Dragon, Karen E. (CDC/NIOSH/EID)

From: Cristine Fargo [cfargo@safetyequipment.org]
Sent: Thursday, March 31, 2011 12:30 PM
To: NIOSH Docket Office (CDC)
Subject: Submittal to NIOSH docket 221, NIOSH Regulatory Agenda for Updating 42 CFR Part 84
Attachments: ISEA recommendations - 42 CFR Part 84 Update.pdf

Dear Docket Officer:

Attached please find comments on behalf of the International Safety Equipment Association (ISEA) on NIOSH's Regulatory Agenda for Updating 42 CFR Part 84 (docket #221). Please contact me if you have any questions.

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INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

Via email: niocindocket@cdc.gov

March 31, 2011

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NIOSH Docket 221
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ISEA Comments on NIOSH Regulatory Agenda for Updating 42 CFR Part 84, NIOSH Docket 221

The International Safety Equipment Association (ISEA) is the trade association foor personal protective technologies, including respiratory protective devices certified by NIOSH. ISEA welcomes the opportunity to respond to NIOSH's request for input on the agency's efforts to update 42 CFR Part 84. ISEA offers the following comments to address those questions posed at the December 9, 2010 stakeholders meeting:

1. What classes of respiratory protection should be addressed next in the regulatory agenda?

The certification requirements contained in 42 CFR Part 84 have not been updated in almost 40 years, except for those that apply to non-powered particulate removing air-purifying respirators. Many of the tests required for NIOSH certification are based on outdated technology that does not reflect state-of-the-art capabilities of respiratory protection devices. In some instances, the methodology used for performance testing is outdated. As a result, ISEA believes that all classes of respirators, with the exception of non-powered particulate removing air-purifying respirators, need to be updated to ensure that the test methods are representative of current technologies, are up-to-date and are relevant to real-use situations.

As part of this overall evaluation, NIOSH is encouraged to establish a hierarchy for those portions of the regulations that need to be addressed and include them on the regulatory agenda based on priority. Specifically related to powered air-purifying respirators (PAPRs), ISEA expects NIOSH to adhere to the rulemaking timeline presented at the December 2010 meeting, rather than include this class of respirators as part of its future regulatory agenda. The agency and stakeholder groups have invested much time and resources into developing performance requirements for these products under Subpart P since the first concept paper was published in December 2007.

2. What aspects of National and International Standards should be considered in updates to 42 CFR Part 84?

ISEA strongly encourages NIOSH to consider only those standards that have been completed, approved and published. Standards that are under development should not be considered unless NIOSH conducts its own studies to validate the standard. Furthermore, only robust performance standards, not ones dictating product design, should be considered.

3. Should NIOSH consider removing specific performance criteria from the regulations?

Yes. As pointed out above, ISEA member companies believe that tests required as part of the certification process should be current and should be germane to real-use applications. NIOSH's evaluation should include updating testing criteria and eliminating tests that are obsolete or have no bearing on the performance of the device, including, but not limited to the following:

- Silica dust test for PAPRs: The silica dust test for powered air-purifying respirators is antiquated and should be replaced by sodium chloride (NaCl) or diocytl phthalate (DOP), which are used for

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other particulate filters. The inclusion of the silica dust test directly influences the design of the PAPR to be larger and heavier without demonstrated value to protect the wearer. Furthermore, as exposure limits have been reduced, the exposures resulting in these high loadings imposed by the test do not exist. Arguably, the silica dust test has been become a design specification and not a performance specification. ISEA is hopeful that this will be addressed as NIOSH moves forward with its PAPR module in the upcoming months.

- Equilibration service life requirement: This testing for organic vapor chemical cartridge respirators should be eliminated as it has no bearing on worker health and safety and becomes a design specification resulting in cartridges that are bigger and more difficult to breathe through than needed. While such an evaluation may have been needed based on cartridges available 40 years ago, current cartridges are wrapped either individually or as pairs and therefore are not potentially exposed during storage prior to use. Furthermore, the testing requirements are too sensitive to relative humidity and temperature within the allowable range.

- Gas testing for organic vapor approvals: Standards in other countries use cyclohexane, which is a safer substitute than carbon tetrachloride, and can achieve the same purpose. The precedent for this update exists as the agency has qualified cyclohexane for use in the certification testing protocols for organic vapors for CBRN devices.

- Service life testing: NIOSH should determine whether service life times should be changed based on current technologies and ensure that service life tests be performance-oriented and allow for different sizes of chemical cartridges. The present service life requirements dictate the size and hence the design of the cartridge. The tests only need to determine they are of good design, and consist of good carbon and not specify the service life.

The same recommendations apply to the current 42 CFR 84 Subpart K, Gas masks. In addition, the test requirement for carbon monoxide (CO) needs to be modified to reflect a pass/fail criteria for the cyclic (inspired air temperature) test and to account for the differences between the catalyst and activated carbon breakthrough as well as the way CO is absorbed in the body. This is based on the justification of the 35 ppm recommended exposure limit (REL), which should be a time-weighted average (TWA) as opposed to an instantaneous value. The REL is an 8- hour time-weighted average. With a TWA, it may be appropriate to include a short term or instantaneous limit as well to ensure that the filter doesn't allow short term, high concentration CO penetration.

4. Should NIOSH consider identifying sector specific performance capability assessments?

No. The needs and concerns of specific sectors using respiratory protection generally do not vary so as to justify resources for developing and certifying individual respirators for sector-specific use. So long as certification is based on performance standards and not design standards, manufacturers will have the flexibility to develop respirators for industry sectors that may have unique needs.

5. Other issues?

As NIOSH seeks to include overall improvements to the regulation, ISEA recommends that NIOSH consider publishing a template as part of the CFR that can be used for any gas or vapor. Such template could identify testing concentrations as multiples of the permissible exposure limit (PEL) and breakthrough as the PEL or some fraction thereof with a minimum time to determine if the cartridge is appropriate.

It would also be helpful for NIOSH to update the regulation to show all of the types of gases that can be certified for chemical cartridges that NIOSH approves. NIOSH has relied on policy to address gases that are not currently identified in the regulation but for which approvals have been granted. Updating the regulation to include the all gases and the conditions for use in a single location can provide benefit to the user to assist in ensuring the respiratory product selected is appropriate for the work environment.

In addition, ISEA requests that NIOSH reassess the basis for establishing the frequency of manufacturer system audits as part of the regulation's review. Audit resources and attention could be better focused by creating a hierarchy of frequency based on the number and complexity of certified items, performance on default-to-test and other product evaluations, and number and nature of field complaints. An option would be to lengthen the frequencies of audits for manufacturers with simple products, good performance, or a combination of the two.

ISEA member companies thank you for considering this input and look forward to working with NIOSH as it moves forward to update its regulation.

Sincerely,

Daniel K. Shipp
President