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Linda Rosenstock, MD, Director
c/o NIOSH Docket Office
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Dear Dr. Rosenstock:

I would like to comment on NIOSH's proposed revisions to the respirator testing and certification regulations (new 42 CFR Part 184), which were published in the *Federal Register* Vol. 59, N. 99, pp. 26850-26889, May 24,1994. The proposal effects at least one major improvement in the certification scheme, that is, using the maximum count penetration of electrostatically neutral submicrometer particles as the measure of filter efficiency. This criterion standardizes the rating of respirator performance, and gives assurance that the filter will be at least as efficient in removing larger (and smaller) particles of concern. However, the proposal also contains several flaws, particularly concerning the approval of respirators used against *Mycobacterium tuberculosis* (*M. tb.*) aerosols. I will begin by addressing the narrow but important issue of *M. tb.* and proceed to more general ideas. Let me add that as an expert reviewer for NIOSH's 1987 *Respirator Decision Logic*, as a member of the ANSI Z88.12 Committee on Respiratory Protection Against Biological Aerosols, and as an author of several articles concerning variability in respiratory protection, I have given considerable thought to the issues involved.

Respirators and Tuberculosis: In this document NIOSH endorses the performance criteria for respirators used against *M. tb.* aerosols as set forth by the Centers for Disease Control and Prevention (CDC) in the October 1993 proposed revisions to CDC's 1990 tuberculosis control guidelines for healthcare settings. As detailed below, I believe this is a serious mistake because: (1) the CDC criteria do not account for exposure intensity and thereby permit excessive *M. tb.* infection risk; (2) by ignoring exposure intensity in recommending respiratory protection, NIOSH is violating its 1987 *Respirator Decision Logic*; and (3) by endorsing the CDC criteria, NIOSH is implicitly changing the presumed degree of faceseal leakage (i.e., the Assigned Protection Factor, APF) for single-use respirators as set forth in the 1987 *Respirator Decision Logic*, in which case NIOSH contradicts its statement that the current proposal does not address APF values; moreover, no justification is provided for changing the APF value.

On page 26852 it is stated that "all six classes of air-purifying, particulate respirators to be certified under the provisions of the new particulate filter tests (filter penetration) would meet or exceed the performance recommendations contained in the CDC document." The three CDC performance criteria are: (*i*) the unloaded filter removes at least 95% of 1 μm diameter particles at a flow rate up to 50 liters per minute; (*ii*) the expectation that most healthcare workers who are successfully fit tested (either qualitatively or quantitatively) will experience no more than 10% faceseal leakage (which signifies that the APF is at least 10 for the respirator); and (*iii*) the ability to fit healthcare workers with different facial sizes, which may *or may not* require marketing at least three sizes of the respirator. A fourth CDC criterion involves conducting fit checks in the field, but this is not really an intrinsic performance characteristic of the respirator.

In essence, the CDC criteria signify that a respirator that permits 5% filter penetration and 10% faceseal leakage for 1 μm particles constitutes adequate protection against *M. tb.* aerosols. Unfortunately, these criteria do not ensure adequate protection. Given the CDC criteria, the volume-weighted penetration of 1 μm particles through the filter and faceseal leaks into the respirator is 14.5%, because %P = [(.90)(.05) + (.10)(1)] x 100%. However, if 1 μm particles carry viable *M. tb.* bacilli as the CDC presumes, this high degree of respirator penetration permits a substantial infection risk. To explain, first note that the most widely accepted model for airborne *M. tb.* infection in indoor environments is the Wells-Riley equation[1-5] which can be written as:

$$R = 1 - \exp(-D)$$

where R is the cumulative infection risk and D is the expected cumulative number of *M. tb.* bacilli that deposit in the alveolar region. The rationale for this formulation was recently presented in the industrial hygiene literature.[6]

The algebraic effect of wearing a respirator is to multiply the expected number of *M. tb.* bacilli that would be received if a respirator were not worn, by the respirator's overall decimal fraction penetration value for the relevant particle size; the new risk of infection corresponds to: [6,7]

$$R = 1 - \exp(-D \cdot P)$$

where P is the penetration value for the respirator. In this case, P is treated as a constant, although it could represent the average penetration value over many respirator use periods.

Next, consider a scenario in which the annual *M. tb.* infection risk without respirator use is 5.5%, as has been reported for pulmonary fellows performing bronchoscopies;[8] the corresponding value of D is .057. If the respirator's decimal fraction penetration value is 0.145, the product $D \cdot P$ is .0083, and the corresponding annual risk of infection is 0.82%. If this annual risk were to continue for just 10 years, the cumulative risk of infection would be 7.9%, or $\Pr\{\text{Infection}\} = 1-(1-.0082)^{10} = .079$. If this annual risk were to continue over a 45-year working lifetime, the cumulative risk of infection would be 31%, or $\Pr\{\text{Infection}\} = 1-(1-.0082)^{45} = 0.31$. I think most everyone would agree that these infection risks are substantial and unacceptable.

Selecting adequate respiratory protection depends on exposure intensity and the acceptable risk to which a worker's probability of infection is to be limited. Unfortunately, the CDC guidelines do not explicitly address acceptable risk, and neither do OSHA's 1993 compliance guidelines. The CDC seems to believe that annual *M. tb.* infection rates of 1.2% to 2.6% are acceptable; the CDC offered these rates as examples of "low risk" in discussing risk assessment in its October 1993 proposed guidelines. However, these annual risks are clearly excessive; if they continued over 10 years they would result in cumulative *M. tb.* infection rates of 11% to 23%, and if they continued over a 45-year working lifetime they would result in cumulative infection rates of 42% to 69%. I doubt that NIOSH wants to accept such cumulative risks.

Several colleagues and I have recommended that a healthcare worker's annual risk of occupational *M. tb.* infection be limited to .01%,[9] which is a value close to the background infection rate in the general U.S. population.[10] Over a 45-year working lifetime, this would result in a cumulative infection risk of 0.45%. I'm certain that many healthcare industry representatives would argue that our recommendation is too strict. On the other hand, in light of the increased incidence of multi-drug resistant *M. tb.* infection, perhaps it is not strict enough. At some point, however, a target risk value must be chosen if only to permit rational selection of control measures such as respiratory protection.

For example, let .01% per year be the target risk in the previous scenario involving pulmonary medicine staff who experience a 5.5% annual infection rate (most likely due to performing bronchoscopies). One can use the Wells-Riley model to show that the decimal fraction respirator penetration value needs to be $\leq .00175$ (corresponding to an APF ≥ 570) to reduce the annual risk to .01%. According to the 1987 *Respirator Decision Logic*, the appropriate respirator is a positive-pressure supplied air respirator equipped with an elastomeric halfmask. In practice, one could probably effect the same exposure reduction by increasing the particle removal rate from the bronchoscopy suite (through mechanical ventilation and in-room HEPA filter units) and using a powered air-purifying respirator equipped with HEPA filters (the new Type A/L&S filter) and elastomeric halfmask.

Whatever the selected combination of control measures, a risk manager needs to be quantitative in considering the degree of current exposure intensity and risk, and the ability of different controls to reduce exposure intensity and risk to the acceptable level. This fundamental risk management principle is incorporated in the the 1987 *Respirator Decision Logic* which directs the respirator program manager to consider a chemical toxicant's airborne exposure concentration, its exposure limit, and the minimum respirator protection factor needed to reduce the inspired concentration to the exposure limit. In the case of *M. tb.* aerosols there is no exposure limit *per se*, but a specified acceptable risk level in combination with the Wells-Riley model leads to defining an analogous limit. The Wells-Riley model can also be used to estimate exposure intensity based on past *M. tb.* infection rates, or to estimate exposure intensity based on the determinants of D. However, by endorsing the CDC respirator performance criteria, NIOSH is violating its own risk management decision logic.

Another consideration is that NIOSH's endorsement implicitly modifies the APF value of five (5) for single-use particulate respirators as also specified in the 1987 *Respirator Decision Logic*. In this regard, the 1987 document attempts a confusing and artificial distinction between single-use and "disposable" respirators. In reality, there is no functional difference between the two categories, and both current 30 CFR Part 11 and proposed 42 CFR Part 184 fail to define a "disposable" respirator as distinct from a single-use device. The primary type of respirator being described is what is better termed a "filtering facepiece." The 3M 8710 is the most popular example (although 3M likely prefers to market its comparable 3M 1814 Healthcare Particulate Respirator to healthcare institutions). Not only does the 1987 *Respirator Decision Logic* specify an APF = 5 for the single-use device, but in footnote number 3 to Table 1, it limits assigning an APF = 10 to a "disposable" respirator (in reality a single-use respirator) unless "it has been properly fitted using a *quantitative fit test*" (emphasis added). The likelihood that healthcare institutions will embark on quantitative fit testing programs is rather low, and the CDC criteria specifically state that a successful *qualitative* fit test leads to assigning an APF = 10.

In effect, by endorsing the CDC respirator performance criteria, NIOSH is changing the APF value for single-use particulate respirators from 5 to 10, which contradicts NIOSH's statement that this proposal is not addressing the APF's. More importantly, NIOSH fails to provide any justification for changing the APF value. As indicated by the footnote to Table 1, the reason that single-use respirators were given an APF = 5 involves the issue of faceseal leakage, yet nothing in this proposal quantifies faceseal leakage. In other words, the new particulate filter respirators to be tested under proposed 42 CFR Part 184 are not required to reduce faceseal leakage below the undefined level of leakage permitted by the current 30 CFR Part 11.

Tightness Testing: The isoamyl acetate (IAA) tightness tests described in 84.181 and 84.182, pp. 26884-26885, lack necessary detail and permit less rigorous testing of single-use ("filtering facepiece") particulate respirators compared to elastomeric halfmask respirators with replaceable filters. An immediate problem is that defining the protocols and permitting less rigorous tightness or fit testing of some respirator classes implicitly involves the issue of APF values. That is, to intelligently discuss tightness/fit testing, one needs to simultaneously address APF values, yet the current proposal tries to uncouple these issues. Further, because APF's are implicitly involved, a *quantitative* tightness/fit test protocol should be used rather than a qualitative IAA protocol.

The simplest problem to solve is lack of detail in the protocols. Unlike the IAA fit test specified in OSHA's general industry lead standard, 29 CFR 1910.1025, the NIOSH tests are basically undefined such that other parties cannot reproduce them. For example, are odor thresholds of the subjects determined and, if so, how are they determined? Must the IAA concentration be verified by measurements and, if so, what is the permissible coefficient of variation for the measurement method? If a subject detects the IAA odor, is the subject permitted to adjust the facepiece position or headstrap tension and be retested?

Beyond specifying test mechanics, the pass/fail criteria for a given respirator's tightness/fit testing also needs definition. That is, how many subjects are to wear the respirator? Is the subject panel anthropomorphically representative of the facial characteristics of the U.S. adult

population? Is it permissible for some subjects to fail the test (even after allowing for facepiece and headstrap adjustments) as long as some specified percentage of subjects pass the test?

Even if the test mechanics and pass/fail criteria were completely defined, two problems would remain: (1) a quantitative test needs to be used, and (2) the test outcomes are not explicitly linked to APF values. First, a quantitative test outcome is more desirable because the APF values are inherently quantitative in nature. In addition, most other test requirements use objective, not subjective, pass/fail criteria; a quantitative test also avoids the problem of accurately determining odor thresholds which are known to vary widely between individuals.(11) Second, the IAA tightness/fit tests implicitly try to account for the current APF values, in which case what is implicit should be made explicit.

According to the 1987 *Respirator Decision Logic*, for single-use respirators the APF = 5; for elastomeric halfmask respirators with replaceable filters the APF = 10; and for elastomeric fullface respirators and various PAPR devices the APF $\geq$ 25. The stringency of the IAA testing follows this APF rank order. That is, a single-use respirator has the least rigorous testing (100 ppm IAA for 2 minutes with no specified test exercises); elastomeric halfmask respirators have more stringent testing (100 ppm IAA for 5 minutes with specified test exercises); and the remaining respirator classes have the most rigorous testing (1000 ppm IAA for 5 minutes with no specified test exercises). Clearly, if APF values are not a consideration, it makes no sense to vary the stringency of the tightness/fit tests for different respirator categories.

Because tightness/fit testing involves APF's, it is logical to explicitly couple the two issues. I recognize that there are difficult technical and policy questions involved in setting APF values, and that addressing them fully would delay the adoption of changes in the certification regulations. However, to ensure promulgation of internally consistent rules that safeguard the health of respirator users, the delay is necessary. The possible argument that speedy adoption is needed to address the TB problem is moot, because simple endorsement of the 1993 CDC criteria does *not* adequately address the TB problem, as previously explained.

Let me outline some considerations in assigning APF values and relating them to certification test requirements; most of these ideas have been previously presented in the industrial hygiene literature.(12-14) First, it must be recognized that the penetration or workplace protection factor (WPF) value experienced by a single respirator user who has been successfully fit-tested will vary from wearing to wearing (constituting *within*-wearer variability), in which case "adequate fit" with respect to an APF value needs to be statistically defined. That is, if a person wears an elastomeric halfmask respirator for which the APF = 10, what percentage of the wearer's WPF's must be $\geq$ 10 to constitute an adequate fit? Most industrial hygienists would likely say 95% or greater, but no governmental agency or private organization has ever specified this percentage. For the sake or discussion, let's specify 95% as the individual criterion for adequate fit, in which case 5% of a wearer's WPF's are permitted to be less than the APF value.

Second, one must also recognize that the average penetration value (i.e., the average across many respirator use periods) experienced by different respirator users varies between users;

some wearers experience more or less penetration, on average, than other wearers (constituting *between*-wearer variability). One outcome is that the percentage of a wearer's WPF values which are below the APF varies between individual wearers. Please note that most analyses of WPF data have failed to account for between-wearer variability, and have led to questionable assignment of APF values.(14) In this regard, the APF for a respirator should account for within- and between-wearer variability, and be defined in terms of a criterion percentage of users who have 5th percentile WPF values less than the APF value, that is, who experience more than 5% of their WPF's below the APF value. For example, if the APF = 10 for a halfmask respirator, NIOSH might require that a certified halfmask respirator perform such that only 1% or less of wearers experience more than 5% of their WPF values below 10. Selecting these criterion percentages inherently involves policy decisions regarding acceptable risk.

Third, although the criteria for adequate performance should be posed in terms of field performance, it is not practical to require individual respirator manufacturers to conduct studies in workplaces as part of the certification process. However, it would be practical to require performance of "simulated WPF" (SWPF) studies in a laboratory setting; that is, respirator penetration would be quantitatively measured while wearers perform a defined set of activities over an extended use period, say, one hour. A problem arises in that there would likely not be a one-to-one correlation between WPF's and SWPF's, which is the same situation observed for paired WPF's and quantitative fit test fit factors.(15,16) However, there would likely be a correlation at the wearer population level between median WPF and SWPF values, and by quantitatively investigating the extent of correlation, one could devise tightness/fit testing criteria. I have a drafted a manuscript which describes the necessary analytical framework,(17) and would be happy to share it with NIOSH if there were interest. At the same time, investigating the possibilities would require that NIOSH conduct or fund a fairly intensive study on at least one large panel of wearers, or that NIOSH locate and analyze an appropriate data set that may already exist.

The U Test Statistic: In 184.184(j), page 26885, NIOSH introduces a test statistic denoted U. Please note that this test statistic is mislabeled as a test "static" throughout the document. NIOSH offers no explanation of this statistic, but I deduce that it is a 95% one-sided tolerance limit on the lower 95% of the presumed normal distribution of filter penetration measurements. That is, the multiplier 2.22 corresponds to a 95% one-sided tolerance limit for the lower 95% of a normal distribution of measurements based on a sample size of 30, which is the number of filters to be tested for penetration (see Table A-7, "Factors for One-Sided Tolerance Limits for Normal Distributions," *Experimental Statistics, NBS Handbook 91*, M.G. Natrella, U.S. Dept. of Commerce, 1966). If this is true, NIOSH proposes to permit 5% of a manufacturer's filters to allow *more* penetration than designated. Absent any justification for using this test criterion, NIOSH seems to be allowing an excessive percentage of poor filters to be marketed. Further, if the distribution of penetration values is markedly right-skewed (note that NIOSH does not state that it will verify the distributional assumption of normality), some of these poor filters may permit a fairly high degree of penetration. I recommend that NIOSH either explain the wisdom of its pass/fail criterion, or adopt a more stringent test statistic.

Color Codings: In 184.180, page 26884, NIOSH proposes to discontinue standard color coding of certified particulate filters in general; instead, only the Type A/L&S high efficiency filters will be labeled a standard color, magenta. This change is ill-advised, because many unsophisticated end users (including respirator program managers as well as wearers) rely on the color codings to select the proper type of filter or cartridge for an air-purifying respirator. While I certainly endorse the idea that every end user should read the label, many end users find a respirator label to be unintelligble technical jargon, and more than a few cannot read English in the first place. For these individuals, the availability in the same workplace of inconsistently colored filters from two or more manufacturers creates the potential for selection error. NIOSH will do an unintended disservice to these users by not mandating standard color coding of all particulate filters.

Definitions: The definition of "mist" in 30 CFR Part 11, and in the current 42 CFR Part 184, is incorrect in that it excludes liquid particles created by atomization and other mechanical processes, and includes only liquid particles formed by condensation. At the same time, if particulate filters are to be classified according to the six proposed types, it seems unnecessary to maintain the definitions for "dust," "fume" and "mist." The definition of "oxygen-deficient atmosphere" also needs to be modified, because it mandates classifying any atmosphere above 2000 feet in elevation as oxygen deficient; I presume this definition will be addressed when the sections dealing with atmosphere supplying respirators are amended.

Ensuring Public Access to NIOSH Test Data: My final comment concerns an item not in the proposal, namely, ensuring that upon verbal or written request, NIOSH will provide specific test results for the respirators it certifies under 42 CFR Part 184. Based on my past dealings with the Testing and Certification Laboratory in Morgantown, requests for specific test results concerning currently certified respirators are routinely denied. No reason is offered aside from one of NIOSH "policy." The fact is, there is no policy rationale to deny access to these test data. The data are not trade secrets, and any competitor could easily obtain the same performance data by buying respirators on the open market and conducting the tests in its own laboratory. Although the NIOSH policy does not affect manufacturers, it does adversely affect respirator end users who want to compare respirator performance in making selection decisions. For example, an end user may want to compare inhalation resistance for Type A/L&S filters made by Manufacturer A versus Manufacturer B to purchase the filter offering the least resistance. NIOSH's current policy denies end users access to information for no discernible reason.

Thank you for allowing me to comment on the proposed regulations. I would be happy to provide further input if you so desire.

Sincerely,

Mark Nicas

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References

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