Date: June 28, 1994

From: Director, NIOSH

Subject: Proposed Regulation, 42 CFR 84, Meeting with Mine Safety Appliances (MSA) and National Institute for Occupational Safety and Health (NIOSH), June 22, 1994

To: The Record

The following were in attendance at the MSA/NIOSH meeting on June 22, 1994:

Linda Rosenstock, M.D., M.P.H., Director, NIOSH
Nancy J. Bollinger, Deputy Director, Division of Respiratory Disease Studies (DRDS), NIOSH
D. Michael Murray, Murray, Scheen and Montgomery
Thomas B. Hotopp, Senior Vice President and General Manager, MSA
Wayde B. Miller, Jr., Vice President and Director, Product Planning and Engineering

The purpose of this meeting was mainly to introduce Dr. Linda Rosenstock, newly appointed Director, NIOSH, to MSA. In the course of the meeting, MSA presented NIOSH with the attached summary of their issues and concerns with Part 84 and briefly went over the list. In response to a request for clarification on item 3, page 3, Wayde Miller responded that MSA felt that tuberculosis (TB) concerns were driving the standard, and that by allowing solid-only and cold DOP tests for certification, the regulations would be less protective than the 1987 proposal. MSA stated that they would also be presenting their concerns at the public meeting on the proposed regulations.

Attachment

cc: T. B. Hotopp

bcc: D. M. Manning, DSDTT (Docket for 42 CFR 84)
N. J. Bollinger, NIOSH
NIOSH, Washington
NIOSH Objectives

In the Federal Register, NIOSH stated four benefits to come from implementation of the proposed rule:

- "Produce significant improvements in the level of protection provided to wearers of respirators."

- "Enable users to easily discern the level of protection that can be expected when using a respirator."

- "Enable classification of filters on their ability to inhibit the penetration of particulates of the most penetrating size."

- "Address an important public health need regarding the control of tuberculosis transmission... with six classes of respirators expected to be markedly less expensive than respirators with HEPA filters."

As presently written, worker protection will be degraded and not improved. The first three benefits will not be achieved, and may well reduce worker protection. The only objective achieved will be less expensive respirators for tuberculosis workers.

Specific Concerns

1. The "tiered system (Type A, B, C) allows one class for "solid" only particulates and one class for "liquid and solid" particulates. This will lead to misuse of lower protection "solid" type respirators in workplaces when mists are present. NIOSH had only one "liquid and solid" class in their 1987 public comment submission. From a worker protection point of view this makes a lot more sense.

2. Use of "cold" DOP challenge aerosol yields test results inferior to more-realistic thermally generated DOP. Electrostatic filters particularly show misleading results when cold DOP is used. In addition, an arbitrary level of 100 or 200 mg aerosol exposure is proposed. This arbitrary level could mislead workers into thinking they are protected over time when they aren't! Continuing the test until performance levels out (as NIOSH proposed in 1987) would make far more sense.

In summary the original 1987 NIOSH objectives and the interests of worker protection can be easily and better served with a very few changes to the proposed rule. These suggestions are:

1. As NIOSH originally intended in 1987, only one filter certification class should be established for "liquid and solid" aerosols to minimize the opportunity for misuse and misapplication of certified filters and respirators.
2. The thermally generated DOP be used as the challenge aerosol since ISEA round-robin testing has shown that it better evaluates filters on their ability to inhibit the penetration of particulates of the most penetrating type—a key goal of 42CFR84.

3. That the filter penetration test not be arbitrarily stopped at a particular loading limit, but that testing continue until penetration and efficiency ratings have stabilized, thus enabling users to easily discern the level of protection expected when using a respirator—another key goal of 42CFR84. This is again simply restating what NIOSH originally called for in the 1987-released proposal.

4. With regard to tuberculosis workers, we share NIOSH's concern to do something quickly. Currently, HEPA filters are required for tuberculosis workers. Since lower cost seems to be the over-riding consideration, a separate rule could be written for tuberculosis workers if the use of less expensive respirators was deemed appropriate by experts in this field. It seems more reasonable to take this approach rather than to reduce protection for millions of workers in other industries.

**Important Considerations With Regard to the 42CFR84 Proposal**

1. The Threshold Limit Value (TLV) could be exceeded based on ISEA round-robin test data. Let's start with an example from the aerospace or nuclear industries—an operator machining a bar of beryllium on a lathe with an oil-based coolant. Beryllium has a threshold limit value of .002 mg/m³. The challenge is 49 times the threshold limit value or .098 mg/m³. The lathe operator is wearing a full face mask, high-efficiency mechanical filter respirator. The filter is certified as 99.97% efficient against dusts and mists and the overall respirator carries an APF of 50. (The filter leakage is based on ISEA round-robin testing.)

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\begin{align*}
\text{(hot DOP)} & \quad \text{The filter leakage could be} \quad 0.013\% \\
& \quad \text{(based on round-robin testing)} \quad 0.00001274 \text{mg/m}^3 \\
& \quad \text{APF leakage could be} \quad 2\% \quad 0.00196 \text{mg/m}^3 \\
& \quad \text{If both are added:} \quad 0.00197274 \text{mg/m}^3 \\
& \quad \quad \text{98.64\% of TLV}
\end{align*}
\]

This performance is close to the .002 mg/m³ threshold limit value.

**NOTE:** These filters increase in efficiency with loading so leakage over time actually declines.

Now using degradable filters (electrostatics):

\[
\begin{align*}
\text{(hot DOP)} & \quad \text{The filter leakage could be} \quad 0.43\% \\
& \quad \text{(based on round-robin testing)} \quad 0.0004214 \text{mg/m}^3 \\
& \quad \text{APF leakage could be} \quad 2\% \quad 0.00196 \text{mg/m}^3 \\
& \quad \text{If both are added:} \quad 0.0023814 \text{mg/m}^3 \\
& \quad \quad \text{119.07\% of TLV}
\end{align*}
\]
NOTE: These filters degrade with time/humidity and the threshold limit value has been exceeded.

2. How the misuse of "solids" and "solids/liquid" classification may degrade worker protection.

Another problem with Part 84 is that the operator could be wearing a "solid only" respirator in which case the hot oil mist could degrade the filter even more. It's interesting to note that many of the DOE nuclear facilities have banned electrostatic filters. OSHA also requires its inspectors to use only mechanical filters enclosed in cartridges or canisters. In other words, no electrostatic filters.

Another example is in the asbestos abatement industry—they work with a solid (asbestos fiber) in a 100% humidity environment. They have a good record using mechanical HEPA dust mist filters, but would probably misuse the Part 84 solid only respirators due to cost considerations. They also use a large number of PAPRs which are not even covered in the proposed Part 84 particulate filter regulation.

3. The Tuberculosis Issue:

In regard to mycobacterium tuberculosis, it appears that Part 84 has been compromised to allow certification of much lower cost respirators because CDC and the hospitals feel that is the only way to solve the current problem. Seminars and literature raise questions about our knowledge of the problem. There are questions about the particle size (about 1 micron droplet), how long the bacillus lives when the droplet evaporates, and the dosage required to cause tuberculosis. If we ran this information through industrial hygiene respirator selection decision logic, we would have to recommend a positive pressure SCBA, just like NIOSH recommends for asbestos. In other words, if no dose is safe, use the highest level of respiratory protection available.

Since tuberculosis is such a great and urgent problem, a separate OSHA emergency standard could be written that can deal with the problems without disrupting the whole industrial respiratory protection field and subjecting millions of American workers to increased risks.

4. We have discussed all of these subjects with NIOSH Morgantown personnel and were told to talk to them in public comment. We intend to do that but felt it might be beneficial to discuss these points with you first. We believe that both NIOSH and MSA have the best interest of the American worker at heart and should be working together rather than at cross purposes.
the respirator face sealing surface and the face. If hair
growth, other than in the clean shaven area of facepiece-to-
face seal, interferes with the proper function of the
respirator such as the exhalation valve, then it shall be
altered or removed so as to eliminate interference. The
Agency's position is to provide negative pressure, half-mask
or full-face piece respirators that can be tested with
available fit testing equipment. The Agency will also
provide tight fitting powered air-purifying respirators
(PAPRs) to CSHO's upon request.

J. Corrective lenses which interfere with the facepiece-to-face
sealing area shall not be used with a full facepiece.
Contact lenses may be worn with a full facepiece with the
approval of the Regional Program Coordinator.

K. Single use, disposable or maintenance free respirators will
not be used by OSHA personnel. Since the CSHOs may
encounter different air contaminants during an inspection,
air-purifying respirators with replaceable cartridges shall
be used because these devices provide more flexibility and
reduce the number of single respirators which need to be
carried by the CSHOs. Furthermore, disposable, maintenance
free or single use respirators provide a poorer facepiece
seal than multi-sized elastomeric facepieces and often it is
difficult to perform an effective negative and/or positive
pressure facepiece leakage test. Only "mechanical type"
high-efficiency particulate air (HEPA) filters enclosed in
cartridges or canisters are acceptable for protection
against any particulate exposure because efficiency of these
filters does not change with dust loading and ambient
conditions.

L. Any respirator may produce undesirable effects on the
wearer. Respirators are uncomfortable, and may reduce field
of vision, require the individual to carry extra weight,
place an additional burden on the respiratory system, cause
a feeling of claustrophobia, and may result in a general
feeling of anxiety. The two areas of greatest interest as
far as physiological effects are concerned are the
respiratory system and the cardiovascular system.

M. Individuals shall be examined medically before being
assigned to use respirators. The examining physician shall
be given information about the equipment to be used. He or