DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
Atlanta GA 30333

DEC 9 1987

Mr. Thorne Auchter
The Jefferson Group
1823 Jefferson Place, N.W.
Washington, D.C. 20036

Dear Mr. Auchter:

Enclosed is a copy of the memorandum to the record following our meeting of yesterday concerning 42 CFR Part 84. As stated in the meeting, this memorandum will be part of the official record and filed in the NIOSH Docket Office. If you have any comments, please address them to:

Dr. Nelson A. Leidel
Docket Officer
National Institute for Occupational
Safety and Heatlh
Mail Stop E-23
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Sincerely yours,

J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

84-034

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date December 8, 1987

From Assistant Executive Officer, NIOSH

Subject Memorandum to the Record: Meeting of December 8, 1987 with Representatives of the Jefferson Group

To

Dr. Nelson A. Leidel
Docket Officer, NIOSH

On Tuesday, December 8, 1987, at NIOSH Headquarters in Atlanta, Dr. J. Donald Millar, Director of NIOSH, met with Thorne Auchter and Mark D. Cowan of The Jefferson Group, at their request. The purpose of their visit was to express concern on behalf of "the industry" about the pending revision to 42 CFR Part 84. Dr. Millar was accompanied by Gene Matthews, Legal Advisor to CDC, and Diane Porter, Assistant Executive Officer, NIOSH.

The meeting began at 9:05 a.m. After the introductions of all present, Mr. Matthews stated that NIOSH is currently engaged in rulemaking proceedings and that we are particularly sensitive about any ex parte communications. We also have been sued by ISEA challenging our authority under Section 301 of the Public Health Service Act. That case is now pending before the U.S. Court of Appeals. Mr. Auchter confirmed that he and Mr. Cowan were here representing ISEA. Mr. Matthews stated his understanding that they were not here to debate with, discuss or depose Dr. Millar about the NPRM, but to share their concerns with Dr. Millar. Furthermore, Mr. Matthews noted that because NIOSH is in the midst of its comment period on 42 CFR Part 84, a memorandum for the record will be prepared by NIOSH and placed in the docket concerning presentations made at this meeting. A copy of the memorandum will be provided to Mr. Auchter and Mr. Cowan for their information and comment.

Mr. Cowan stated that The Jefferson Group was not providing legal counsel to ISEA but representing them on public affairs and public policy issues. He said that they were not technical representatives and that they were not here to discuss the technical merits of the proposal. They requested this meeting, on behalf of ISEA. The purpose of the meeting was to ask NIOSH to withdraw the proposed rule, 42 CFR Part 84. Three arguments were addressed by Mr. Cowan as reasons for NIOSH to withdrawn the proposed rule:

1. The proposed rule is not a "minor rulemaking," as described by Executive Order 12291 but has "massive implications" for industry. The industry has estimated the cost of compliance with the proposal to be between $700 and $900 million. They are requesting that a full economic impact analysis be completed.

2. The proposal is "woefully incomplete" in that it lacks a protocol for workplace testing. The industry has stated that there is not sufficient information to "comment intelligently" on the pending

regulation. They understand that no protocol for workplace testing exists that has been properly peer reviewed and approved by NIOSH, and for this reason alone, the proposal should be withdrawn. Mr. Cowan indicated that ISEA was "fully willing to cooperate" in developing a new proposal and testing protocol. He stated that while they did not represent organized labor, they have had discussions with them and have found similar concerns among labor representatives.

3. The industry believes in the "absolute technical infeasibility" of the proposal because of the need to conduct workplace testing solely in mines. The proposal "ignores the fact that 90% of all respirators are used in a non-mining environment."

Mr. Cowan described these three issues as "external" to a hearing process and requested that NIOSH re-think its decision to proceed with this proposed rule. He stated that ISEA agrees that the current regulation needs revision and that it is outdated, but the proposal as currently written is inappropriate at this time.

Mr. Auchter stated that industry wants "to sit down with the interested parties in order to reframe the regulation on a consensus basis." A regulation could be developed that was more feasible, less costly, and without the inherent problems posed in the current proposal. He requested that NIOSH withdraw the proposed rule now before the hearing process begins and work on a "consensus approach."

Dr. Millar then described the revision to 30 CFR Part 11 as something he has faced since he became the Director of NIOSH and that revisions to this regulation had been under consideration for at least ten years. He understands that industry is very interested in completing a revision. He stated that the old regulation (30 CFR Part 11) is viewed by many as stifling innovation in the respirator industry and thus is less protective of workers than would be a rule that encourages innovation. He stated his desire that when a respirator is purchased that there be some confidence that it will work under field conditions, and therefore he supports field testing.

Dr. Millar stated that he did not understand the resistance of the industry to the flexibility afforded them in this regulation. Rather than being bound by a cookbook-type approval process, respirator manufacturers would be given maximum opportunity to innovate new or improved products.

Although Mr. Cowan has not been party to the discussions from the beginning of this revision, he said that sometimes changes are wanted by industry, but when they actually come, problems are found. The industry sees this regulation as just the opposite of what Dr. Millar described. He cited an example of carbon filters, which would be required under the proposal, and would require the

increase in size of these filters four fold. He stated that when our scientists in Morgantown were confronted with this issue, they said it was their intention that Whitco Carbon would be used. Actually, Whitco Carbon has been out of business since the early 1980's. Mr. Cowan stated that no one recognizes the innovative features of this revision.

Dr. Millar reinterated his belief that this revision could be a real stimulus to innovation. Based on a process very similar to the one on which this revision was modeled, American industry leads the world in the development of new drugs and vaccines.

Mr. Auchter stated his desire for collegiality and that he believed there could be a consensus reached on this issue. He stated his concern that the issues discussed here may not be appropriate for a hearing.

Mr. Matthews encouraged them to write or comment orally at the hearings on anything concerning the proposed revision. He further noted that they agreed that the current certification system is obsolete and that they are now taking strong exception to the NIOSH proposal. Mr. Matthews then asked if they were intending to present Dr. Millar with their version of a new certification system.

Mr. Auchter responded that they were not prepared to present an alternative certification system but were presenting an "alternative process" to develop a resolution through concensus building. Further, he stated that the industry is very concerned over the proposal because it is so open ended. He equated it to playing on a field with no boundaries.

Dr. Millar responded that there are boundaries; the respirator "must work" in order to be approved.

Mr. Auchter stated that the industry does not know what data NIOSH will use to base its decisions for approval or disapproval.

Dr. Millar questioned Mr. Auchter on what better ideas the industry may have for regulating their products.

Mr. Auchter stated that ISEA proposed a process of jointly arriving at a new standard.

Mr. Cowan asked how the hearing process will proceed (i.e. similar to the OSHA process with informal questioning or cross examination). Mr. Matthews stated that it was likely that he would chair the sessions; that it would be an opportunity for all interested parties to present their views. There will be field representatives from the Institute there to listen and observe. NIOSH does not envision a question and answer session. Time will be allotted equally depending on the numbers of persons who request to testify.

The meeting concluded at 9:24 a.m.

Diane D. Porter