NIOSH Criteria Document Development

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In a way, my appearance here today is somewhat breaking one of the cardinal rules which I've established for my Office concerning staff involvement in meetings to discuss NIOSH criteria documents. The rule is essentially that once we've developed a criteria document and published a recommended standard, it's time to put that work aside and move on to other responsibilities. Too often, I — and I'm sure many of you — have seen a situation develop where not only do people devote a lifetime of study to a given problem, sometimes quite appropriately so, but they also devote a lifetime of writing and talking to others about it. Now, I'm not necessarily saying that this is the situation with inorganic lead, except to the point that we in NIOSH have developed a recommended standard and criteria document, and it's up to others to carry it forward.

How expeditiously this goal of developing a permanent occupational health standard is reached, considering the real and appropriate needs for public hearings, of publishing a proposed standard, and getting comments from affected parties, remains to be seen. However, that is a concern of OSHA. When one considers the spectrum of hazards that faces the American working man and woman, and the resources that are available to define and attack these problems, I hope you can at least see our concern and the rationale for our feeling that when NIOSH's job is done, it's time for others to carry on. Since we are a governmental agency which has certain well-defined responsibilities, I'm sure you can understand this viewpoint.

Consequently, so as not to feel too guilty about being here today and meeting with you on the question of inorganic lead, a hazard for which we have already developed a criteria document, I thought I might take the opportunity to discuss some of our philosophies and new developments in the broader area of criteria document development, where possible using lead as an example.

First of all, let me start off with a statement as to my basic belief that without well-prepared, defendable standards, the goal of preventing occupational injury and illness is meaningless. Standards are not only the cornerstone upon which to build any type of program, they are also the measure as to what we should or shouldn't do with a whole array of actions that are necessary to prevent work injuries and illnesses. Standards are the starting point, not only for inspections, but just as importantly, they are needed for voluntary compliance efforts, to train employers and employees in safe and healthful work practices, and they certainly are needed for any approach to resolving problems through joint employer and employee negotiations.

Now, whether or not you accept my thesis as to the predominant importance of occupational safety and health standards, let's go further and discuss NIOSH's role in this area, particularly on the health side. At this point, I think we can use our recommended standard of inorganic lead as an example. With the lead standard, NIOSH's actions and recommendations have, in my opinion, come under the broadest spectrum of criticism seen in a long time. This might be expected, because with the lead standard we have a forerunner of future standards that are concerned with some basic occupational health issues, not the least of which is the application and use of biological limits. Also, criticisms include the universal ones, which range from developing a document that goes into too much detail and evaluation, to the charge that not only didn't we consider all the pertinent data, what we did consider was done inadequately.

I can only respond that fortunately you have the record before you. There are no backroom or taxi-cab decisions, no unverified or unavailable references. Instead, you have a complete documen-

tation, not only of what we considered, but more importantly, the explanation as to our process of critical review.

Certainly, this is something that should be expected of a governmental agency with responsibilities such as ours. It is probably this process of critical review which, more than anything else, is the least understood, and where it *is* understood, it may be least appreciated. For it is in this process that, essentially, we start *not* with the conclusions that are drawn by any given expert for the hazard being considered, but rather, we start with the basic data and information and follow it wherever it leads. This is not to say that our heads are in the sand, for as you know, we continually expose our developmental process — maybe not to public scrutiny, but certainly to peer review, both within and external to NIOSH. When our review leads to conclusions different from those held by others, we stand by them if we feel they can be defended. But, most important of all, we then make them available for all to see and comment on long before they achieve the status of a formal regulation.

One of the earlier administrators of OSHA was concerned that NIOSH, by taking such a deliberative approach, was "locking in" our recommendations as far as permanent rulemaking was concerned. I think time and experience have proven this *not* to be the case. As a matter of fact, we feel that the present procedure does not allow for enough professional input into the development process, and consequently, we will institute in the near future professional symposia to be conducted in the latter stages of the criteria document development process.

The other major points of concern for our lead document, at least as I understand them, involve requirements for work practices, biological and other medical examinations. I mention work practices primarily to spread the notice that in the future, recommended standards from NIOSH, especially where data are available to develop safe environmental exposure levels, will emphasize healthful work practices. And, please note that these are positive work practices for both the employer and the employee.

There are some professionals who don't like work practices, primarily, I think, because they are often thought of as specifications, as opposed to performance standards, with the latter, the performance standards, theoretically allowing for different solutions to arrive at a desired goal. I think we have to be a little bit more honest with ourselves in this area. All we can hope to achieve through formal regulation of work practices is really to take the cream off the top. Consequently, we, as occupational health professionals, will not be able to whip off the old standby solutions to a problem, in that they will be covered in a regulation. You're right; that's work, because we will have to dig in and come up with more detailed and specific in-depth recommendations to achieve the true goal of the standard.

As to biological and medical monitoring, again there seems to be the polarization that either they are the only requirements that should be in a standard or that they shouldn't be there at all. This philosophy must have crept into this program because I note that it states that a subsequent panel will discuss air *or* biological standards, as opposed to any possibility, apparently, that you might have either air *or* biological standards, or both.

I don't feel that either position alone is tenable. As I've stated before, prevention is not best done as the last line of defense. If the standards, where appropriate, identify safe and healthful work practices, backed up by both environmental and biological monitoring, we will be providing several lines of defense for the prevention of occupational illness, such that if one should fail, there are other safeguards. And I categorically state that anybody who says NIOSH's recommended standards rely upon or even emphasize only one line of defense, either he can't understand the English language or, more probably, he hasn't taken the time to really read our criteria document.

I sympathize with the concern for safeguarding the individual's rights as to confidentiality of information concerning his health, and, furthermore, that such results should not be used indiscriminately to deprive the worker from earning a living, especially where health degradation has resulted because of that specific employment. Apparently, however, safeguards to prevent these unfortunate happenings essentially lie outside the present authority of the Federal government.

In conclusion, for better or for worse, and in sickness — but, hopefully, in health, you have our recommendations. It is now in the public domain, and you, along with OSHA, have to move into the process of formal rule-making. We at NIOSH have done our best, and have already moved on to other concerns and problems.

Discussion

DR. NEELD (DuPont): Since Mr. Rose mentioned that he drew this draft up, I'd like to bring to his attention that on page 11, in the middle, under "Medical Biological Monitoring," where it talks about 0.08 mg of lead per liter of urine as an unacceptable . . . shouldn't that read "blood"?

MR. ROSE: I think my comment was that I was *not* involved in drawing this up.

DR. NEELD: I misheard you. Sorry.

MR. ROSE. Right. I would think if it does say 0.08 mg, obviously, it's referring to blood.

DR. MAJORIE LUNDQUIST (Globe-Union): I'd like to ask whether there is any plan in OSHA's plant evaluation of the final draft that they've put together to involve NIOSH medical personnel, so far as you know?

MR. ROSE: As far as I know, there is no plan to do that. The Office of Standards in OSHA has come up with this new approach to try out standards before they are promulgated, and it's not a cooperative effort at the present time.

MR. NELSON (American Smelting): Mr. Rose, you talked about the critical review given the literature and the very careful work done in the preparation of these documents. I have two comments; really, kind of complaints. One is that the advisory committees would meet, would discuss the subject in depth, and there would often be disagreement among the members of the committee. But then the committee would disband and some time later the document would appear. The committee members, in other words, had no opportunity to comment upon the draft of the document that was to be printed and distributed, and there was still disagreement among them. Yet, the document appeared with committee members listed, as though they had all agreed and this represented the consensus. That's one complaint.

A second complaint is that it was my understanding that only published literature was to be used, quoted at least, in these documents. And yet, in a recent one, I find unpublished articles referred to. Now, what are the rules?

MR. ROSE: As to your first point, this is something that you can also talk about to Herb Stokinger. It is something we face not only externally to the Institute, but also internally with our first review using NIOSH professionals. I understand your concern. We are not seeking consensus standard, and I hope everyone understands this. We don't have the years to wait to try to reach a consensus standard. The people who assist us are consultants. We ask for their best thoughts, their honest and professional input into that stage of development. After we've received their input, it is reviewed and is considered in our next draft. But, in no way, shape, or form do we plan on trying to arrive at a consensus standard, that is, to call the reviewers together again to resolve the issues.

In the preface to a criteria document, there is a statement which is probably sometimes lost or overlooked, which essentially says that although we've listed external and internal consultants, in no way does this mean that all of them agree or particularly disagree concerning the NIOSH recommendations or conclusions. We do not try to reach a consensus standard. That leaves us with a problem. Either (1) we don't use any consultants internal or external, or (2) we don't list their names, thereby recognizing the fact that they had input. Does anybody have any ideas as to how we might resolve this apparent problem?

As to unpublished literature, it is our basic rule that anything we reference or cite in a criteria document is public information. Consequently, if anybody sends us data that is not published, we advise them that it will become public information. If this is not agreeable, we will send the data back. Consequently, we do want to use the latest and most up-to-date information in our documents and we may, therefore, use unpublished information. But once the criteria document is published, our record is open and available for public inspection and, of course, if anybody wants copies of anything, we've referenced the data and it will be provided.

DR. STOKINGER (NIOSH): In possibly answering the complaint of the advisory committee members, couldn't we simply, in the document, preceding the listing of their names, merely state that NIOSH appreciated the contributions of the Advisory Committee Members, but does not necessarily agree to take all of their comments in final form?

MR. ROSE: Well, anybody who has served as either an internal or external reviewer, and would like to come up with a few words and mail them in to me, I guarantee you we'd be most pleased to take something like this and reflect it in our criteria documents. We need your continued input into these documents, either individually, later on when we hold professional symposia, and where we use professional societies. The professional societies are of tremendous assistance in the review process.

DR. COLE: Certainly, organized labor plays a very key role in judging and evaluating standards. We are very pleased to have with us today Mr. Sheldon W. Samuels, who is Director of Health and Safety and Environmental Affairs for the Industrial Union Department of the AFL-CIO. Mr. Samuels is located here in Washington. I found it particularly interesting, and I think we are quite fortunate to have Mr. Samuels with us today, because I notice that recently the Industrial Union Department has formed a lead task force and Mr. Samuels is listed as a consultant to this task force. So, welcome, Mr. Samuels. We're very pleased to have you.

MR. SAMUELS: Thank you very much. When Dr. Lynam invited me to participate, mostly because we couldn't find another person to do the job, I looked at him and I thought to myself, "He must be a masochist; he knows what I'm going to say." But then, since I'm a masochist for being here, why, I guess it's sort of a trade off.