

**Memorandum**

Date . 28 December 1990

From Senior Science Advisor, OD, NIOSH

DOCKET OFFICE COPYSubject Memorandum to the Record: Meeting of 15 November 1990 with
Mr. Schumacher of The Jefferson GroupTo
The Record

On 15 November 1990, at 2:55 p.m. a brief meeting was held with Mr. Larry Sparks, Acting Deputy Director of NIOSH. The meeting was held at the request of Mr. Schumacher. It followed five other meetings held over the period 1987-1990 regarding the NIOSH rulemaking for 42 CFR Part 84.^{1,2,3,4,5} The following people were in attendance at this meeting.

Nelson Leidel, Senior Science Advisor, NIOSH
Randy P. Schumacher, Senior Vice President, The Jefferson Group
Larry W. Sparks, Acting Deputy Director, NIOSH
Gwen Strickland-Cid, Attorney Advisor, CDC

Ms. Strickland-Cid opened the meeting by informing all parties that since NIOSH was currently in rulemaking on respirator testing and certification,⁶ Dr. Leidel would be making a record of the discussion to be inserted into the docket of the respective rulemaking activities. Mr. Schumacher was meeting with Mr. Sparks as

¹Memorandum to the Record: Meeting of December 8, 1987 with Representatives of the Jefferson Group (December 8, 1987).

²Memorandum to the Record: Meeting of April 27, 1988, with Representatives of the Jefferson Group and Industrial Safety Equipment Association (May 2, 1988).

³Memorandum to the Record: July 15, 1988 Meeting of Dr. Windom with Representatives of the Jefferson Group, Industrial Safety Equipment Association and Senator Strom Thurmond's Office (July 21, 1988).

⁴Memorandum to the Record: Meeting with the Jefferson Group Concerning NIOSH Respirator Regulation 42 CFR Part 84 (January 9, 1989).

⁵Memorandum to the Record: Meeting with the Jefferson Group (April 26, 1990).

⁶NIOSH Notice of Proposed Rulemaking for 42 CFR Part 84 in *Federal Register* of August 27, 1987 (52 FR 32401).

a representative of the Industrial Safety Equipment Association (ISEA), which is a trade association for a substantial portion of the respirator manufacturing industry affected by the NIOSH rulemaking. The Jefferson Group also represents the 3M Company and other business organizations who have an interest in the NIOSH rulemaking.

Mr. Schumacher first commended Mr. Sparks for getting NIOSH, OSHA, and MSHA together on a single policy for respiratory protection. He stated the Jefferson Group had working with the Office of Management and Budget (OMB) to see that this occurs. Regarding the Prerulemaking Technical Conference to be held in January 1991,⁷ Mr. Schumacher made several points. First, the Jefferson Group hopes to bring forth several relevant studies that their client companies have performed. Second, perhaps they can touch on some issues that were not specifically raised in the meeting notice. Third, they have encouraged their member companies to play a constructive role in the meeting. If their members feel they cannot do actual workplace testing, then they have been encouraged to discuss what type of performance testing they feel they can do. Mr. Sparks noted that validated simulated-workplace testing is an important option that NIOSH would like to see discussed at the meeting.

Mr. Schumacher stated that we need to get to the question of how respirators perform under workplace-like conditions. He also stated that the respirator manufacturers' primary concern is that OSHA regulates respirator use by design, not performance. He noted that respirator manufacturers are not just concerned about product liability issues, but also the performance afforded wearers. Mr. Schumacher then displayed a 3M disposable-halfmask respirator (NIOSH certification #TC-23C-859), which was very similar in appearance to many nondisposable halfmasks. He noted that manufacturers were concerned that some disposables would be "discriminated against" if they were regulated simply as "disposables."

Mr. Schumacher then asked about the role of the "advisory committee" that NIOSH will have at the meeting. Mr. Sparks corrected Mr. Schumacher by noting that the consultants NIOSH has hired do not constitute an advisory committee. The Institute's Division of Safety Research has brought on several consultants to help it assess information given to NIOSH at the meeting.

Mr. Schumacher then asked about the intended format for the meeting. Mr. Sparks responded by saying that one major option being considered was blocking out time periods (sessions) around major technical issues (e.g., those raised in the

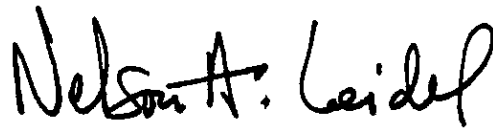
⁷NIOSH Assessment of Performance Levels for Industrial Respirators: Prerulemaking Technical Conference: Meeting notice in *Federal Register* of October 19, 1990 (55 FR 42482).

meeting notice) rather than giving time blocks to individuals or groups (e.g., as in OSHA public meetings on NPRMs).

Mr. Schumacher asked if validated simulated-workplace testing is the best solution, then is NIOSH in a position to fund research for this type of testing? Mr. Sparks answered by noting that possible research on this issue in the new Morgantown-facility building has already been factored into to NIOSH planning.

Mr. Sparks noted that current NIOSH certifications are based only on laboratory tests demonstrating that devices perform at *minimum* levels on those tests. The next step is to provide information to purchasers and users concerning what *quantitative values* came out of those lab tests. The third step is to determine how well respirators are manufactured, that is, the performance of masks used in the workplace. Mr. Sparks also noted that NIOSH does not certify that any respirator was correctly selected nor that workers were properly trained and the mask was correctly worn.

The meeting concluded at 3:45 p.m.



Nelson A. Leidel, Sc.D.

cc: A. Amendola
N. Bollinger
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R. Schumacher
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