

84-274
Memorandum

Date May 2, 1988

From Senior Science Advisor, OD, NIOSH

Subject Memorandum to the Record: Meeting of April 27, 1988, with Representatives of the Jefferson Group and Industrial Safety Equipment Association

To The Record

On Tuesday, April 27, 1988, at NIOSH Headquarters in Atlanta, Dr. J. Donald Millar, Director of NIOSH, met with representatives of the Jefferson Group and the Industrial Safety Equipment Association (ISEA), at their request. The Jefferson Group was represented by Mr. Mark D. Cowan and Mr. Frederick J. Hannet. Representatives from the ISEA included Mr. Frank E. Wilcher, Jr., President, ISEA; Mr. Richard D. Grunberg, Mine Safety Appliances Company; Mr. Robert J. Hershock, 3M Company; and Mr. James Spool, Siebe North, Inc. Dr. Millar was accompanied by Dr. Murray Cohen, Acting Director, Division of Safety Research, NIOSH; Dr. Nelson A. Leidel, Docket Officer, NIOSH; Mr. Gene Matthews, Legal Advisor to CDC; Mrs. Diane Porter, Assistant Executive Officer, NIOSH; and Mr. Larry W. Sparks, Executive Officer, NIOSH.

The meeting began at 10:40 a.m. Dr. Millar welcomed the visitors and had all participants introduce themselves. He then noted that NIOSH was in an active rulemaking process and asked Mr. Matthews to "set the legal context" in which the meeting was being held. Mr. Matthews stated that the same ground rules applied as had applied in a previous meeting with Mr. Cowan and Mr. Thorne Auchter of the Jefferson Group (December 8, 1987). He noted that NIOSH is currently engaged in formal rulemaking proceedings and that the agency is particularly sensitive about *ex parte* communications. Mr. Matthews stated that a memorandum for the record will be prepared and placed in the Docket at its next opening.

Mr. Cowan stated that the purpose of the visit of the group was to present to NIOSH three ideas for consideration concerning further development of the NIOSH proposed 42 CFR 84 (August 27, 1987). At the end of the meeting he would leave Dr. Millar three documents covering the details of the suggestions. He and his associates were visiting on behalf of the respirator manufacturing industry, which was obviously very concerned about the NIOSH proposal. He observed it was unusual for an agency to alter course in the middle of formal rulemaking. However, because in this case he felt the comments to the Docket were "so overwhelmingly in opposition" to the proposal as published, it was hoped NIOSH would seriously reconsider its course.

The first idea Mr. Cowan proposed for NIOSH consideration was the recommendation that NIOSH pursue a process of "negotiated rulemaking." He felt there was nothing to "preclude" NIOSH from utilizing this approach during formal rulemaking. He said that rulemaking was perhaps "new, novel, and extramural" for NIOSH and that all possible approaches should be considered. He noted that the Environmental Protection Agency (EPA) had produced ten regulations with this approach. None of these had been followed by litigation. In addition, EPA has recently published a book on the subject. Other government departments are also using this approach. In EPA's experience this approach reduces contention and has eliminated adversarial legal proceedings after the rule was promulgated. Mr. Hannett noted that negotiated rulemaking has been used by the Department of the Interior to set air quality standards for oil drilling off the California coast, a quite complex rulemaking activity.

Mr. Cowan noted that his firm has done considerable research on negotiated rulemaking. He stated that the government agency wins in several ways. The rulemaking agency still has the chair and makes the final decisions for the regulation. The agency acts as a catalyst for resolution. He felt that the use of negotiated rulemaking results in a shorter time frame for production of the regulation and that it minimizes the likelihood of litigation. Mr. Hannett noted that the agency does not delegate rulemaking responsibility. Mr. Cowan requested that we seriously consider negotiated rulemaking. He offered help and assistance to NIOSH to implement this approach. He said that "no group with whom we have met opposed negotiated rulemaking, including organized labor."

The second issue Mr. Cowan discussed was the Regulatory Impact Analysis (RIA) being prepared by NIOSH for the proposed 42 CFR 84. He noted that the ISEA was very concerned because NIOSH has not contacted the industry to obtain information. He stated that the industry was willing to work with NIOSH to obtain the information necessary for the RIA, some of which is "semiconfidential." Mr. Spool stated that the industry is preparing its own analysis of regulatory impact. He noted that there are questions regarding many elements of the proposal, which made it difficult to perform an impact analysis. He said "we are making the assumption that cooperation between NIOSH and the industry would be helpful."

The third issue presented by Mr. Cowan was on the workplace testing of respirators. He said "no one disagrees with the general idea." However the industry could not identify a testing protocol with which to actually do it. He proposed that a "Workplace Studies Task Force" be established with "all affected parties" represented and chaired by NIOSH to investigate if field testing can be done and if so, how it can be done. He felt that labor organizations and manufacturers would like to participate in this type of effort. The ISEA members would contribute hardware development, protocol development and validation, and personnel. He recommended that the Task Force be chartered as an Advisory Committee to NIOSH concerned with "the whole question" of testing and certification. In conclusion, Mr. Cowan reiterated that industry "wants to cooperate" and said that their purpose in coming to Atlanta was to work with NIOSH to obtain the "maximum consensus."

Dr. Millar invited the other five visitors to fully share their ideas with him. None responded at that moment. He then asked Mr. Matthews if he had "further thoughts." Mr. Matthews stated appreciation for the comments given today. He noted that the agency is in a delicate position in that the Technical Team was currently in the process of evaluating the comments in the Docket and that no staff conclusions and recommendations have been presented to Dr. Millar. However, the Director is aware of the major issues raised in comments to the Docket.

Mr. Sparks also expressed appreciation for the ideas presented today. He noted that NIOSH is not at a decisionmaking point. Mr. Hannett asked for a time frame on the 42 CFR 84 rulemaking. Mr. Sparks responded by noting the major activities involved the RIA preparation and the Docket Review by the NIOSH Technical Team. He estimated that the Docket Review would not be finished before July 1, 1988. Mr. Hannett observed that the ideas presented today could be used before preparation of the final RIA and Docket analysis.

Mr. Sparks stated that NIOSH intends to "honor the record" and all those that submitted comments by fully considering their remarks. He noted that NIOSH owes all parties a careful review of their remarks. NIOSH has to do its own careful assessment of all comments. Mr. Spool stated that their real purpose today is to suggest that there is enough material in the Docket to suggest that a cooperative effort is indicated to lead to a new version of the August 27, 1987 proposal. Mr. Sparks noted that the agency has excluded no option from consideration.

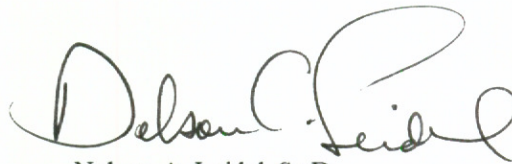
Mr. Spool stated that a revision to 30 CFR 11 is clearly required, that "we have a lot of self interest in a good rule," and that the ISEA can contribute a substantial amount to the process. He stated that an inadequate rule is "no protection for us" since the industry has "liability problems hanging out there." He noted that an "inadequate rule" gives industry "no protection from liability" and that "an adequate rule is clearly in our interest."

Dr. Millar reiterated that NIOSH was in the process of a full analysis of the Docket and would reach no decision until it has been completed. He thanked the visitors for presenting their ideas. He wished to comment on Mr. Cowan's characterization of NIOSH's rulemaking efforts as "new, novel, and extramural." Dr. Millar stated that NIOSH's role in rulemaking is not new and that NIOSH does not view the effort as anything of secondary importance. NIOSH's effort is a "fundamental and mainline responsibility of the agency." NIOSH will exercise its rulemaking effort with the same diligence and zeal for integrity with which it conducts its scientific research. Dr. Millar noted that the rulemaking involves a "complex tapestry of interested parties" including manufacturers of respirators, other businesses which buy respirators, as well as the workers themselves "whose lives may depend on using an effective respirator." All are entitled to a "just and thorough review of their comments." He noted that earlier NIOSH had publicly committed itself to providing a field testing protocol, if a Final Rule requiring field testing of respirators is published.

Dr. Millar stated that he has a strong personal interest in a Final Rule that assures one thing – "a respirator that will work, to protect the health of workers." Every buyer and user of NIOSH-certified respirators needs to be able to see the NIOSH name on a product and "feel that it means something, namely, that it protects." His goal is the best possible protection for all those whose lives depend on using a respirator. Dr. Millar stated that the vast majority of commenters think the present rule is not adequate to do that and the issue is how best to achieve the change needed. He noted that "in my experience the Government can not afford to ignore any good ideas."

Mr. Cowan replied that his "new and novel" characterization referred only to the process of negotiated rulemaking. His "extramural" remark regarding NIOSH's rulemaking efforts was intended to mean "not everyday." Mr. Cowan concluded by presenting Dr. Millar with three 1-page position papers from the ISEA: *Negotiated Rulemaking*, *Regulatory Impact Analysis (RIA)*, and *Workplace Studies Task Force*.

The meeting concluded at 11:20 a.m.

A handwritten signature in black ink, appearing to read "Nelson A. Leidel". The signature is fluid and cursive, with the first name "Nelson" and last name "Leidel" clearly distinguishable.

Nelson A. Leidel, Sc.D.

Attachments (3)



NEGOTIATED RULEMAKING

ISEA requests that the current rulemaking process employed by NIOSH for 42 CFR 84 be amended to utilize negotiated rulemaking. We believe this to be the most efficient and effective method that can be employed to address the many important issues in the proposed rule. It is important to understand that if negotiated rulemaking is initiated for this rule, ISEA would recognize NIOSH's proper role as chair, and ISEA's members would be committed to supporting the process with resources necessary to make the process a success. Negotiated rulemaking is the opposite of adversarial rulemaking. It involves the direct discussion of opposing points of view among interested parties to an issue. It forces the parties to deal with the values, needs and perceptions of each other and to prioritize their own demands, thus creating an incentive to compromise.

The concept was first articulated by John Dunlop, Secretary of Labor during the Ford Administration. Since the early 1980's, it has been employed by several agencies to address rules involving a number of issues, both complex and relatively straightforward. The Environmental Protection Agency has utilized the process to develop quite a number of standards, including those for wood stoves, and exposure levels for farmers working with pesticides. The Department of Interior has utilized negotiated rulemaking to develop air quality standards for off-shore drilling activities in California. OSHA, of course, has also utilized the process. The point is the process is an extremely flexible tool which can be applied in a number of ways to diverse regulatory dilemmas. It has been shown to be particularly effective when applied to situations involving multiple issues and parties.

Negotiated rulemaking has many advantages over the more traditional process. It serves as an excellent vehicle for information sharing, not just between government and the public, but also, among public parties who may have opposing views and among government agencies who may not agree. The process serves to clear the air of extraneous or highly charged issues and rhetoric by making all players openly accountable for their actions and comments. All players gain a vested interest or concept of joint ownership in the final product and this usually results in higher compliance and less litigation--both highly desirable goals for any government agency. Finally, even if a true consensus cannot be reached, the process always increases the level and scope of communication among the players.



REGULATORY IMPACT ANALYSIS (RIA)

ISEA understands that NIOSH is preparing an RIA as required under Executive Order 12291 for all major rule-makings, while also revising the proposed rule for final publication. We are concerned that we have not been asked to provide any input specific to the RIA and question whether NIOSH can prepare a meaningful analysis without such input from manufacturers and other impacted parties.

We have identified some twenty items in the proposed regulation, in addition to workplace testing, which would have a significant impact on the industry. Because of the lack of an on-going dialogue, we do not know how each of these items will appear in the final rule; whether they will be modified, expanded, or eliminated.

Given this lack of information, ISEA is compelled to prepare its own analysis. However, because we do not know what NIOSH's intent is with respect to these and other provisions, we must make assumptions which may or may not reflect NIOSH's position. Thus, in the end, both RIAs could be seriously flawed by subjective assumptions made in the absence of available data. This need not be the case.

ISEA proposes that a second working group or task force be established to serve as a vehicle for sharing information between NIOSH and the manufacturers as to the intent of the proposed rule and the impact it will have on industry. We believe that this exchange will provide an information base from which the best possible RIA can be made.



WORKPLACE STUDIES TASK FORCE

ISEA proposes that a Workplace Studies Task Force be established and chaired by NIOSH with participation from all affected parties. The task force would be charged to begin development of accepted methods to evaluate respirator performance in the workplace. We are aware of NIOSH's current efforts in this area and believe we have many assets which could contribute toward reaching this goal. In addition, members of the ISEA have been in contact with user organizations and labor who expressed interest in contributing to this joint project.

ISEA's membership would contribute much to this project in terms of hardware development, protocol development and validation, and personnel. User involvement would contribute much in terms of test site availability and personnel to do the testing. Labor involvement would assure greater assistance and cooperation with the test subjects. A joint project would go a long way toward resolving the major concerns surrounding workplace testing in a very efficient manner.

ISEA recommends that the task force be chartered as an advisory committee under NIOSH and composed of members qualified to address and resolve the technical issues concerning workplace testing. As chair of the task force, NIOSH would have veto power over implementation of any recommendation the task force made. As further evidence of ISEA's faith in this form of cooperative effort, manufacturers on the task force would convert from an active to passive participant (i.e. observer) during any actual workplace testing. This would remove any question or concern regarding the objectivity of the study.

As ISEA has stated previously we believe workplace testing could be a valuable tool in determining a respirator's performance. We believe this approach would be the most expeditious method of resolving the many issues currently clouding the performance of workplace testing.