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COMMENTS

on

Revision of Tests and Requirements for
Certification of Permissibility of Respiratory
Protective Devices Used in Mines and Mining

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On August 27, 1987, NIOSH proposed new respirator certification regulations to replace the current regulations contained in 30 CFR Part 11. 52 Fed. Reg. 32402 et seq.. While we do not object in principle to the creation of new certification standards, there are numerous fundamental shortcomings both in the content and procedures used to promulgate the standard which mandates its revocation. Consequently, we seek to have the proposed regulations withdrawn until the legal and technical errors are corrected.

Primarily, the legal transgressions emanating from the promulgation of the new certification regulations are threefold: (1) the failure to provide adequate notice and opportunity to comment on the details of the proposed rule as required by the Administrative Procedure Act and the Due Process Clause; (2) the failure to engage in a regulatory flexibility analysis as required under 5 U.S.C. §603; and (3) the failure to comply with the Federal Paperwork Reduction Act of 1980.

I. FAILURE TO PROVIDE ADEQUATE NOTICE

The most fundamental legal error arising from the promulgation of the proposed regulations is the failure to provide interested parties with adequate notice of the proposed regulations. Guaranteed by both the Administrative Procedure Act and The Due Process Clause, this failure cannot withstand judicial scrutiny. Western & Oil Gas Association v. Environmental Protection Agency, 633 F.2d 803 (9th Cir. 1980)

(failure to comply with Administrative Procedure Act requirements of prior notice and comments will invalidate agency's rules and regulations); Crown Zellerbach Corporation v. Marshall, 441 F. Supp. 1110 (D.Cal. 1977) (rules adopted in violation of notice and hearing procedures may be invalidated). Further, the absence of effective notice nullifies other due process guarantees, such as the right to present meaningful comments.

The Administrative Procedure Act mandates that for all rulemaking actions, interested parties must be given notice of the proposed rule, consisting of "either the terms or substance of the proposed rule, or a description of the subjects involved", and an opportunity to comment on the merits of the rule. 5 U.S.C. §553(b)-(c). The goals sought to be achieved through imposition of notice and comment procedures are twofold: Providing the agency with an opportunity to benefit from the experience and input of parties who file comments, and insuring that the agency maintains a flexible and open-minded attitude towards its own rules. National Tour Brokers Association v. United States, 591 F.2d 896 (D.C. Cir. 1978) (purpose of notice and comment requirement is to allow public participation in the promulgation of rules which have a substantial impact on those regulated).

There are no fixed guidelines to measure the adequacy of notice and comment opportunities provided by an agency. Under the Due Process Clause, however, these procedures must meet minimum standards of fundamental fairness. Lassiter v.

Department of Social Service of Durham County, N.C., 452 U.S. 18 (1981) (due process expresses requirement of fundamental fairness). In essence, this consists of an opportunity to be heard at a meaningful time and in a meaningful manner. Royal Typewriter Co. v. N.L.R.B., 533 F.2d 1030 (8th Cir. 1976). Thus, while the specific process may vary from case to case, interested parties must be given an opportunity to effectively participate in the promulgation of agency rules and regulations.

The importance of public participation becomes even more critical when the proposed rules consist of technical data available only to the agency. In addressing this scenario, courts have strictly adhered to the view that when a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it. Metropolitan Hospital, Inc. v. Heckler, 762 F.2d 1561 (11th Cir. 1985); see also Home Box Office, Inc. v. F.C.C., 567 F.2d 9 (D.C. Cir. 1977) (information supplied to the public must disclose in detail the thinking that has animated the form of the proposed rule and the data upon which it was based).

In the instant matter, interested parties have been denied the opportunity to review the scientific data relied on by NIOSH. While providing general notice of the new certification requirements and basic details on how the regulations will be implemented, NIOSH fails to provide the degree of detail necessary to effectively comment on many of the proposals. In several instances, critical details are either entirely absent, or so

ambiguous as to render their value meaningless. Additionally, NIOSH fails to detail the reasoning underlying many substantial departures from existing certification procedures.

Perhaps the most prominent area impacted by the defective notice involves the imposition of workplace testing without a corresponding protocol. In a substantial departure from existing respirator certification, the NIOSH proposal requires that all respirators be tested under workplace, or simulated workplace conditions. While this idea may sound good on paper, its feasibility is unclear at best.

Specifically, the absence of clear guidelines detailing the requirements of workplace testing makes commentary impossible. This fact becomes patently obvious upon close scrutiny of many of the NIOSH proposals. For example, the NIOSH proposal does not specify how many workplaces need to be included in the tests nor how many subjects in each workplace need to be studied. Further, the NIOSH proposals require a manufacturer to utilize a testing methodology which will gauge respirator effectiveness against hazardous substances found in the workplace. However, the technology does not exist to perform such workplace testing and if it does, the industry is unaware of it. Despite this, NIOSH has failed to disclose the methodology it assumes will work.

NIOSH is also proposing to allow the use of simulated workplace testing in lieu of workplace testing if good correlations can be established. However, the variables involved in

workplace testing are so large that satisfactory correlations cannot be developed. In fact, to date no lab tests have correlated to any workplace. Thus, what is ostensibly an attempt to relieve the burden of workplace testing is in reality another area where NIOSH assumes that appropriate technology exists, yet fails to specify the underlying methodology used to arrive at that conclusion.

In addition to the complete absence of many critical details, the NIOSH proposals also contain specific requirements which are too vague to implement or comment on. This is as egregious an error as providing no details, and yields the same result - defective notice nullifying the opportunity to comment.

For example, the proposed regulations mandate that all major respirator modifications require resubmission and recertifiation by NIOSH. However, the definition of major modification is so broad that <u>all</u> changes would require recertification. In addition, this proposal does not state what NIOSH will do if the modification meets the requirements and is approved. Will a new approval be issued? Will the old approval be modified? It is simply impossible to comment without knowing NIOSH's intention.

A final area in which defective notice hampers the ability to comment involves instances wherein the NIOSH proposals significantly depart from existing certification practices. This problem is amply demonstrated by the requirement that all respirators be tested under mining conditions. Why mining conditions? Ninety percent of all respirators in use today are

used in non-mining areas, primarily for industrial and construction purposes. Additionally, an insufficient number of mines exists in which to do the testing. Despite this, NIOSH clings to the requirement that all tests be done under mining conditions. Without access to the reasoning underlying this selection, it is impossible to provide meaningful comment and assistance to the agency.

Given the technical nature of the proposed rule and the impact on the regulated industry, the failure to provide adequate notice and opportunity for meaningful comment is dispositive as to the reasonableness of the rule. Consequently, the rule should be withdrawn until interested parties can be fully informed about the specific details of the proposal. Then, and only then can the Administrative Procedure Act and Due Process Clause guarantees be met.

In addition to the defective notice just discussed, there are other significant legal errors which also point to the need for the withdrawal of the proposed rule.

II. Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 requires that a flexibility analysis be prepared in conjunction with any rulemaking that would significantly impact small businesses. 5 U.S.C. §603. Despite this mandate, NIOSH concluded that a flexibility analysis in the instant matter was unnecessary

because of the minimal impact on small businesses. 52 Fed. Reg. 32404.

Contrary to NIOSH's conclusion, small entities will be uniquely affected by the proposed regulations. Not only will small respirator manufacturers be effected, but small companies purchasing respirators will also be severely impacted.

Under the proposed regulations, respirator manufacturers are facing substantially increased production costs. The imposition of workplace testing sharply increases the costs of recertifying existing respirators as well as the cost of producing new respirators to meet the proposed standard. Further, the costs of plant audits and additional paperwork requirements have also raised the economic stakes for manufacturers.

Increased production costs will force small manufacturers to choose between charging higher prices for their products, rendering them less marketable, or ceasing production altogether. While large manufacturers may be able to absorb the increased costs without stopping production or substantially raising prices, smaller manufacturers will not be as fortunate. Consequently, economic realities may force these manufacturers to stop production altogether.

In addition to the impact on small respirator manufacturers, small companies purchasing respirators for employee use will also be adversely affected. Because of the higher cost of respirators, many such companies will be forced to cut back on respirator purchases and provide them only to those employees who

absolutely require them. Employees in marginal need areas - those who would benefit from respirator use but who are not required to wear them - will be left in the cold. Hence, these companies will be forced to reduce respirator purchases thereby impinging on worker safety and efficiency, as well as reducing the market for respirators.

Given the potentially devastating impact on small entities, NIOSH's decision not to conduct a regulatory flexibility analysis is clearly flawed. While the Regulatory Flexibility Act provides no independent cause of action itself, failing to consider the impact on small entities will be subject to judicial review. Thompson v. Clark, 741 F.2d 401 (D.C. Cir. 1984). Consequently, NIOSH cannot ignore with impunity the effect of its rules on small entities as it has done to this point. Small Refiner Lead Phase-Down Task Force v. Environmental Protection Agency, 705 F.2d 506 (D.C. Cir. 1983).

Had a regulatory flexibility analysis been prepared, small businesses would have had an opportunity to comment and suggest methods to minimize the impact of the rule on these entities. However, without the opportunity to participate in a flexibility analysis, small businesses have been denied rights guaranteed by both the Administrative Procedure Act and the Due Process Clause.

III. Federal Paperwork Reduction Act

In addition to the legal errors addressed thus far, the NIOSH proposals also conflict with the Federal Paperwork

Reduction Act of 1980. 44 U.S.C. §3501. By the terms of this Act, government agencies are directed to minimize the federal paperwork burden for individuals and companies, and minimize the cost to the government of collecting information.

Despite this mandate, the NIOSH proposals increase both the burden on individual companies and the costs to the government. For example, extensive paperwork and "informational material" must accompany all certification or recertification applications, burdening both the manufacturers preparing this information and the agency which must wade through the material. 52 Fed. Reg. 32406. Likewise, the paperwork burdens are unnecessarily increased by the requirement that manufacturers notify NIOSH whenever a rejected lot of respirators is produced, regardless of whether they are shipped out. 52 Fed. Reg. 32410. The value of this requirement is unclear. If a defective lot of respirators is produced but not sold, NIOSH should have no interest in the respirators. Instead, the manufacturer must prepare paperwork for NIOSH, and NIOSH must analyze the data. But for what purpose and for whose benefit?

While certainly not as serious a legal problem as the defective notice and failure to engage in a regulatory flexibility analysis, the failure to comply with the Paperwork Reduction Act further compounds the problems with the new rule and provides additional support for withdrawal of the proposed certification regulations.

CONCLUSION

In conclusion, I would like to reiterate our request to have the proposed certification regulations withdrawn. NIOSH's failure to provide adequate notice and opportunity to comment, to engage in a regulatory flexibility analysis, or to comply with the Paperwork Reduction Act mandates this conclusion.

However, in lieu of revocation of the proposed rule, and without intending in any way to waive the legal objections presented today, NIOSH can redress some of the Industrial Safety Equipment Association's concerns. By publishing the workplace testing protocols, and then holding hearings subsequent to their publication, NIOSH could at least provide some due process protections for interested parties and allow them to meaningfully comment on a process that is currently unclear and incomplete.