minimal objective medical information. We are calling this method ''Compassionate Allowances.'' In December 2007, April 2008, November 2008, and July 2009, we held Compassionate Allowance public hearings. These hearings concerned rare diseases, cancers, traumatic brain injury and stroke, early-onset alzheimer's and related dementias, respectively. This hearing is the fifth in the series. The purpose of this hearing is to obtain your views about the advisability and possible methods of identifying and implementing compassionate allowances for young adults with Schizophrenia. We plan to address other medical conditions at subsequent hearings.

DATES: This hearing will be held on November 18, 2009, between 8:30 a.m. and 5 p.m., Pacific Standard Time (PST), in San Francisco, CA. The hearing will be held at the Parc 55 Hotel in the Cyril Magnin Room. The hotel's address is 55 Cyril Magnin Street, San Francisco, CA 94102. While the public is welcome to attend the hearing, only invited witnesses will present testimony. You may also watch the proceedings live via Webcast beginning at 9 a.m., Pacific Standard Time (PST). You may access the Webcast line for the hearing on the Social Security Administration Web site at *http://www.socialsecurity.gov/compassionateallowances/hearings.htm.*

ADDRESSES: You may submit written comments about the compassionate allowances initiative with respect to young adults with Schizophrenia, as well as topics covered at the hearing by (1) e-mail addressed to *Compassionate.Allowances@ssa.gov*; *or* (2) mail to Nancy Schoenberg, Acting Director, Office of Compassionate Allowances and Disability Outreach, ODP, ORDP, Social Security Administration, 4671 Annex Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. We welcome your comments, but we may not respond directly to comments sent in response to this notice of the hearing.

FOR FURTHER INFORMATION CONTACT: *Compassionate.Allowances@ssa.gov*. You may also mail inquiries about this meeting to Nancy Schoenberg, Acting Director, Office of Compassionate Allowances and Disability Outreach, ODP, ORDP, Social Security Administration, 4671 Annex, 6401 Security Boulevard, Baltimore, MD 21235–6401. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778, or visit Social Security online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Background

Under titles II and XVI of the Act, we pay benefits to individuals who meet our rules for entitlement and have medically determinable physical or mental impairments that are severe enough to meet the definition of disability in the Act. The rules for determining disability can be very complicated, but some individuals have such serious medical conditions that their conditions obviously meet our disability standards. To better address the needs of these individuals, we are implementing the Compassionate Allowance initiative to quickly identify diseases and other medical conditions that invariably qualify under the Listing of Impairments based on minimal objective medical information.

Will We Respond to Your Comments?

We will carefully consider your comments, although we will not respond directly to comments sent in response to this notice or the hearing.

Additional Hearings

We have held four hearings since December 2007. The hearings were on rare diseases, cancers, and traumatic brain injury (TBI) and stroke, early-onset alzheimer's and related dementias. You may access the transcripts of the hearings at *http://www.socialsecurity.gov/compassionateallowances*. We plan to hold additional hearings on other conditions and will announce those hearings later with notices in the **Federal Register**.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.006, Supplemental Security Income. (72 FR at 62608).

Dated: October 26, 2009.

Michael J. Astrue,

Commissioner of Social Security.

[FR Doc. E9–26194 Filed 10–29–09; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

RIN 0920–AA33

Total Inward Leakage Requirements for Respirators

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention (''CDC'') proposes to establish total inward leakage (TIL) requirements for half-mask air-purifying particulate respirators approved by the National Institute for Occupational Safety and Health (''NIOSH'') of CDC. The proposed new requirements specify TIL minimum performance requirements and testing to be conducted by NIOSH and respirator manufacturers to demonstrate that these respirators, when selected and used correctly, provide effective respiratory protection to intended users against toxic dusts, mists, fumes, fibers, and biological and infectious aerosols (*e.g.* influenza A(H5N1), severe acute respiratory syndrome (SARS) coronavirus, and *Mycobacterium tuberculosis*).

DATES: CDC invites comments on this proposed rule from interested parties. Comments must be received by December 29, 2009.

ADDRESSES: You may submit comments, identified by RIN: 0920–AA33, 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 (HHS INSERT RIN NUMBER) and ''42 CFR part 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. 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*.

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 #137,'' 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 at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html* 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.

Testing, quality control, and other requirements under Part 84 are intended to ensure that respirators supplied to U.S. workers provide effective protection when properly employed within a complete respiratory protection program, as specified under MSHA and OSHA regulations. NIOSH requirements governing approval of the type of respirators covered by this proposed rule are specified in 42 CFR part 84, principally under Subpart K—Non-Powered Air-Purifying Particulate Respirators. These were last updated in 1995 (60 *FR* 30336–30404). At that time, NIOSH proposed but ultimately omitted requirements for testing the performance of these respirators with respect to TIL [1] to allow for further research on the effectiveness of TIL testing methods.[2]

The performance of the facepiece-to-face seal and other potential sources of leakage for this type of respirator are important because these determine how much unfiltered contaminated air the worker might inhale. The facepiece-to-face seal leakage can be substantial in the case of a poorly fitting respirator.

Effective fit testing technology and procedures now exist to assure that respirators approved by NIOSH under Subpart K of Part 84 have adequately performing facepiece-to-face seals and sufficiently control TIL. The purpose of this rulemaking is to promulgate general requirements for such TIL testing and performance. The draft specific technical procedures to be applied under such requirements can be found at *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*. When finalized, the procedure will be detailed with all other NIOSH respirator certification testing procedures on the NIOSH Web page at *http://www.cdc.gov/niosh/npptl/stps/respirator_testing.htm*.

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.

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 the last line of protection for workers, respirators must be designed and manufactured to perform reliably and tested for compliance to a specified minimum level of performance. The worker might not be able to detect ineffective 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, is intended to strengthen this assurance.

C. Need for Rulemaking

This rulemaking would establish TIL performance requirements and testing of half-mask, air-purifying particulate respirators currently approved under the requirements of Part 84 Subpart K—Non-Powered Air-Purifying Particulate Respirators. These respirators are used by two million U.S. workers: For example, they are used in health care settings by caregivers and staff to patients with tuberculosis and other respiratory infections; in foundries, chemical manufacturing, and other production facilities with potentially hazardous aerosol exposures such as metals, coal, plastics, fibers, nano materials, and silica; and at construction and landscaping sites where workers are exposed to wood, silica, and other dusts from the grounds and building materials. These respirators are also stockpiled in large caches for deployment to public safety, health care, and other service personnel in the advent of an influenza pandemic.

NIOSH evaluation of the TIL performance of these respirators would provide increased assurance to respirator purchasers and users that NIOSH-approved respirators can be expected to effectively protect the user against particulate contaminants, when properly donned and used. NIOSH has conducted benchmark testing of 101 respirator models currently on the market, using a testing regimen similar to that being proposed in this rulemaking, to assess their TIL performance. Approximately 30 percent of this class of respirators have facepiece seals that did not perform adequately to achieve a fit factor of 100 (limiting total inward leakage to no more than 1 percent), as specified by OSHA,[3] for substantial numbers of the human subjects donning them for

[1] TIL is the combination of contaminated air leaked through various potential sources including the facepiece-to-face seal, exhalation valves (if any), and gaskets (if any) and any contaminants that have penetrated the filter.

[2] The isoamyl acetate or American National Standards Institute (ANSI)/OSHA accepted fit tests.

[3] *See* 29 CFR 1910.134 (f)(7).

benchmark testing. This finding is supported by published research.[4 5]

There are three implications of this finding from benchmark testing, which define the need for this rulemaking. One, when an employer purchases one of these respirator models with poor TIL performance for use within a complete respirator program, as specified by OSHA and MSHA, fit-testing of the employees should reveal that a substantial proportion of the employees do not achieve an adequate fit. This presumably compels the employer to purchase other respirators and conduct additional fit-testing on employees, continuing such purchases and fit testing until respirators are identified, through trial and error, that provide all employees with adequately fitting respirators.

This process of identifying respirators that provide an adequate fit to each employee would be streamlined through NIOSH evaluation of TIL performance as proposed in this rulemaking, using panels of test subjects representative of intended users of a particular respirator model and size. The employee is more likely to achieve a good fit from a respirator make that has been demonstrated through testing to achieve a specified minimum level of performance in this respect.

The second implication applies to situations in which these poorly performing respirators are being used by employees and other individuals without the benefit of a complete respirator program that includes fit testing. A recent NIOSH/Bureau of Labor Statistics (BLS) survey of respirator use among U.S. workers found that 40 percent of employers are not selecting respirators for their employees based on fit testing.[6] Self-employed workers in industries such as construction may be even less likely to perform fit testing.

For these employee and worker populations, the poor fit might not be recognized, increasing the likelihood that substantial numbers of these respirator users are not being adequately protected from their hazardous exposures. While the only way to ensure that a particular respirator make and size performs adequately for a user is through fit testing of that user, NIOSH testing and evaluation of TIL performance would increase the likelihood that these workers who lack fit testing will be protected, by obtaining respirators that are demonstrated to generally provide a good fit to intended users when worn properly.

The third implication applies to the stockpiling of respirators for use in case of an influenza pandemic. During a disease outbreak, such respirators might be deployed without a respirator program and without fit testing. Currently, the selection of NIOSH approved respirators provides no assurance that stockpiled respirators are likely to provide adequate protection to the health care, public safety, and other personnel who might use them without a respirator program and fit testing. The availability of NIOSH certification with respect to TIL performance would increase the likelihood that such users would obtain an adequate fit and protection, even though it could not provide the same level of assurance as is obtained from fit testing of each individual for the selection of respirators.

In summary, revising Part 84 to incorporate minimum performance requirements governing TIL is a necessary step to ensure that NIOSH-approved half-mask air purifying particulate respirators have facepiece-to-face and other seals that perform adequately to provide effective protection to most intended users. While this certification testing will not substitute for individual fit testing, respirator training, and other components of a complete respiratory protection program critical to worker protection, it will substantially improve the current circumstances by approving only respirators that demonstrate the ability to meet minimum specified performance requirements and are likely to provide adequate protection to most intended users when properly fitted and worn.

D. Public Meetings for Discussion and for Comment

NIOSH held public meetings to discuss underlying issues and technical matters addressed in this proposed rule on August 25, 2004, at the Key Bridge Marriott, Arlington, VA, and June 26, 2007, at The Embassy Suites Pittsburgh International Airport, Coraopolis, Pennsylvania.[7] Official transcripts of the meetings, as well as public comments submitted subsequently, are available in Docket #36 from the NIOSH Docket Office at the address provided above.

One issue of concern raised in response to NIOSH presentations was that the NIOSH rule would prevent respirator manufacturers from producing models targeted to specific demographic subpopulations, such as women, for example. The current proposal would not impose any such limitation. NIOSH will construct test subject panels for the certification testing that represent the population targeted by the manufacturer, as described in the manufacturer's user instructions.

Another concern raised by commenters is that this rulemaking would shift responsibility for the fit achieved by employees from the employer, who is required to conduct fit testing under OSHA and MSHA regulations, to the respirator manufacturer. No such substitution is intended or effected by the rulemaking. As discussed above, NIOSH would require that manufacturers produce respirators that have effective face seals, such that they can be expected generally to fit intended users and control TIL adequately when the respirators are properly fit tested, donned, and used. This general assurance does not replace individual fit testing to be conducted by employers, which ensures that each individual employee obtains an effective fit, as required by OSHA and MSHA.

NIOSH already requires adequate TIL performance for other types of respirators under Part 84. NIOSH omitted such requirements for the category of respirator covered in this rulemaking only because of testing limitations that existed in 1995 when Part 84 was established.

NIOSH received concerns regarding the use of various testing technology and methods to evaluate TIL. The technology is identical to that in common use for measuring respirator fit and is accepted by OSHA.[8]

Comments were received questioning the representativeness of the test panel with respect to the population of respirator users. The test panel was developed by NIOSH to replace a panel developed decades ago by Los Alamos National Laboratory using military personnel. The new panel has been the subject of publications and multiple reviews, including a review by the

[4] Coffey C, Lawrence R, Campbell D, Zhuang Z, Calvert C, Jensen P. Fitting Characteristics of Eighteen N95 Filtering Facepiece Respirators. *JOEH.* 2004;1: 262–271.

[5] Lawrence R, Duling M, Calvert C, and Coffey C. Comparison of Performance of Three Different Types of Respiratory Protection Devices. *JOEH.* 2006;3:465–474.

[6] NIOSH/BLS [2003]. Respirator usage in private sector firms, 2001 (*PDF only* 1,118 KB (278 pages)). Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

[7] Notice of these meetings was published in the **Federal Register** (FR69:133:42059) (FR72:102:29501–29502). 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.*

[8] 29 CFR 1910.134, Appendix A, Part I, C, 3.

Institute of Medicine.[9] [10] [11] It is documented in testing and agreed by reviewers that the proposed panel represents a substantial improvement over its predecessor panel and should be implemented.

Commenters also questioned the number of test subjects and the pass/fail criteria. NIOSH has changed the pass/fail criteria and the number of test subjects as a result of these comments. A full technical discussion of the statistical basis for the proposed standards described below is provided in a paper titled ''Statistical Basis for TIL Testing'' in the NIOSH Docket for this rulemaking posted at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*. The maximum allowable leakage is now equivalent to the fit test criteria required by OSHA for this type of respirator.[12]

These concerns have been given consideration in the design of this proposed rule and will be considered further in the development of testing procedures to be implemented under a final rule. NIOSH encourages interested parties to submit any technical concerns along these lines, as well as policy concerns, in response to this proposed rule.

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 in the vicinity of Washington DC and will be announced in a separate notice in the **Federal Register**. This meeting will also be available through remote access capabilities. Participants will be able to simultaneously listen and view presentations over the Internet, as well as comment.

III. Summary of Proposed Rule

This proposed rule would establish new TIL requirements for half-mask air-purifying particulate respirators approved by NIOSH, or NIOSH and MSHA, under 42 CFR part 84—Approval of Respiratory Protective Devices. These provisions would be added to Subpart K. 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. For the convenience of readers, the regulatory text presents the amended sections in their entirety, including the proposed new and revised paragraphs and those that would remain unrevised under the amended sections.

Subpart K

Section 84.175 Half-Mask Facepieces, Full Facepieces, Hoods, Helmets, and Mouthpieces; Fit and Total Inward Leakage (TIL); Minimum Requirements

This section includes a variety of general requirements governing the fit and functionality of the various designs of non-powered air-purifying particulate respirators. NIOSH proposes to amend this section to incorporate TIL standards and a general specification of testing requirements. Paragraphs in this section that are not discussed below are current provisions that NIOSH is not proposing to amend.

A. Half-Mask Respirators Designed for Specific Segments of the Population

Paragraph (a)(3) is new. It would allow applicants to seek approval for half-mask respirators designed to fit a specific segment of the population, such as ''women'' or persons within specific dimensional limits. Currently, respirators must be designed to fit the population broadly, either by providing one size that fits diverse facial shapes and sizes or by providing multiple sizes. It is advantageous to employers and other respirator purchasers to supply a respirator that fits the population broadly because it simplifies their selection and purchasing of such equipment. It also increases the likelihood that the majority of workers and other respirator users will obtain respirators that fit. However, in connection with public discussions regarding the concepts underlying TIL standards and testing, several respirator manufacturers have advocated that they have the option of producing respirators designed to fit particular subpopulations, presumably to more reliably achieve a fit for certain face shapes that might not obtain a good fit from generally-targeted designs. Furthermore, while NIOSH benchmark testing and other research have indicated that many respirators do not actually provide a good fit to substantial segments of the population, it is possible that some of these respirators are well designed to fit particular subpopulations.

NIOSH accepts the proposition that in some cases it might be effective to design respirators to fit specific subpopulations that share common facial characteristics, resulting in better TIL performance. Since this approach would rely on purchasers recognizing an appropriate match, NIOSH has specified that the membership of the subpopulation, as described, must be somehow identified. Thus, for example, sex is clear. However, it is unclear to NIOSH whether there are other demographic classifications or descriptors for subpopulations that could be both reliably interpreted by users and reliably determinative in terms of respirator fit. Users must be provided sufficient information to permit them to self-identify. They might not effectively self-identify to match a manufacturer's intentions if provided only vague general descriptions of intended facial shapes or characteristics.

A new paragraph (g) would require that any part of a respirator that would have to be removed to conduct a user seal check must be replaceable without disturbing the fit of the respirator. This is a current requirement for other types of respirators and is essential to assuring the validity of the seal check.

Paragraph (h) is also new. It would require the user instructions of a half-mask respirator to specify the intended users of the respirator, by facial size, if applicable, and by other descriptive information as might be necessary for respirators designed for specific subpopulations, as explained above. This information would be relied upon by purchasers and users and by NIOSH in conducting TIL testing, as discussed below.

B. Half-Mask Respirator TIL Testing Requirements

General Discussion

Subsection (i) is new. It proposes the general procedures, requirements, and performance standards for TIL of non-powered half-mask air-purifying particulate respirators. The standards have been designed statistically to identify and pass with high accuracy (greater than 90 percent probability) those respirators that provide adequate TIL performance to the large majority of intended users (in the range of 80 to 90 percent of intended users) while failing with near certainty (greater than 99 percent probability) those respirators that do not provide adequate TIL performance to a majority (50 percent or more) of intended users. Adequate TIL performance is a TIL value of 1.0,

[9] Zhuang Z, Bradtmiller B, and Shaffer R.E. New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce. Journal of Occupational and Environmental Hygiene 2007;4: 647–659.

[10] Zhuang Z, Groce D, Ahlers H, Iskander W, Landsittle D, Guffey S, Benson S, Viscusi D, Shaffer R. Correlation between Respirator Fit and Respirator Fit Test Panel Cells by Respirator Size. Journal of Occupational and Environmental Hygiene. 2008;5: 617–628.

[11] Institute of Medicine. Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users. The National Academies Press, Washington, DC (2007).

[12] 29 CFR 1910.134(f)(7).

equivalent to a fit factor of 100, which is the level of performance for these respirators specified by OSHA.[13] The number of test subjects proposed for the testing has been limited to maintain reasonably modest testing costs for NIOSH and respirator manufacturers while achieving a representative cross-section of the intended user population and providing sufficient ''statistical power'' to evaluate TIL performance accurately. A full technical discussion of the statistical basis for the proposed standards described below is provided in a paper titled ''Statistical Basis for TIL Testing'' in the NIOSH Docket for this rulemaking posted at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*. NIOSH requests public comment concerning the judgments inherent to these proposed standards, as well as comment on the supporting statistical analysis referenced here.

NIOSH invites public comment on the proposed standards specified in this subsection. There are several critical factors that the public should consider in providing such comments:

1. What percentage of the intended user population should be able to achieve adequate TIL performance for the respirator to be approved by NIOSH? NIOSH has proposed that 75 percent or higher should be able to achieve such performance. This performance level is based on the design and statistical considerations presented above in this General Discussion section; essentially, using this 75 percent testing parameter would provide strong assurance (90 percent probability) that testing identifies for approval respirators fitting the large majority—80 to 90 percent—of intended users, while rejecting with near certainty (99 percent probability) respirators that fit only a minority—less than 50 percent—of intended users.

2. As the percentage of the intended user population capable of achieving adequate TIL performance from a respirator declines, at what point, if any, should NIOSH set the limit to be nearly certain (e.g., 99 percent or higher probability) that the respirator would not be approved? NIOSH has proposed that a respirator should be rejected with near certainty if it does not provide adequate TIL performance to at least a majority (50 percent or greater) of intended users. NIOSH believes this is a reasonable standard for defining the performance of a poorly fitting respirator that should not be approved.

3. How many test subjects should be included in the testing, considering the fact that testing accuracy increases with the number of test subjects, but that the cost of testing also increases with the number of test subjects? Do the numbers of subjects proposed by NIOSH (15 to 35 test subjects, as specified under § 84.175(i)(4)) reflect an appropriate balance between limiting manufacturer testing costs and providing sufficiently accurate results? What level of testing cost is supportable, in the view of manufacturers? Would manufacturers prefer a higher numbers of test subjects and associated higher costs, to reduce further the likelihood that a respirator with adequate TIL performance is denied by chance?

Discussion of Specific Provisions

Paragraph (i)(1) specifies that NIOSH will apply solely the user instruction information describing the intended users of a respirator to select an appropriate panel of TIL test subjects. Thus, NIOSH will be interpreting the user instructions with the same limitations as a purchaser or intended user.

This provision would have no practical effect in the case of a respirator designed to fit the general population, either through one size that fits all users or a comprehensive set of differing sizes. In such a case, the respirator would be tested against the NIOSH testing panel, which respirator manufacturers can replicate in their pre-application TIL testing to ensure that their respirator is designed and manufactured to achieve an adequate fit on the testing panel to meet the NIOSH TIL standard. On the other hand, this provision limiting NIOSH to the information provided in the user instructions could be important in the case of a respirator designed for use by a specific subpopulation. As a consequence, if the applicant were to have selected test subjects for pre-application TIL testing using additional criteria or distinguishing factors not specified in the user instructions, it is possible the applicant would obtain a panel of test subjects substantially different from that selected by NIOSH for its TIL testing. A substantial difference in test panels could produce different testing results and potentially result in the failure of the respirator to pass the TIL performance standard.

Paragraph (i)(1) also specifies the number or minimum number of representative test subjects to be used in TIL testing; 35 for a respirator intended to fit the general population and a minimum of 15 for a respirator intended to fit one or more specific subpopulations. These numbers are proposed in combination with the performance standards specified in paragraph (i)(4) to provide a sufficiently accurate measure of a respirator's TIL performance for at least 75 percent of intended users while minimizing the chance of either approving a respirator that did not achieve adequate TIL performance for at least 50 percent of intended users or of disapproving a respirator that only by chance failed to achieve the TIL performance standard for at least 75 percent of intended users. A full technical discussion of the statistical bases of these standards is provided in a paper titled ''Statistical Basis for TIL Testing'' posted at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*.

Paragraph (i)(2) specifies that test subjects will conduct a user seal check or other donning procedure prior to each test. This is appropriate practice for a worker donning this type of respirator, to ensure that it is positioned correctly on the face to provide an optimal facepiece-to-face seal.

Paragraph (i)(3) specifies that the TIL test will be administered to each test subject up to three times, terminating testing either when a test has produced a TIL value of 1.0 percent or less or after the third test, whichever occurs first. The TIL value of 1.0 percent is equivalent to a fit factor of 100, which is the minimum acceptable fit factor for half-mask respirators specified by OSHA under 29 CFR 1910.134 (f)(7). The limit of administering the test up to three times to achieve this performance standard is integral to the statistical basis establishing the accuracy of the TIL testing, as discussed above and in technical detail in the paper ''Statistical Basis for TIL Testing'' posted at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*.

Paragraph (i)(4) provides the TIL performance standards for approval of these respirators, differing under clauses (i) and (ii) to account for the lower minimum number of test subjects (a minimum of 15 versus 35) that would be used to test a respirator intended to fit one or more specific subpopulations under clause (ii). Given the lower number of test subjects, a higher proportion of the test subjects (80 percent versus approximately 75%) would be required to achieve a TIL value of 1.0 percent or less for the respirator to be approved. This difference is statistically based in the decreasing reliability of an individual test as the total number of test subjects declines. It is discussed and illustrated in the paper ''Statistical Basis for TIL Testing'' posted at: *http://www.cdc.gov/niosh/docket/NIOSHdocket0137.html*. The proposed use of a minimum of 15 test subjects for respirators intended to

[13] *See* 29 CFR 1910.134(f)(7).

fit one or more subpopulations of users allows for the use of a larger number of test subjects for subpopulations that are more diverse and hence, require a more diverse panel of test subjects to provide sufficiently comprehensive representation of facial dimensions.

Paragraph (i)(5) specifies that the probe would be located halfway between the wearer's nose and mouth for TIL testing of the respirator. This specification is consistent with the technology used for such testing and is necessary to ensure a reproducible determination of TIL.

Paragraph (i)(6) specifies the use of sodium chloride (table salt) as the challenge aerosol for TIL testing and specifies a particle size range of 0.02 to 0.06 micrometers within a concentration range of 1,500 to 3,000 particles/cm^3. Sodium chloride is used because it is safe for the test subjects and has appropriate physical properties for the test. The particle size range represents the most penetrating particle sizes, producing an atmosphere that challenges the limits of the respirator's TIL performance. The concentration range allows for accurate measurement using the current technology available for TIL testing.

Paragraph (i)(7) specifies the sequence of exercises that comprise the TIL test. These are the standard, OSHA-required set of exercises to be used in fit-testing these respirators. They provide for realistic respirator use conditions that challenge the respirator's TIL performance through typical work movements, postures, grimaces that can disturb the facepiece-to-face seal, talking, and deep breathing to increase the negative pressure inside the facepiece.

Paragraph (i)(8) specifies that the test exercises will be performed using the OSHA protocol provisions specified at 29 CFR 1910.134 Appendix A, Part I.A.14(b). This protocol paragraph specifies the duration of each test exercise used in fit testing. Currently, OSHA requires each exercise be performed for one minute except for the grimace, which is performed for 15 seconds. By specifying this element of the OSHA protocol, NIOSH would ensure that NIOSH TIL testing remains consistent with OSHA fit testing requirements in this regard.

Paragraph (i)(9) specifies that the test subject will not adjust the facepiece position once the TIL test exercises begin, and that any such adjustment would void the test, requiring that it be repeated. This is current fit-testing practice and is required by OSHA under 29 CFR 1910.134 Appendix A, Part I.A.14(b). The intent of this requirement is to realistically reflect the practices and conditions of workers when wearing respirators. A worker typically would adjust the facepiece if he sensed a poor facepiece-to-face seal. However, a worker might not adjust the facepiece for many reasons, such as not sensing a poor facepiece-to-face seal, or being engaged in a task that occupies both hands. Moreover, the need to adjust the facepiece periodically after donning the respirator indicates an undesirable TIL performance characteristic. For example, the need to make such adjustments during a work task would constitute a hazard if safe work practice requires that the worker's hands and/or attention be fully engaged in the work task.

Paragraph (i)(10) specifies how TIL is determined. TIL results are expressed as the percentage quantity of the ambient concentration of sodium chloride measured inside the respirator. For example, if the ambient concentration were 1000 particles/cm^3 and the respirator reduced this concentration to 10 particles/cm^3, then the TIL would be expressed as 1.0 percent, because the concentration inside the respirator facepiece was reduced to 1.0 percent of the ambient level. This is equivalent to a fit factor of 100, which is the inverse of the TIL and is calculated as the ratio of the ambient concentration over the concentration inside the respirator facepiece.

Paragraph (i)(11) specifies design and performance attributes of the instrumentation to be used to take measurements of TIL. These include the use of a condensation nuclei counter, the ability to measure sodium chloride challenge aerosol in the specified size range of 0.02 to 0.06 micrometers, and during measurement, responding linearly to changes in the aerosol concentration, within plus or minus five percent, over the ambient concentration range of 70 to 3,000 particles/cm^3 and TIL $\leq$ 5.0 percent. These attributes are sufficient to meet the needs of TIL testing as proposed and to ensure that NIOSH and manufacturers use equivalent instrumentation.

Section 84.205 Facepiece Test; Minimum Requirements

This section specifies facepiece test requirements for chemical cartridge respirators. Some of these respirators are designed as half-mask, combination chemical cartridge/particulate filtering (i.e., air-purifying) respirators. For such combination respirators, NIOSH proposes applying the identical TIL test requirements as proposed under § 84.175 in this rulemaking for all half-mask air-purifying particulate respirators. These TIL test requirements would be in addition to the current facepiece test requirements already covered under this section for chemical cartridge respirators. Paragraphs in this section that are not discussed below are current provisions that NIOSH is not proposing to amend.

A. Non-Germane Technical Revisions to General Provisions of § 84.205

Paragraphs (c) and (d) would be revised, substituting the term ''user seal check'' for ''fit test'' to be consistent with current terminology in use.

Paragraph (d)(1) would be revised to reduce the specified ambient concentration of isoamyl acetate vapor in the testing chamber from 1,000 to 500 parts per million (ppm) for testing full facepieces, mouthpieces, hoods, and helmets. This represents current practice, which the NIOSH respirator certification program instituted when NIOSH lowered the IDLH (Immediately Dangerous to Life or Health concentration) for isoamyl acetate to 1,000 ppm.

B. Coverage of Combination Half-Mask Chemical Cartridge/Particulate Filtering Respirators by TIL Testing Requirements of § 84.175

A new paragraph (e) would be added to require TIL testing under the proposed provisions of § 84.175(i) for all combination half-mask chemical cartridge/particulate filtering respirators. The NIOSH respirator certification program currently conducts qualitative testing using isoamyl acetate vapor to evaluate the fit of chemical cartridge respirators under § 84.205, including these combination respirators. The proposed TIL testing would ensure that the particulate filtering protective capacity of these combination respirators is as effective as the single-purpose air-purifying respirators addressed by this rulemaking.

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 considered economically significant, as defined in section 3(f)(1) of the executive order. However, this proposed rule is a ''significant regulatory action'' within the meaning of the executive order and has been reviewed by OMB.

For the leading U.S. respirator manufacturers who obtain approvals from NIOSH, likely to represent a majority share of the current market supply of NIOSH-approved products covered by this rulemaking, NIOSH benchmark testing indicates that the new TIL requirements can be met by current products without additional development or manufacturing costs. For those manufacturers whose products do not meet the proposed TIL testing standards, NIOSH has estimated design and retooling costs ranging from $55,000 to $200,000 per model or models of respirator with a unique facepiece, depending on the unit volume of production, the type of facepiece seal, and the degree of automation of the manufacturing operation. NIOSH invites comment from manufacturers on these estimates, all of which are based on expert opinion.

It is not possible to estimate the number of current approval holders whose products would not meet the proposed TIL requirements and who would redesign their products to seek new NIOSH approvals, incurring design and retooling costs. However, to the extent that some manufacturers may decide not to redesign products and seek new approvals, the proposed implementation schedule for the new requirements (*see* Section IV.J of this preamble) would provide other manufacturers sufficient time to increase production capacity and replace products exiting the NIOSH-approved respirator market. NIOSH invites comment from approval holders on their intent to seek new approvals under the proposed requirements.

All manufacturers intending to continue to hold NIOSH approvals for respirators covered by this rulemaking would incur additional costs for TIL testing. NIOSH estimates these costs would range from $8,500 to $12,000 per respirator approval, which would cover a respirator produced in multiple sizes and may also cover multiple respirator models employing the same respirator facepiece. The testing costs would vary based on the number of test subjects required. NIOSH anticipates applications for up to 500 approvals during the first two years of implementation of TIL requirements, when NIOSH expects the majority of requests for approval would be received. NIOSH estimates total testing and certification costs to manufacturers of up to $3.1 million annually for these two initial implementation years.[14] NIOSH anticipates TIL testing associated with routine submissions for new product approvals in subsequent years will be required for less than 15 percent of the NIOSH-approved product market annually, for estimated costs of $825,000 annually.[15]

NIOSH does not anticipate additional costs to consumers (*e.g.,* employers, self-employed workers) as a result of the proposed TIL requirements. The current NIOSH-approved products that NIOSH expects to pass the proposed requirements do not differ substantially in price from comparable products that are not expected to pass without modification.

NIOSH anticipates the TIL requirements will also result in substantial benefits, although NIOSH lacks information to estimate them quantitatively. Of greatest importance, substantial numbers of workers are more likely to derive the expected respiratory protection from hazardous particulate exposures as a result of using respirators with adequate TIL performance. As discussed in Section II.C. of this preamble, NIOSH benchmark testing and other research indicate that many respirators covered by this rulemaking do not perform well in preventing substantial inward leakage when tested against diverse facial types and sizes. Over 50 percent of workers and other respirator users do not have the benefit of individual fit testing, let alone a complete respiratory protection program. This suggests that substantial numbers of workers may receive improved protection as a result of instituting TIL testing for the certification of these respirators, increasing the likelihood that a worker without fit-testing or training might obtain adequate TIL performance. Such improved protection will result in reduced work-related disease and disability among the workforce, including such conditions as work-related silicosis, chronic obstructive pulmonary disease (COPD), asthma, and cancer, and biological and infectious diseases such as avian influenza, SARS,[16] and tuberculosis.[17] [18] Work-related COPD and asthma alone are estimated to cost $6.6 billion annually.[19] The costs of this rulemaking would be covered by the prevention of a small fraction of a percent of the occupational disease burden associated with workplace respiratory hazards.

In addition, as discussed in Section II.C. of this preamble, respirators that do not perform adequately in TIL testing would be expected to fail fit testing for employees among employers who conduct fit testing as required by OSHA. This is presumably causing the employers to purchase additional respirator models until all employees have respirators that fit adequately, incurring costs for the non-fitting respirators, for repeated respirator fit testing, and for lost employee work time consumed by the repetitive fit testing. NIOSH invites comments from employers regarding the current extent of such costs.

In summary, while NIOSH cannot estimate the total costs associated with this rulemaking, available information indicates these costs are modest and also suggests that they are likely to be considerably outweighed by economic benefits reaped by improved worker protection and the promotion of increased efficiency among employer respiratory protection programs.

[14] This estimate assumes testing and certification of 250 units annually for two years at an average annual cost of $11,000 per unit for a panel of test subjects and $1,250 in other certification costs. About 30 percent of these other certification costs will be borne by the manufacturers irrespective of this proposed rulemaking as a result these products having a typical product life cycle of 5 to 10 years (see note 10 below).

[15] The product life cycle of these respirators is typically 5 to 10 years; meaning between 10 and 20 percent of 500 NIOSH-certified respirators could be expected to be redesigned annually on average. However, product redesigns would not necessarily involve redesign of the facepiece in such a way that would require TIL retesting.

[16] Eninger R, Honda T, Adhikari A, Heinonen-Tanski H, Reponen T, and Grinshpun S. Filter Performance of N99 and N95 Facepiece Respirators Against Viruses and Ultrafine Particles. *Ann. Occup. Hyg.* 2008;52(5):385–396.

[17] Willeke K, Qian Y, Donnelly J, Grinshpun S, Ulevicius V. Penetration of Airborne Microorganisms Through a Surgical Mask and a Dust/Mist Respirator. *American Industrial Hygiene Association Journal.* 1996;57(4):348–355.

[18] Qian Y, Willeke K, Grinshpun S, Donnelly J and Coffey C. Performance of N95 Respirators: Filtration Efficiency for Airborne Microbial and Inert Particles. *American Industrial Hygiene Association Journal.* 1998;59(2):128–132.

[19] Leigh JP, Romano P, Schenker MB, and Kreiss K. Costs of Occupational COPD and Asthma. *Chest.* 2002;121:264–272.

Through this rulemaking, NIOSH is inviting public comment from respirator manufacturers, employers, and others to provide greater specificity for NIOSH estimates of economic costs and benefits anticipated in association with the implementation of the proposed TIL 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 producing half-mask air-purifying particulate respirators approved by NIOSH and covered by this rule 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 TIL requirements applicable to respirators approved by NIOSH for use in potentially hazardous work atmospheres involving toxic, obstructive, and carcinogenic dusts, nanoparticles, and biological and potentially infectious aerosols. Workers don these respirators for protection in a wide variety of industrial sectors, such as mining, manufacturing, construction, and agriculture, and service sectors, such as health care, where medical, nursing, and custodial staff are exposed to biological and potentially infectious aerosols. These respirators are also being stockpiled and would be employed extensively by health care, public health, safety, and other first responders who would be engaged in the case of a pandemic influenza outbreak.

This rulemaking will result in additional costs for TIL testing and certification by NIOSH, for all respirator manufacturers intending to continue to hold NIOSH approvals for respirators covered by this rulemaking. As explained in Section IV.A of this preamble, NIOSH estimates the testing costs would range from $8,500 to $12,000 per respirator approval, which would include a respirator produced in multiple sizes and may also cover multiple respirator models employing the same respirator facepiece. The cost would vary depending on the number of test subjects required. NIOSH anticipates applications for up to 500 approvals during the first 2 years of implementation of TIL requirements, when the majority of requests for approval would be received. NIOSH estimates total testing and certification-related costs to manufacturers of $3.1 million annually for these 2 implementation years. NIOSH anticipates TIL testing associated with routine submissions for new product approvals in subsequent years will be required for less than 15 percent of the NIOSH-approved product market annually, for estimated costs of $825,000 annually.

These total testing and certification costs, from the initial 2-year implementation period, when annualized over an average 7.5-year product life-cycle, amount to less than $1.01 million annually. This is a small fraction of one percent of the annual revenues of respirator manufacturers, which totaled $1.7 billion in 2001 for all products and have grown extensively since.[20] Although respirator manufacturers produce a wide range of products beyond those covered by this rulemaking, half-mask air-purifying particulate respirators, including chemical gas mask/filtering respirators, represent the highest volume respirator sales and comprise a large component of total revenues.

After implementation, the routine annualized costs to manufacturers resulting from TIL testing associated with the redesign of products would be less than $141,000.[21]

As discussed in Section IV.A of this preamble, this rulemaking is not anticipated to result in any additional costs to small employers or self-employed workers and may result in lower costs. Based on NIOSH benchmark testing, respirators likely to represent a majority share of the current market supply are expected to pass the proposed TIL standards without modification, and these respirators are priced comparably to respirators that are not expected to pass as currently designed. Furthermore, the costs incurred by employers and by self-employed workers in selecting adequately fitting respirators through trial-and-error processes should be reduced as the implementation of this proposed rule curtails the supply of NIOSH-approved respirators with poor TIL performance.

NIOSH invites the public to provide more specific and current revenue data on the respirator market covered by this rulemaking.

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 information from respirator manufacturers under OMB Control No 0920–109 (Respiratory Protective Devices), which covers all information collection under 42 CFR part 84. This rulemaking would require NIOSH to collect new TIL testing information from manufacturers applying for approval of half-mask air-purifying particulate respirators covered by this rulemaking.

NIOSH estimates that the proposed TIL requirements will result in a minor increase in reporting burden to manufacturers. TIL testing would require the submission in the application package of one additional page of data describing the test results. These test results would already have been recorded by the applicant within the testing process so the only additional burden to the applicant would be any reformatting that might be necessary and the transfer of the results electronically to NIOSH. NIOSH anticipates this reporting, as part of the standard application package transmitted to NIOSH, would take no longer than 1 hour for completion; the current information collection approval pursuant to OMB Control No 0920–109 (Respiratory Protective Devices) estimates 86 hours per submission for each complete application under 42

[20] Frost and Sullivan Research Service; *http://www.frost.com/prod/servlet/report-brochure* published 30 March 2005.

[21] This assumes new products would be introduced for 15 percent of the product market annually, resulting in $865,000 of annual TIL testing costs. These are annualized over a 7.5 year period (the average life-cycle of these products.

CFR 84.11. Accordingly, in conjunction with this rulemaking, NIOSH will submit a request to OMB to amend its approval under OMB control No 0920–109 to collect this additional information.

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 TIL requirements it would apply uniformly to all applications from manufacturers of half-mask air-purifying particulate 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.

J. Effective Date

NIOSH proposes that the final rule would take effect 30 days from publication in the **Federal Register** for all new respirator approval applications for half-mask air-purifying particulate respirators. Approval holders could continue to sell and ship respirators certified under current provisions subpart K as NIOSH/MSHA certified respirators throughout a transition period of three years from the effective date of the final rule and NIOSH would continue to consider modifications to such approvals for two years from the effective date. Continued use of distributed respirators is under the jurisdiction of OSHA and MSHA and would not be affected by this rule. NIOSH anticipates that OSHA and MSHA would permit continued use of those respirators since certifications will not be revoked for respirators sold and shipped by the approval holder during the three-year transition period. The authority for an approval holder to sell and distribute under a NIOSH certification any half-mask air-purifying particulate respirator certified under the current provisions of subpart K would expire at the end of the three-year period.

This 3-year transition period is proposed to ensure the timely replacement of respirators that demonstrate poor TIL performance while allowing an ample supply of respirators to remain available for use, since even a respirator with poor TIL performance may provide degrees of protection to different users. This timeframe would provide sufficient time for manufacturers to have respirators approved and manufactured in quantities to meet demand. According to NIOSH benchmark testing and other research, significant numbers of currently approved respirators of manufacturers with significant production capacity are likely to pass the proposed TIL testing and performance standards without modifications. On the other hand, NIOSH also seeks to ensure that total quantity of product supply remains sufficient during the transition period for current and potentially higher levels of demand. Such a demand spike could be anticipated if an influenza pandemic were to develop or increase in threat, instigating expanded stockpiling of respirators by health care, public health authorities, employers, workers, and the general public.

NIOSH encourages the public to comment on this proposed implementation schedule and any related issues. Some specific issues for comment include the following:

1. Do manufacturers believe they can meet the proposed TIL performance standards and testing requirements and provide adequate product supply to meet anticipated market demand within the proposed 3-year deadline?

2. Would any parties affected by this proposed rule incur an exceptional and unsupportable financial or other burden as a consequence of the proposed 3-year limit on the sale and distribution by approval holders of respirators certified under the current requirements (which omit TIL standards and testing)?

3. Would a different implementation schedule be better justified in terms of balancing the public health, practical, and economic benefits of removing from the market NIOSH-approved respirators with inadequate TIL performance against the public health, practical, and economic benefits of ensuring that an adequate supply of NIOSH-approved respirators remains constantly available? Please describe the advantages and disadvantages of extending or contracting the implementation schedule.

4. Are other factors that have not been identified by NIOSH important to deciding an appropriate implementation schedule?

List of Subjects in 42 CFR Part 84

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

Text of the Proposed Rule

For the reasons discussed in the preamble, NIOSH proposes to amend 42 CFR part 84 as follows:

PART 84—APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

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 K—Non-Powered Air-Purifying Particulate Respirators

2. Amend § 84.175 by revising the heading and adding new paragraphs (a)(3), and (g) through (i) to read as follows:

§ 84.175 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit and total inward leakage (TIL); minimum requirements.

(a) * * *

(3) Half-mask facepieces may be designed and constructed to fit only one or more defined subpopulations of the general population of respirator users, such as ''women'' or persons with faces within specific dimensional limits, provided that the membership of the subpopulation is readily discernable by the intended users.

* * * * *

(g) Any respirator part that must be removed by the respirator user to perform a user seal check shall be replaceable without special tools and without disturbing the facepiece seal.

(h) User instructions for half-mask respirators shall specify information necessary to identify the intended population of users:

(1) The applicant shall specify in the user instructions the face size or sizes that the respirator is intended to fit; pursuant to this requirement, one respirator may be intended to fit all face sizes; and

(2) If appropriate pursuant to paragraph (a)(3) of this section, then the applicant shall also specify in the user instructions any additional descriptions necessary to indicate the subpopulation(s) the respirator is intended to fit, such as sex, general facial characteristics, and/or precise facial measurements.

(i) Half-mask respirator TIL[1] testing requirements:

(1) NIOSH will employ specifications provided in user instructions, pursuant to paragraphs (h)(1) and (h)(2) of this section, to select representative test subjects for TIL testing, without further guidance from the manufacturer. NIOSH will conduct testing on 35 test subjects for a respirator of a single size or multiple sizes intended to fit the general population of respirator users, or on 15 or more test subjects for a respirator of a single size or multiple sizes designed to fit one or more specific subpopulations of respirator users.

(2) Immediately before each test, test subjects will conduct the user seal check or other donning procedures as specified in the user instructions.

(3) The TIL test shall be administered to each test subject up to three times, terminating testing either when a test has produced a TIL value of 1.0 percent or less or after the third test administered to the test subject, whichever occurs first.

(4) A TIL value of 1.0 percent or less shall be achieved by at least:

(i) 26 out of 35 test subjects for a respirator of a single size or of multiple sizes, designed to fit the general population of respirator users; or

(ii) 12 out of 15 test subjects (or 80 percent of test subjects if there are more than 15) for a respirator of a single size or multiple sizes designed to fit one or more specific subpopulations of respirator users.

(5) Each respirator used for testing will be probed approximately halfway between the wearer's nose and mouth.

(6) The TIL will be measured in the presence of a sodium chloride challenge aerosol with a concentration of 1,500 to 3,000 particles/cm^3 within the size range of 0.02 to 0.06 micrometers.

(7) The TIL will be measured while the following sequence of test exercises is conducted:

(i) Normal breathing;

(ii) Deep breathing;

(iii) Turn head side to side while pausing for two normal inhalations at each side;

(iv) Move head up and down while pausing for two normal inhalations in the head up position and in the head down position;

(v) Recite the Rainbow Passage;[2]

(vi) Reach for the floor and ceiling while pausing for two normal inhalations in the arms-up position and in the arms-down position;

(vii) Grimace (measurements during the grimace are not included in the TIL determination); and

(viii) Normal Breathing.

(8) Each test exercise will be performed using the OSHA protocol as specified at 29 CFR 1910.134 Appendix A, Part I.A.14.(b).

(9) The facepiece position will not be adjusted once the TIL test exercises begin; any adjustment performed will void the test and the test will be repeated in its entirety.

(10) The TIL will be determined by the ratio of the averages of the sodium chloride aerosol challenge concentration inside the facepiece to the challenge concentration outside the facepiece during the test; the TIL results will be expressed as a percentage: TIL = $[C_{in}/C_{out}] \times 100\%$.

(11) The instrumentation used to measure the concentration inside and outside the facepiece will:

(i) Utilize a condensation nuclei counter;

(ii) Measure only the concentrations of sodium chloride challenge aerosol in the approximate size range of 0.02 to 0.06 micrometers (mass median aerodynamic diameter); and

(iii) Respond linearly to changes in the aerosol concentration, within ±5 percent, over the ambient concentration range of 70 to 3,000 particles/cm^3 and TIL ≤ 5.0 percent, within the particle size range of 0.02 to 0.06 micrometers.

3. Amend § 84.205 by revising paragraphs (c), (d) and (e) to read as follows:

§ 84.205 Facepiece test; minimum requirements.

* * * * *

(c) Any chemical cartridge respirator part which must be removed to perform the facepiece or mouthpiece user seal check shall be replaceable without special tools and without disturbing facepiece or mouthpiece fit.

(d) The facepiece or mouthpiece user seal check using the positive or negative pressure recommended by the applicant and described in his instructions will be used before each test.

(1) Each wearer will enter a chamber containing 100 p.p.m. isoamyl acetate vapor for half-mask facepieces, and 500 p.p.m. for full facepieces, mouthpieces, hoods, and helmets.

(2) The facepiece or mouthpiece may be adjusted, if necessary, in the test chamber before starting the test.

(3) Each wearer will remain in the chamber for 8 minutes while performing the following activities:

(i) Two minutes, nodding and turning head;

(ii) Two minutes, calisthenic arm movements;

[1] TIL is the combination of contaminated air leaked through various potential sources including the facepiece-to-face seal, exhalation valves (if any), and gaskets (if any) and any contaminants that have penetrated the filter.

[2] The Rainbow Passage is a public domain text used in respirator testing to fully challenge the face seal to distortions that might arise from talking while wearing the respirator. It is widely available on the internet using any Internet search engine by entering ''Rainbow Passage.'' It is also available in the OSHA respirator rule at 29 CFR 1910.134 Appendix A, part I.A.14(a)(5).

(iii) Two minutes, running in place; and

(iv) Two minutes, pumping with a tire pump into a 28-liter (1 cubic-foot) container.

(4) Each wearer shall not detect the odor of isoamyl-acetate vapor during the test.

(e) In addition, any combination half-mask chemical cartridge/particulate filtering respirator shall meet the TIL testing requirements specified in paragraph (i) of § 84.175.

Dated: August 18, 2009.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440, 447 and 457

[CMS–2232–P2; CMS–2244–P2]

RIN 0938–AP72 and 0938–AP73

Medicaid Program: State Flexibility for Medicaid Benefit Packages and Premiums and Cost Sharing

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed Rule.

SUMMARY: This document proposes to temporarily delay the effective date of the November 25, 2008 final rule entitled, ''Medicaid Program; Premiums and Cost Sharing'' and the December 3, 2008 final rule entitled, ''Medicaid Program; State Flexibility for Medicaid Benefit Packages.'' Upon the review and consideration of the new provisions of the American Recovery and Reinvestment Act of 2009, the Children's Health Insurance Program Reauthorization Act of 2009, and the public comments received during the reopened comment period, we believe that it is necessary to revise a substantial portion of the November 25, 2008 and the December 3, 2008 final rules. To allow time to make these revisions, the Department has determined that it needs several more months to revise the rule. Accordingly, we are asking for public comment on this proposal for delaying the effective date of the final rules until July 1, 2010.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 19, 2009.

ADDRESSES: In commenting, please refer to file code CMS–2244–P2 or CMS–2232–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2244–P2 or CMS–2232–P2, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–2244–P2 or CMS–2232–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Frances Crystal, (410) 786–1195 for State Flexibility for Medicaid Benefit Packages. Christine Gerhardt, (410) 786–0693 for Premiums and Cost Sharing.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received*: http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. State Flexibility for Medicaid Benefit Packages

On December 3, 2008, we published a final rule in the **Federal Register** (73 FR 73694) entitled ''Medicaid Program; State Flexibility for Medicaid Benefit Packages.'' The December 2008 final rule implements provisions of section 6044 of the Deficit Reduction Act (DRA) of 2005, (Pub. L. 109–171), enacted on February 8, 2006, which amends the Social Security Act (the Act) by adding a new section 1937 related to the coverage of medical assistance under approved State plans. Section 1937 provides States increased flexibility under an approved State plan to provide covered medical assistance through enrollment of certain Medicaid recipients in benchmark or benchmark-equivalent benefit packages. The final rule set forth the requirements and limitations for this flexibility, after consideration of public comments on the February 22, 2008 proposed rule.

Subsequent to the publication of the December 3, 2008 final rule, we published an interim final rule with comment period in the **Federal Register** on February 2, 2009 (74 FR 5808) to temporarily delay for 60 days the effective date of the December 3, 2008