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**Sent:** Friday, March 26, 2010 3:38 PM
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**Subject:** RIN: 0920-AA33 42 CFR Part 84 Comments from Cal/OSHA and CDPH
**Attachments:** RIN 0920-AA33 Cal-OSHA CDPH comments.pdf

Attached are the comments approved by the California Division of Occupational Safety and Health (Cal/OSHA) and the California Department of Public Health on the NIOSH Total Inward Leakage proposal. Thank you for your consideration.

<<RIN 0920-AA33 Cal-OSHA CDPH comments.pdf>>

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TO: **DOCKET RIN: 0920-AA33**

March 26, 2009

**Total Inward Leakage Requirements for Respirators**
Comments on Docket RIN 0920-AA33, 42 CFR Part 84

Submitted March 26, 2010
California Department of Industrial Relations, Division of Occupational Safety and Health (Cal/OSHA), and California Department of Public Health (CDPH)

Cal/OSHA and CDPH have prepared these comments in response to RIN 0920-AA33. Cal/OSHA operates a state plan under the authority of the 1970 Occupational Safety and Health Act, and is responsible for protecting the health and safety of California's eighteen million workers. CDPH is the designated state lead agency for response to public health emergencies . The Occupational Health Branch of CDPH prevents occupational injury and illness through a non-regulatory program of public health surveillance, investigation, technical assistance, research and education.

Based on National Institute for Occupational Safety and Health (NIOSH) estimates and other information received by Cal/OSHA, we believe that at least 500,000 California workers rely on respirators to protect themselves against hazards that include carcinogens, reproductive hazards, other toxic substances, and infectious aerosols. Both agencies are therefore very appreciative of the work done by NIOSH to ensure that respirators provide effective and consistent protection.

Half-facepiece respirators rely upon the seal that is made between the respirator and the face in order to ensure that air passes through filters or cartridges and contaminants that the wearer would otherwise inhale are removed. We are therefore encouraged that NIOSH has proposed to add a Total Inward Leakage (TIL) test to the approval procedures for these respirators. We strongly support the NIOSH effort to adopt an effective TIL test procedure as part of the certification process as soon as possible in order to ensure that respirators that provide a good fit will be available to employees. Our specific comments and areas of concern are outlined below. Any questions NIOSH may have regarding these comments may be directed to Deborah Gold, MPH, Senior Safety Engineer, Cal/OSHA Research and Standards Unit, 510-

286-7006, dgold@dir.ca.gov; or Barbara Materna, PhD, CIH, Chief, Occupational Health Branch, CDPH, 510-620-5730, barbara.materna@cdph.ca.gov.

**1. The current proposal addresses a critical need in the use of respiratory protection. It is extremely important that NIOSH approved respirators be tested to ensure that they will provide a reliable and satisfactory fit to the intended users.**

Employers and employees benefit from being able to choose respirators for initial fit-testing that are likely to fit the employee. Experienced fit-testers often are familiar with certain brands and models, and may be able to make intelligent initial selections for employees to try. In some cases, employees will be able to select a respirator that fits well from a variety of respirators prior to purchase. However, in large institutions, respirators are purchased in bulk. For those institutions, even in the best case scenario, only a small variety of already purchased models are tested on each employee until one that fits has been selected. The cost of the respiratory protection program is significantly increased if repeated fit-tests must be performed on each employee for several different models in order to find a respirator that will pass.

As stated in the notice, some respirators, particularly filtering facepiece respirators, are stockpiled by public and private entities for use during emergencies such as health care surge events like the recent H1N1 outbreak. It is not possible to know the ultimate users of these respirators at the time of purchase. In 2006-2007, the State of California purchased 50 million respirators, including several different models, as part of the state's preparations for health care surge. By October 2009, hospitals and other affected employers reported that they had been unable to obtain an adequate supply of respirators through commercial sources. In some cases, local agencies had also exhausted, or were nearing exhaustion, their respirator stockpiles. The State of California released a portion of its stockpile to local jurisdictions for distribution to facilities as needed. At the time of the release, the need was seen as critical, as many health care facilities reported that without this support they would not be able to follow CDC/CDPH recommendations to provide respirators to employees in direct contact with H1N1 patients. Employers were also concerned about their ability to comply with the Cal/OSHA Aerosol Transmissible Diseases standard, which became effective in August 2009.

The predominant model in the state stockpile had been recommended by the respirator manufacturer as being a respirator designed for use by the general worker population. However, initial qualitative fit-testing by one large health care organization at several locations using a challenge agent produced an unacceptable rate of fit-test failures. The respirator failed to fit 15 of the initial 15 people tested (100 percent). One additional test was terminated by the employee prior to

completion. The respirator manufacturer was asked to provide technical assistance, and attempted to fit-test 20 people, utilizing a PortaCount with the N95 adapter. Even with additional training and some repeated trials, the respirator could only be fit to eight (forty percent) of the people tested.

The low fit-test success rate made the use of these 30 million stockpiled respirators infeasible. At significant additional cost, the State was able to re-sort its supply and temporarily fill the gap created by the inability to use a majority of the stockpile by providing different models from the state and federal stockpiles. We are now faced with the task of restoring an adequate total number of respirators in the state stockpile. Fortunately, H1N1 cases started to decline at the end of the year. Otherwise, the failure of this respirator model to fit a significant fraction of employees could have had even more serious results.

At the request of California, NIOSH agreed to conduct a limited study of this poorly-fitting respirator model. Respirators of this model type sampled from three lots in the state stockpile were tested for filter effectiveness and no problem was found. NIOSH then conducted two fit-testing trials utilizing a protocol similar to the TIL proposed protocol which included up to three chances for the respirator to pass the fit-test for each subject, and utilizing the quantitative fit-test method. Preliminary results of the NIOSH trials report that the respirator eventually passed the fit-test trials on 55 percent of one panel, and 62.5 percent of another. We have not seen the detailed results.

The California stockpile experience illustrates both the critical need for NIOSH to include a Total Inward Leakage component in the respirator approval process and the need for this procedure to be reasonably predictive of the respirator's performance as tested and used in the workplace.

**2. The Total Inward Leakage (TIL) protocol should require the manufacturer to accurately identify the intended user population for each respirator model, and should provide reasonable assurance that the model will fit a substantial majority of the intended population.**

The bivariate matrix of anthropometric measurements of length and width proposed for use is a significant improvement over previous matrices.[1] This matrix should be utilized to full benefit in ensuring that the intended user population is accurately identified, and represented in TIL test panels. We believe that it is important that data

[1] The bivariate matrix, however, does not capture elements such as nosebridge height and width that may significantly affect facepiece fit. Facial characteristics not captured by the matrix are likely to contribute to within-cell variability of fit. While we encourage NIOSH to move forward with this proposal we also encourage NIOSH to continue to research ways to better characterize and identify the intended user population.

be provided in the TIL process for each cell the respirator is intended to fit. NIOSH should establish both the criterion for the percentage of intended users that the respirator must fit, and the acceptable lower confidence limit for the fit-testing used to determine whether the respirator meets the criterion. We suggest that the criterion be that the respirator fit at least 80 percent of intended users.

NIOSH has proposed a panel size of 35 for each respirator intended for general use (or a panel of 15 for respirators intended for a subpopulation), with the further specification that the respirator fit a minimum of one panel member in each cell of the matrix. Although we have reviewed the information referenced in the Federal Register pertinent to this issue, we do not believe NIOSH has provided sufficient scientific justification to support these minimum panel sizes. We believe that these numbers are insufficient to ensure that respirators approved by NIOSH will fit a substantial majority of the intended users. The test panel should include a sufficient number of members so that the pass rate and the lower confidence limit of the pass rate can be calculated for each cell. This information should be made available to purchasers so that they can determine how that respirator model may be useful in fitting a portion of their respirator users. We believe that this will require a substantial number of panel members in each cell. Manufacturers of respirators designated for a sub-population should similarly be required to obtain and make available TIL results for each cell or subgroup.

As written, the proposal and its documentation are unclear as to how respirators intended for a sub-population (e.g., small, medium, large or other designation) would be tested, and how manufacturers would describe the intended population. These points should be further clarified.

In regards to the required panel size and pass rate, the notice stated that "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." (Federal Register Vol. 74, No. 209, Page 56145) Read on its face, the statement does not make sense. Why would a 75 percent pass rate among the test panel predict with 90 percent probability that 80 to 90 percent of intended users will experience an adequate fit? If 80 to 90 percent of intended users are expected to experience an adequate fit, why would the experienced subjects in the test panel do worse?

The quoted statement does not appear to accurately represent the statistical analysis accompanying this proposal. To support the recommended panel size and pass criteria, the notice refers to a document titled "Statistical Basis for TIL Testing." We

did not find that document at the published web address, but were informed by the Docket Office that the actual document is entitled "Determination of Sample Size and Passing Criteria for Respirator Fit Test Panels." [2] That document stated that requiring a 74 percent (26/35) passing rate among a subject panel of 35 would result, 94 percent of the time, in the rejection of a model that fits only 60 percent of the intended users. Under these criteria, a model that actually fits 80 to 90 percent of the intended user population would pass the TIL procedure over 80 percent of the time. The statement in the notice represents the converse of these conclusions and cannot be assumed to be true. Dr. Doug Lansittel, the author of Determination of Sample Size, stated in a presentation on this subject that a sample size of 35 cannot with certainty discriminate between a respirator likely to fit 60 percent of the intended population and a respirator likely to fit 80 percent of the intended population.[3]

We recognize that providing assurance that an approved respirator will fit 80 percent of the designated population will require an increased panel size, and therefore increased costs during testing. However, these one-time (or rarely repeated) costs must be balanced against the costs to employers and other respirator users of poorly-fitting respirators nationwide; these costs include the cost of purchasing respirators that may not be usable because employees cannot pass a fit-test with them, employer costs due to repeated fit-tests, as well as the impact on employee health if marginal respirators are purchased and used without fit-testing.

We believe that the most important consideration must be the ability of the respirator to actually protect the user, and we also believe that costs of administering a respiratory protection program must be taken into account. If requiring an increase in test panel size seems to represent too great a cost in the approval process, we recommend that NIOSH consider the magnitude of potential costs for employers, for example, the increased cost to a single hospital with 2000 respirator users if the actual fit-test success rate is 60 percent as compared to 80 percent.

In summary, we recommend that NIOSH adopt a test procedure requiring each respirator model to demonstrate with 90% certainty that it will fit 80 percent or more of the members in each cell that is inclusive of the intended population.

3. **TIL test procedures should predict performance of respirator models in protecting employees in the workplace, and in workplace respirator fit-testing.**

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[2] Landsittel D, et al. Determination of Sample Size and Passing Criteria for Respirator Fit Test Panels." available at: http://origin.cdc.gov/niosh/docket/pdfs/NIOSH-137/0137-081809-DraftNIOSHReport.pdf

[3] Landsittel D. Statistical Explanations for Development of TIL Criteria." available at: http://www.cdc.gov/niosh/docket/pdfs/NIOSH-036/0036-062607-landisttel_pres.pdf.

Respirators should form an effective seal to the face under normal working conditions, which include many kinds of physical movements as well as facial gestures and speaking. If respirators temporarily lose their seal to the face, the respirator should be capable of reseating itself and reforming the seal. Because TIL testing will be used to approve respirators for use in the workplace, TIL testing procedures should be at least as sensitive as workplace fit-testing methods in detecting unacceptable fits.

There is an inconsistency between the supporting document, RCT-APR-STP-0068, Revision 1, and the Federal Register proposal. The test procedure document specifies a 30-second test for each exercise in the fit-testing protocol, while the proposal states that the OSHA fit-testing protocol, which uses 1 minute per exercise, will be followed. We believe that the OSHA method should be followed.

Cal/OSHA and CDPH are concerned about proposed subsection (i)(3) which requires the TIL test to be administered to each test subject up to three times, until a passing result is obtained. We have read the documentation of this proposal and a number of background documents and have yet to understand the basis for using three tries to obtain a pass. We believe that this process will produce inflated pass rates, which will lead to the approval of marginally-fitting respirators, and will be misleading to employers and other purchasers. Although some fit-testers in the workplace may conduct a second trial if a respirator does not fit the user during the first fit-test after readjusting the respirator, a second trial is not required by OSHA regulations.[4]

According to procedure RCT-APR-STP-0068, the first trial is supposed to occur after the person has read the user instructions, performed an assisted donning of the respirator, been permitted time to make appropriate adjustments to the facepiece, and performed a user seal check. The test subject is also required to have worn the respirator for five minutes. If these procedures are not sufficient for the subject to obtain a satisfactory fit, then the respirator is unlikely to provide a satisfactory fit under the conditions of use in the workplace, which do not include testing the fit of the respirator each time it is donned, and readjusting the respirator if it fails. It is important that each employee who follows the manufacturer's donning procedures for his or her assigned respirator be able to achieve a satisfactory fit each time the respirator is worn.

In addition, section (i)(10) requires that the TIL be calculated from the average of the ratios of the concentration inside the respirator and the concentration outside the respirator for each exercise during the test. This permits a respirator to pass the fit-

[4] If this proposed procedure were intended to address individual between-test variability, then a specified number of tests should be conducted on each subject, and a mean or geometric mean of the tests would be used to determine passing. This proposal only requires more than one test per subject if the respirator does not pass the initial test.

test for a given subject, even though it may fail one or more component. Although this is the procedure used in workplace quantitative fit-tests, we believe this is inappropriate for use in the TIL procedure. The OSHA fit-test procedure measures the fit-factor during seven exercises: normal breathing, deep breathing, head turning, head up and down, talking (recite the rainbow passage), bending, and normal breathing. Grimacing is performed prior to the last normal breathing, but is not measured. These exercises are designed to simulate typical workplace movements some of which may temporarily unseat the respirator. For any given employee, the proportion of the day spent in performing activities represented by these exercises is unknown.

Although OSHA's quantitative fit-testing averages the results of each test to obtain an overall fit-factor, qualitative fit-testing, which uses a challenge agent, does not. The respirator fails the test at any point at which the employee detects the challenge agent. Therefore a respirator that is not capable of maintaining a seal, or reseating itself, will fail a qualitative fit-test in the workplace.

The difference between the TIL protocol, which permits a respirator to pass even if it fails on one or more exercises, and qualitative fit-testing makes the TIL test much less sensitive to momentary unseating of the respirator and the respirator's capability to reseal itself. This makes the TIL protocol poorly predictive of the respirator's performance on qualitative fit-tests performed in the workplace.[5]

More importantly, since NIOSH is attempting to ensure that approved respirators will protect the intended user population throughout their work activities, the TIL test procedure should reflect normal conditions of use in the workplace, which do include physical movement, talking, laughing, yelling, and any number of other activities that may temporarily unseat the respirator. Therefore, a respirator that fails to maintain a seal during each maneuver should be considered to have failed for that subject during TIL testing, even if the arithmetic average penetration remains below one percent. A half-face air purifying respirator is expected to reduce the contaminant concentration inside the respirator to 10 percent of the outside concentration throughout the work shift. All components of the test should therefore be passed in order to predict a satisfactory fit. Although this requirement may challenge some marginal respirators, it is important to the end user that NIOSH certified respirators protect the worker throughout their work activities. Although TIL testing and workplace fit-testing utilize similar protocols, each TIL subject is representing the ability of the respirator to fit thousands or tens of thousands of respirator users.

[5] The proposed protocol does not explain whether the PortaCount as used in the TIL test procedure will utilize the N95 mode limit of a fit-factor of 200 (penetration 0.5 percent), or will be operated in the normal mode, in which the fit-factor on each exercise is not limited. Averaging is a greater problem if the results for any exercise is unlimited.

We believe that California's experience with the stockpiled respirator illustrates the sensitivity problem with the proposed TIL test procedures. This respirator was a single-size respirator intended for the general population. The health care employer who brought the problem to our attention had achieved no successful fits using qualitative fit-testing. The manufacturer conducted a trial in California, testing 20 subjects using a PortaCount in N95 mode. Their procedures included conducting an additional fit-test in some cases where the respirator did not pass on some subjects. They reported a 40 percent success rate.

NIOSH then tested samples from two respirator lots on a panel of 40 experienced subjects, and reported a 55 percent pass rate for one lot and 62.5 percent pass rate on the other, using up to three trials per subject on each test. Although less than NIOSH's proposed 75 percent success rate, the TIL-style success results did not well represent the performance of the respirator in real-world situations.

While some of the variability may reflect the actual composition of the different groups of subjects, we believe that, as proposed, the TIL procedure will result in inflated pass rates compared to those achieved in the workplace for three reasons:

1. The proposed TIL procedure does not require that manufacturers of respirators designated for the general population or specific populations test the respirators to determine their performance, with an adequate sample size, for anthropometrically determined sub-populations, and to make that information available to purchasers. Therefore, workforces with employee populations whose face size distribution does not match the 10-cell grid may experience substantially different fit-test results than the test panel.
2. The proposed TIL procedure permits up to three trials permitted per subject to be recorded as a single passing test.
3. The proposed TIL procedure uses a quantitative fit-test protocol that permits a test to be counted as passing when the respirator fails one or more exercises.

We understand that NIOSH prefers to use a quantitative method for TIL testing. Quantitative methods are less subjective than qualitative fit-test methods using challenge agents. In workplace respiratory protection programs, however, half-facepiece respirators are most commonly fit-tested using qualitative fit-test methods. We believe that the discrepancies we have identified can be addressed, particularly by requiring that passage of a test for a given TIL panel subject mean that the test was passed in one trial, and a passing result was obtained during each measured exercise.

In closing, Cal/OSHA and CDPH recommend that NIOSH move forward as quickly as possible to adopt TIL testing as part of the approval process. We believe that our suggested changes to the protocol will improve the usefulness of this proposal to respirator purchasers and users.

Thank you for the opportunity to comment on this important proposal.

Sincerely,

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