(a) largely reflects the current practices of these NIOSH audit programs. The purpose of the audits is to provide assurance of the safety, performance, functionality, and reliability of approved respirators that have been produced.

Paragraph (a)(1)(i) would require the applicant to provide to the NIOSH representative conducting a facility audit, upon request, any documents or records germane to the auditing of facilities or products as provided for under this section.

Paragraph (a)(1)(ii) would limit the frequency of NIOSH facility audits, except for cause, to balance the need for such evaluation against the burden to applicants of hosting such audits and responding to the related informational requests.

Paragraph (a)(2)(i) would require an applicant to provide NIOSH-approved respirator or respirator component samples as necessary during the facility or product audit and would specify the timeliness with which such samples must be provided. Evaluation of these products is an essential, existing element of NIOSH audits. The paragraph would also allow for alternative schedules for the provision of such samples, as provided for by other sections of Part 84 that cover requirements for specific types of respirators.

The proposed new subsection § 84.45(b) would require applicants to conduct an annual quality control audit on each approved respirator or respirator family (set of respirators assembled using a subset of common components) for which the respirator or respirator family is not manufactured and sold as a complete device. Some applicants sell certain respirators unassembled and sell respirator components separately. The requirement that applicants annually audit such respirators or families of respirators is important to ensure that the components continue to assemble to produce an effective respirator as approved under NIOSH certification testing. Presently, such assembly and evaluation is required only once, at the time the applicant submits the respirator for approval by NIOSH. It is possible, however, that over time, changes in manufacturing materials and processes could affect the compatibility of components and the performance of the completely assembled respirator. NIOSH has observed such circumstances through NIOSH product audits. This required annual quality control audit would ensure that the quality assurance programs of applicants that produce such respirators periodically address this quality factor.

Quality System Records Retention (Section 84.46)

This section would complement the ISO standard for Quality Management Systems, which covers recordkeeping practices for records providing evidence of conformity to requirements and of the effective operation of the quality management system. The section would further specify that the applicant retain such quality management system records relevant to the manufacture of NIOSH-approved respirators for a period that is at least as long as the expected life of the respirator's major components and for a minimum of two years.

Some NIOSH evaluations of respirator problems have been stymied because of the lack of appropriate recordkeeping or accessibility. The proposed specifications for records retention will ensure that relevant records are available for NIOSH audits and for evaluation in case potential problems are identified through complaints to either the applicant or directly to NIOSH. Ensuring the availability of these records is essential for NIOSH to determine the cause and extent of a problem and will assist the applicant in rectifying problems identified.

IV. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the executive order. Under section 3(f), the order defines a

''significant regulatory action'' as an action that is likely to result in a rule (1) Having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this executive order.

This proposed rule is not being treated as a ''significant regulatory action'' within the meaning of the executive order. 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 sections 3(f)(2)–(4).

For the leading U.S. respirator manufacturers who obtain approvals from NIOSH, the most substantial elements of the proposed new requirements are already standard practice. Approximately three-quarters of these manufacturers are already registered as compliant with the ISO Q9001–2000 standard and virtually all of the manufacturers with NIOSH approvals appear to be complying already with the most essential requirements of the ISO standard, according to NIOSH quality assurance audits conducted in recent years. Substantial additional quality improvement costs are unlikely to be incurred by any NIOSH approval holders. NIOSH expects this rule will allow some respirator manufacturers to achieve quality control cost savings, as discussed below.

The new sampling plan performance requirements proposed in § 84.42(a)(5) will be the most important change for respirator manufacturers, particularly to those manufacturers with either the least or most stringent quality management systems. The proposal would require respirator manufacturers that have not developed stringent quality control of their production processes to either tighten the quality performance of their production processes or to increase their quality control inspection regimen. These changes would enable such manufacturers to provide greater assurance of the performance of their products by reducing the level of consumer risk currently allowed under existing quality control plan requirements of Subpart E, as explained under section III of this preamble. On the other hand, manufacturers who already operate stringent quality management systems would be able to reduce their inspection regimen substantially under the proposed new requirements, since the current regulations, which are more than three decades old, require all respirator manufacturers to continue a system of inspections appropriate to much lower levels of process control than is achieved by some manufacturers today. Hence, high-performing respirator manufacturers are likely to be conducting redundant product quality inspections, maintaining compliance with current regulatory requirements but achieving little benefit in terms of quality assurance.

NIOSH would welcome information from respirator manufacturers on costs and cost savings that might be associated with compliance with proposed new sampling plan requirements. NIOSH recognizes that manufacturers who are not already achieving compliance with the performance requirements associated with the proposed sampling plan options would have difficulty estimating costs and cost savings associated with implementing more stringent process controls. However, if such a manufacturer planned to simply increase its inspection regimen, which is an option under the proposed requirements, the manufacturer could estimate the costs of an increased rate of product inspections and perhaps also estimate the potential cost savings of avoided product recalls. On the other hand, manufacturers that are already achieving the proposed performance requirements might be able to provide insight into other potential effects of this rule, particularly if they have retained documentation of relevant quality improvement costs and the resulting quality performance improvements. Cost savings related to the latter that might be documented include reduced inspection costs resulting from well controlled production processes; reduced losses associated with nonconforming materials, components, and final assembled products; and reduced losses associated with product recalls. At minimum, for companies that have well controlled production processes, it should be relatively straightforward to estimate the cost savings associated with eliminating redundant inspections presently conducted to maintain compliance with the current, outdated sampling plan requirements.

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. The Department of Health and Human Services (''HHS'') certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

The majority of respirator manufacturers are small businesses as defined under the Small Business Act (Pub. L. 85–536) for this industry sector (NAICS 339112—Medical Instruments and Equipment Manufacturers), employing fewer than 500 employees. For these manufacturers, the proposed rule would establish new quality assurance requirements applicable to respirators approved by NIOSH for use in potentially hazardous work atmospheres of every type, including toxic gases; radiological, toxic, obstructive, and carcinogenic dusts; oxygen deficient atmospheres; and biological aerosols. Workers don these respirators for their protection in a wide variety of goods production industrial sectors, such as mining, manufacturing, construction, and agriculture. NIOSH-approved respirators are also worn by workers in service sectors, such as firefighters and other emergency responders in public safety, maintenance workers in public utilities, and nursing and medical staff exposed to pharmaceutical and biological aerosols in health care.

The new quality assurance requirements would replace requirements that are considerably less specific in part, and where specific, are out-of-date with typical quality control and assurance practices of today's respirator manufacturing industry. As discussed under section IV.A of this preamble, most of the respirator manufacturers that seek and maintain approvals from NIOSH are essentially in compliance already with most or all of the proposed new requirements. The requirements most likely to require changes in the quality assurance practices of some of these manufacturers are the new set of options for quality control sampling plans and their

associated performance requirements, which provide a higher level of consumer protection than those they replace, by reducing ''consumer risk,'' as discussed under section III of this preamble. As discussed under section IV.A, manufacturers who are not currently achieving a sufficient degree of process control for critical characteristics of the respirators they produce would have to either increase the intensity of the product inspections or improve their production process controls. On the other hand, manufacturers with high degrees of process control will not have to make any changes in quality control practices and furthermore will be able to eliminate redundant product inspections required under the current, out-of-date regulations.

NIOSH does not have access to information to estimate costs and cost savings associated with changes some manufacturers might make in response to the proposed sampling plan requirements. NIOSH is soliciting information from the manufacturers that might be useful in establishing such an estimate, but NIOSH expects that any companies that would be required to make changes would have difficulty estimating *ex ante* the potential economic impact of the changes.

There are substantial difficulties in making such estimates for a company that lacks well-controlled production processes: First, the causes of quality problems must be identified; and second, once such cause or causes are identified, there are likely to be multiple alternatives for solving the problems identified. On the other hand, such a company would be in a position to estimate some of the possible cost savings associated with quality improvements, such as (1) reduced inspection costs; (2) avoided losses associated with nonconforming materials, components, and final assembled products; and (3) reduced losses associated with product recalls. As discussed in section IV.A of this preamble, most respirator manufacturers who obtain approvals from NIOSH operate quality assurance systems in line with current quality management practices and are likely to have the records needed for an analysis of potential cost savings.

For the reasons provided, a regulatory flexibility analysis, as provided for under RFA, is not required.

C. What Are the Paperwork and Other Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under This Rule?

The Paperwork Reduction Act is applicable to the data collection aspects of this rule. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees unless the agency has submitted a Standard Form 83, Clearance Request, and Notice of Action, to the Director of OMB, and the Director has approved the proposed collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

NIOSH has obtained approval from OMB to collect the information that NIOSH would collect from respirator manufacturers under this rule under OMB Control No. 0920–109 (Respiratory Protective Devices), which covers all information collection under 42 CFR part 84. The information NIOSH would collect under this rule does not differ substantially from the information presently collected by NIOSH from respirator manufacturers who obtain NIOSH certification of their products.

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.

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 quality assurance requirements it would apply uniformly to all applications from manufacturers of respirators. 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.

List of Subjects in 42 CFR Part 84

Incorporation by reference, Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

Text of the Rule

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 [AMENDED]

1. The authority citation for Part 84 continues to read as follows:

Authority: 29 U.S.C. § 651 *et seq.*, and 657(g); 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

Subpart A—General Provisions

3. Amend § 84.2 by:

A. Revising paragraph (a),

B. Removing paragraph (e),

C. Redesignating paragraphs (d), (f) through (u), (v) through (w), (x) through (z), (aa) through (bb), and (cc) as paragraphs (e), (g) through (v), (x) through (y), (bb) through (dd), (hh) through (ii), and (kk),

D. Adding new paragraphs (d), (f), (w), (z), and (aa), and adding paragraphs (ee) through (gg) and (jj) to read as follows:

§ 84.2 Definitions.

As used in this part—

(a) *Applicant* means an individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator or who holds such an approval issued by NIOSH.

* * * * *

(d) *Authorized NIOSH Representative* means an employee of NIOSH, a NIOSH contractor, or an employee of a NIOSH contractor acting on behalf of NIOSH.

* * * * *

(f) *Certified Equipment List* means a list of approved respirators maintained and published by NIOSH.

* * * * *

(w) *Manufacturing facility* means the building(s) where a respirator is manufactured or assembled, including any building used to manufacture or assemble the respirator that is operated by any supplier whose quality system is a component of the applicant's quality system.

* * * * *

(z) *NIOSH* means the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

(aa) Nonconformance means a failure to meet a requirement of this Part or of an approval under this part.

* * * * *

(ee) *Quality Assurance* means the set of planned and systematic actions necessary to provide a high degree of confidence that a respirator will satisfy all design, quality, fitness-for-use, and performance requirements.

(ff) *Quality Control* means the operational activities, processes, and techniques used to provide a high degree of confidence that individual units of an approved respirator that are produced will meet all safety, performance, and regulatory requirements.

(gg) *Quality System* means the entire organizational structure, responsibilities, procedures, specifications, processes, and resources used or required for quality assurance and control.

* * * * *

(jj) *Standard Application Procedure* means the detailed instructions provided by NIOSH on its Web page (*http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html*) for applicants requesting an approval, or modification of approval, for a device under this part.

Subpart B—Application for Approval

4. Amend § 84.10 by:

A. Removing paragraph (b),

B. Redesignating paragraphs (c) through (e) as (d) through (f),

C. Adding new paragraphs (b) and (c), and

D. Revising paragraphs (d) and (e), to read as follows:

§ 84.10 Application procedures.

* * * * *

(b) Applications may be submitted to NIOSH following the instructions provided in the Standard Application Procedure on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html.*

(c) NIOSH reserves the right to suspend the processing of applications of any applicant who NIOSH has found to be noncompliant with any provisions of Subpart E. This suspension of processing shall remain in effect until such time as NIOSH finds that the applicant is complying with such provisions.

(d) Except as provided in § 84.64, the examination, inspection, and testing of all respirators and the auditing of manufacturer facilities shall be conducted by NIOSH or an authorized NIOSH representative.

(e) Applicants, manufacturers, or their representatives may visit or communicate with NIOSH to discuss the requirements for approval of any respirator or the proposed designs thereof. NIOSH shall not charge for such consultation nor issue any written report to applicants, manufacturers, or their representatives as a result of such consultation.

* * * * *

5. Revise § 84.11 to read as follows:

§ 84.11 Contents of application.

Each application shall include the following elements:

(a) A complete written description of the respirator for which approval is requested;

(b) Drawings or specifications that depict or describe the respirator assembly and all of it major components, including accessories;

(c) User instructions;

(d) Evidence of compliance with or current registration under ISO Q9001:2000 [5] for the quality system under which the respirator will be manufactured, as specified in Subpart E of this part.

(e) A copy of the current quality manual, as specified in Subpart E of this part.

(f) A quality control plan flowchart, as specified in Subpart E of this part.

(g) A table that lists each section and paragraph of this Part with which the respirator complies and that cross-references the stage or stages in the manufacturing process during which compliance with the listed section or paragraph is evaluated through quality assurance or control procedures.

(h) A statement that the respirator has been pre-tested by the applicant as specified in § 84.64 and documentation of the results of such tests;

(i) A statement that the respirator and component parts submitted for approval are not prototypes and were made using regular production tooling, with no operation included that will not be incorporated in regular production processing; and

(j) Applicants may obtain detailed guidance specified in the Standard Application Procedure on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html.* (The information collections contained in this section are approved under OMB control number 0920–0109.)

6. Amend § 84.12 by revising paragraph (b) to read as follows:

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

* * * * *

(b) The applicant shall deliver, at his own expense, the number of completely assembled respirators and component parts required for testing, to the location

[5] ISO Q9001:2000, the International Standard: *Quality management systems—Requirements,* 3rd edition. This standard is incorporated by reference under § 84.40(a) of this Part.

designated in the Standard Application Procedure on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html.*

* * * * *

Subpart D—Approval and Disapproval

8. Revise § 84.34 to read as follows:

§ 84.34 Revocation of certificates of approval.

NIOSH reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, or failure to maintain or cause to be maintained the quality assurance or quality control requirements of the certificate of approval.

9. Amend § 84.35 to revise paragraph (c) to read as follows:

§ 84.35 Changes or modifications of approved respirators; issuance of modification of certificate of approval.

* * * * *

(c) The application shall be accompanied by appropriate drawing(s) and by a proposed quality control plan and quality assurance provisions that meet the requirements of Subpart E of this part.

* * * * *

§ 84.36 [Redesignated as § 84.38]

10. Redesignate § 84.36 as § 84.38.

11. Add a new § 84.36 to read as follows:

§ 84.36 Changes in device or applicant ownership.

(a) When there is a change in either the ownership of the manufacturing rights to a device approved by NIOSH under this Part or the ownership of an applicant that holds a NIOSH approval for one or more devices under this Part, as might occur through the sale of a product line from one manufacturer to another or through a merger, buy-out, or other means of corporate acquisition or divestiture, the new owner acquiring the rights to the manufacture of the device or acquiring the applicant that holds the approval for the device shall submit an Application for Modification of Certificate of Approval for each approved device, pursuant to the requirements of § 84.35. The new owner making or having made such an acquisition shall complete the application submissions and must receive a modified certificate of approval from NIOSH for each device prior to any continued manufacture of the device after ownership of the device or applicant is changed.

(b) The new owner making or having made an acquisition as described under paragraph (a) of this section shall submit to NIOSH documentation of the resulting change in ownership with the Application for Modification of a Certificate of Approval.

(c) Units of an approved device manufactured by an applicant prior to a change in ownership, as described in paragraph (a) of this section, may continue to be sold as NIOSH-approved devices following the change in ownership.

(d) The failure by an owner that has made an acquisition, as described in paragraph (a) of this section, to obtain approval from NIOSH prior to the continued manufacture of a related NIOSH-approved device, may be deemed as sufficient cause for revocation of the relevant approval(s).

11. Add a new § 84.37 to read as follows:

§ 84.37 Changes in manufacturing facility or quality system.

(a) The applicant shall notify NIOSH in writing, within 20 work days, of a final decision to change the location of a manufacturing facility or of a final decision to make any substantive change in the quality system associated with one or more approved devices. Failure to notify NIOSH within this deadline may be deemed cause for revocation of the relevant approval(s).

(b) Prior to implementing a change specified under paragraph (a) of this section, the applicant shall submit to NIOSH for approval a revised quality manual, revised quality control plans, and revisions of any other materials and information previously submitted to NIOSH under Subpart E of this part that require revision to incorporate the reported change. Failure to obtain such approval from NIOSH prior to implementing the change or changes may be deemed cause for revocation of the relevant approval(s).

12. Revise newly designated § 84.38 to read as follows:

§ 84.38 Delivery of changed or modified approved respirator.

Upon request, the applicant shall deliver to NIOSH, as soon as it is commercially produced, one unit of an approved respirator for which NIOSH has issued a formal certificate of modification. The unit must include all required markings and be provided in its customary commercial container.

13. Revise Subpart E to read as follows:

Sec.

Subpart E—Quality System

Subpart E—Quality System

§ 84.40 Quality system, general requirements.

The applicant shall be responsible for the establishment, execution, and maintenance of a quality system that ensures that devices produced under the applicant's certificate of approval meet the specifications to which they are certified under this Part and are reliable, safe, effective, and otherwise fit for their intended uses.

(a) To request and to maintain an approval under this Part, the applicant shall establish and maintain a quality system that is compliant with the International Organization for Standardization (ISO) Q9001:2000 standard: *Quality management systems—Requirements,* 3rd edition, approved on December 15, 2000. ISO Q9001:2000 is incorporated by reference into this section and has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* A copy is also available for inspection at NIOSH, National Personal Protection Technology Laboratory, Bruceton Research Center, 626 Cochrans Mill Road, Pittsburgh, PA 15236. To arrange for an inspection at NIOSH, call 412–386–6593. Copies of the standard are also available for purchase from the American National Standards Institute, 25 West 43rd St., New York, NY 10036; Web page: *http://www.ansi.org;* phone 212–642–4900.

(b) If deemed necessary by NIOSH, NIOSH shall evaluate the compliance of the applicant with the ISO Q9001:2000 standard on the basis of an audit conducted by NIOSH.

(c) The applicant shall submit to NIOSH either of the following, as appropriate, to document compliance with the ISO Q9001:2000 standard:

(1) For applicants who are registered by a qualified registrar under the ISO 9001:2000 standard or any update to this ISO standard, a copy of the most recent registration; or

(2) For all other applicants, a statement self-attesting to being in compliance with the ISO 9001:2000 standard.

§ 84.41 Quality manual requirements.

(a) The applicant shall submit a copy of the current quality manual to NIOSH together with the initial application for respirator certification under § 84.11 of this part.

(b) The applicant shall also submit to NIOSH a current copy of the quality manual:

(1) Whenever it is substantially revised or, at a minimum, once every four (4) years; and

(2) Upon the request of NIOSH.

§ 84.42 Quality control plan content.

(a) The applicant shall develop a quality control plan that documents all manufacturing, assembly, inspection, testing, and servicing processes applicable to the respiratory device for which certification is sought and maintained. The quality control plan shall contain the following elements:

(1) Quality control plan flowchart. The flowchart must depict all processes used in the production of the approved device, including processes comprising manufacturing, assembly, inspection, testing, and servicing of the device and its components. All inspection and testing activities conducted throughout the entire production process must be included. The quality control plan flowchart must be submitted with each application for approval of a device submitted under § 84.11 of this Part.

(2) Design, Production, and/or Engineering Drawings and Specifications. Drawings and specifications must be accurate and sufficiently detailed to fulfill their use in procurement, manufacturing, assembly, inspection, and testing activities. Upon request by NIOSH, the applicant shall provide copies of these drawings or specifications to NIOSH or an authorized NIOSH representative for inspection and review.

(3) Assembly, Inspection, and Testing Procedures. The applicant shall design, document, and validate procedures for all assembly, inspection, and testing activities, whether procured or performed by the applicant, to ensure that sufficient process description is available to successfully perform all necessary production activities. Acceptance and rejection workmanship criteria must be incorporated into relevant procedures to assure that the approved device meets all design, performance, and regulatory requirements. Upon request by NIOSH, the applicant shall provide copies of these procedures to NIOSH or an authorized NIOSH representative.

(4) Critical to Quality Characteristics (CTQC).

(i) The applicant shall generate, maintain, and update as necessary, CTQC documents for each stage in the production process for an approved respiratory device. A CTQC document shall list all Critical, Major A, Major B, and Minor characteristics for which inspection or testing shall be performed. Upon request by NIOSH, the applicant shall provide copies of CTQC documents to NIOSH or an authorized NIOSH representative.

(ii) The applicant shall incorporate the criteria listed in a CTQC document into inspection procedures established pursuant to paragraph (a)(3) of this section at the appropriate stages of assembly. The appropriate stage of assembly for a criterion is a stage at which the criterion can be fully evaluated by the assembler without the evaluation being obstructed or otherwise limited as a result of the addition to the assembly of other hardware, components, or performance elements.

(iii) The applicant shall classify each of the CTQC of the device according to the importance of the potential effect of a nonconformance, into the following classes:

(A) Critical. A nonconformance that judgment and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator;

(B) Major A. A nonconformance, other than critical, that is likely to result in failure to the degree that the respirator does not provide any respiratory protection, or a nonconformance that reduces protection and is not detectable by the user;

(C) Major B. A nonconformance, other than Major A or critical, that is likely to result in reduced respiratory protection and is detectable by the user; and

(D) Minor. A nonconformance that is not likely to materially reduce the usability of the respirator for its intended purpose, or a nonconformance that is a departure from established standards and has little bearing on the effective use or operation of the respirator.

(5) Incoming, In-process, and Final Inspection Sampling Plan Requirements. Incoming, in-process, and final inspection sampling shall conform to one or more of the following quality assessment sampling plans:

(i) The use of zero defect sampling plans where inspection is used. The sampling plans in Military Standard MIL–STD–1916 provide levels for verifying component acceptability for each of the CTQC:

(A) Critical characteristics shall use verification level VII;

(B) Major A characteristics shall use verification level VI;

(C) Major B characteristics shall use verification level III;

(D) Minor characteristics shall use verification level II.[6]

(ii) The use of sampling plans based on consumer risk. The sampling plans in ANSI/American Society for Quality Control[7] Standard Q3–1988 provide levels of component acceptability for each product characteristic:

(A) Critical characteristics shall use a Limiting Quality (LQ) of 0.50;

(B) Major A characteristics shall use a Limiting Quality (LQ) of 0.80;

(C) Major B characteristics shall use a Limiting Quality (LQ) of 2.00;

(D) Minor characteristics shall use a Limiting Quality (LQ) of 3.15.

(iii) The use of statistical process control to determine product quality. Process capability indices (Cpk) and statistical control processes must meet or exceed the following process characteristics:

(A) Critical characteristics shall have a Cpk > 2.00;

(B) Major A characteristics shall have a Cpk > 1.33;

(C) Major B characteristics shall have a Cpk > 1.33;

(D) Minor characteristics shall have a Cpk > 1.00.

Under this paragraph, upon approval of the quality assessment plan by NIOSH, the applicant may reduce or eliminate inspection sampling when the plan criteria are met or exceeded.[8]

(iv) The applicant also may use a sampling plan not specified under this section if NIOSH finds the proposed plan to be statistically equivalent to the plans described in paragraphs (a)(5)(i) through (iii) of this section.

(6) Sampling plan grandfather period. The following provisions apply to any sampling plan in effect at the time this rule becomes effective:

(i) Applicants may continue to use the Acceptable Quality Level (AQL) inspection plan under which a device was approved by NIOSH prior to the

[6] Refer to Department of Defense Handbook MIL–HDBK–1916, *Companion Document to Mil-Std-1916*, Notice 1, 20 April 2004, Section 8, pp. 37–42 for relevant guidance and details on the sampling plans.

[7] Renamed American Society for Quality.

[8] Refer to Department of Defense Handbook MIL–HDBK–1916, *Companion Document to Mil-Std-1916*, Notice 1, 20 April 2004, Section 5, pp. 11–30, for definitions of Cpk and for guidance on statistical process control.

effective date of this provision for up to three years from the effective date of this revision. After such time, applicants shall employ only the quality assessment sampling plans approved under paragraphs (a)(5)(i) through (iv) of this section in the manufacture of devices approved under this Part.

(ii) For any AQL inspection plan in use, the levels of component acceptability are as follows:

(A) Critical characteristics shall be inspected 100 percent;

(B) Major A characteristics shall have an acceptable quality level of 0.65 percent;

(C) Major B characteristics shall have an acceptable quality level of 2.50 percent;

(D) Minor characteristics shall have an acceptable quality level of 4.00 percent.

(7) Destructive inspection or test sampling. The applicant may also use a sampling plan not specified under paragraphs (a)(5)(i) through (iv) of this section for destructive inspection or test sampling. Such sampling plans must be approved by NIOSH.

(8) If attribute sampling plans are used and characteristics are recorded as pass/fail, when failures occur, the applicant shall record the failed characteristic's actual value.

(9) All necessary sampling plan documents shall be available for use at the location of the assembly, inspection, or testing activities.

(b) NIOSH reserves the right to request additional documentation as necessary.

(c) The applicant's document control system required by section 4.2.3 of the ISO Q9001:2000 standard shall include the control of all drawings, plans, and other documents required in this section.

§ 84.43 Proposed quality control plans; approval by NIOSH.

(a) Each proposed quality control plan submitted in accordance with this subpart shall be reviewed by NIOSH to determine its adequacy for ensuring the quality of respiratory protection provided by the respirator for which an approval is sought.

(b) If NIOSH determines that the proposed quality control plan submitted by the applicant will not ensure adequate quality control, NIOSH shall require the applicant to modify the procedures and/or testing requirements of the plan prior to acceptance of the plan and issuance of any certificate of approval.

(c) NIOSH shall incorporate approved quality control plans of the applicant into each certificate of approval issued to the applicant. The applicant shall comply with such plans. NIOSH may deem noncompliance with such plans as cause to revoke any and all relevant certificates of approval of the applicant, as provided under § 84.34 of this part.

(d) Applicants may submit to NIOSH revisions to approved quality control plans as necessary. NIOSH shall review, consider the approval, and incorporate such plans into an applicant's relevant certificates of approval as provided under paragraphs (a) through (c) of this section.

§ 84.44 Respiratory device complaints.

(a) Each applicant shall establish and maintain procedures for receiving, reviewing, evaluating, and resolving complaints related to the safety, quality, or performance of an approved device. Such procedures shall require that:

(1) Complaints, whether written or oral, are documented, reviewed, evaluated, investigated as necessary, and resolved.

(2) When a complaint is not investigated, the applicant shall maintain a record that specifies the reason that the complaint was not investigated and the name of the individual or individuals responsible for the decision.

(3)(A) The applicant shall immediately evaluate and investigate any complaint that:

(i) Arises from an incident involving a death, injury, near-miss, or other hazardous circumstance involving the health or safety of the user; or

(ii) Indicates a Critical, Major A, or Major B nonconformance, as classified by the applicant under § 84.42(a)(4)(iii) of this subpart.

(B) The applicant shall notify NIOSH in writing within three work days of any such complaint. The notification shall include a summary of the complaint, the current results of the investigation, and the current plans for any additional investigation and/or remedial activities. Notification shall be submitted to NIOSH by e-mail, facsimile, or in hardcopy by overnight delivery, to the addresses provided on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/resources/certpgmspt/default.html.*

§ 84.45 Audit programs.

(a) NIOSH audits.

(1) Authorized NIOSH representatives shall conduct onsite compliance audits at manufacturing facilities involved in the production of respiratory devices approved or submitted for approval under this part.

(i) During onsite compliance audits, the applicant shall make available to the NIOSH representative(s) upon request any documents or records germane to the provisions of this section (§ 84.45).

(ii) The frequency and extent of onsite compliance audits shall be determined by NIOSH. NIOSH shall not conduct such audits of a particular manufacturing facility more than once per calendar year per approved device or more than once within a six-month period, except for cause.

(2) NIOSH shall conduct product audits of the safety, quality, and performance of approved respiratory devices that have been produced.

(i) Applicants shall provide, upon request, sufficient samples of approved devices, or components thereof, as NIOSH determines necessary to conduct the audit. For onsite compliance audits, applicants shall provide such samples within 30 days of the request by NIOSH. For product audits, applicants shall provide such samples within 90 days of the request by NIOSH, or as otherwise provided under this part.

(ii) The applicant must choose audit samples randomly from the manufacturing process or the inventory of completed devices.

(iii) The applicant must provide documentation describing the procedure by which the audit samples were selected.

(3) NIOSH shall provide a final report of the audit process and results to the management representative of the applicant.

(4) NIOSH audit results that demonstrate a failure to comply with requirements of this Part may be deemed cause for revocation of a certificate of approval as provided under § 84.34 of this part.

(5) Failure to supply audit samples shall be deemed cause for revocation of a certificate of approval under § 84.34 of this part.

(b) Applicant audit program.

(1) Applicants shall conduct an annual audit on each respirator or respirator family for which the respirator or respirator family is not tested as a complete device during the manufacturing process. During such audit, the applicant shall notify NIOSH within three work days of finding any nonconformance of a critical or major characteristic, as classified by the applicant under § 84.42(a)(4)(iii) of this subpart. Reports of these audits shall be made available upon request to NIOSH and retained by the applicant for a period of three (3) years.

(The information collections contained in this section are approved under OMB control number 0920–0109)

§ 84.46 Quality system records retention.

The applicant shall establish a retention period for the records required by section 4.2.4 of the ISO Q9001:2000 standard that is at least as long as the expected service life of the respirator's major components; in no case shall the retention period be less than 24 months.

Dated: July 23, 2008.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

[FR Doc. E8–29236 Filed 12–9–08; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 0811281532–81534–01]

RIN 0648–XL64

Fisheries in the Western Pacific; Bottomfish and Seamount Groundfish Fisheries; 2008–09 Main Hawaiian Islands Bottomfish Total Allowable Catch

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed specifications; request for comments.

SUMMARY: NMFS proposes to establish a total allowable catch (TAC) for the 2008–09 fishing year of 241,000 lb (109,316 kg) of Deep 7 bottomfish in the main Hawaiian Islands (MHI). The TAC would be set in accordance with regulations established to support long-term sustainability of bottomfish in the Hawaiian Archipelago.

DATES: Comments must be received by December 26, 2008.

ADDRESSES: Comments on this proposed specification, identified by 0648–XL64, may be sent to either of the following addresses:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov;* or
- Mail: William L. Robinson, Regional Administrator, NMFS, Pacific Islands Region (PIR), 1601 Kapiolani Blvd, Suite 1110, Honolulu, HI 96814–4700.

Instructions: All comments received are a part of the public record and will generally be posted to *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the commenter may be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (if you wish to remain anonymous, enter ''NA'' in the required name and organization fields). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the Fishery Management Plan for Bottomfish and Seamount Groundfish Fisheries of the Western Pacific Region (Bottomfish FMP) and related Environmental Impact Statement are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or www.wpcouncil.org.

An environmental assessment (EA), including a Regulatory Impact Review (RIR), was prepared that describes the impact on the human environment that would result from this proposed action. Copies of the EA are available from *www.regulations.gov*, or William L. Robinson (see **ADDRESSES**).

FOR FURTHER INFORMATION CONTACT: Toby Wood, NMFS PIR Sustainable Fisheries, 808–944–2234.

SUPPLEMENTARY INFORMATION: This **Federal Register** document is also accessible at the Office of the Federal Register Web site *www.gpoaccess.gov/fr*.

The bottomfish fishery in Federal waters around Hawaii is managed under the Bottomfish FMP, developed by the Council and implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing bottomfish fishing by U.S. vessels in accordance with the Bottomfish FMP appear at 50 CFR part 665 and subpart H of 50 CFR part 600. Currently, bottomfish stocks in the Hawaiian Archipelago are not experiencing overfishing, and efforts to minimize local stock depletion in the MHI Management Subarea are precautionary. The MHI Management Subarea refers to the portion of U.S. EEZ around the Hawaiian Archipelago lying to the east of 161 20' west longitude. For all the bottomfish TACs considered in this specification, the estimated risk of overfishing in the Hawaiian Archipelago is zero.

On April 4, 2008, NMFS published a final rule (73 FR 18457) that implemented Bottomfish FMP Amendment 14. The provisions established under Amendment 14 include a non-commercial bag limit of five Deep 7 bottomfish (all species combined) per fisherman per trip. Amendment 14 also established a requirement for NMFS to set an annual TAC limit for Deep 7 bottomfish in the MHI, based on a recommendation from the Council, considering the best available scientific, commercial, and other information, and taking into account the associated risk of overfishing. The Deep 7 bottomfish are onaga (*Etelis coruscans*), ehu (*E. carbunculus*), gindai (*Pristipomoides zonatus*), kalekale (*P. sieboldii*), opakapaka (*P. filamentosus*), lehi (*Aphareus rutilans*), and hapu'upu'u (*Epinephelus quernus*).

When the TAC for the year is projected to be reached, NMFS will close the non-commercial and commercial fisheries until the end of the fishing year (August 31). During a fishery closure for Deep 7 bottomfish, no person may fish for, possess, or sell any of these fish in the MHI, except as otherwise authorized by law. Specifically, fishing for, and the resultant possession or sale of, Deep 7 bottomfish by vessels legally registered to Mau Zone, Ho omalu Zone, or Pacific Remote Island Areas bottomfish fishing permits, and conducted in compliance with all other laws and regulations, are not affected by the closure. There is no prohibition on fishing for or selling other non-Deep 7 bottomfish species throughout the year.

Last year (2007–08 fishing year), the Council recommended and NMFS implemented a Deep 7 bottomfish TAC of 178,000 lb (80,739 kg) (73 FR 18718; April 7, 2008). Monitoring of the commercial fishery indicated that the MHI bottomfish fishery harvested the TAC in April 2008. In accordance with the regulations at § 665.72, and as a result of reaching the TAC, NMFS published a temporary rule closing the non-commercial and commercial bottomfish fisheries on April 16, 2008 (73 FR 18717; April 7, 2008), and a related correction notice (73 FR 20001; April 14, 2008).

At its 142nd meeting in Honolulu in June 2008, the Council learned that new data were available for the bottomfish fishery that would be integral to the analysis performed by NMFS to update the bottomfish stock assessment. An updated stock assessment provides the best scientific basis upon which the Council can make its recommendation on a TAC, as required by regulation § 665.72(a) and Magnuson-Stevens Act National Standard 2. Because the updated bottomfish stock assessment was not available at the June 2008 meeting, the Council did not recommend a 2008–09 TAC. Instead,