HEALTH STANDARDS AND STANDARD SETTING IN THE UNITED STATES

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In the past, the setting of health standards has been as much art as science. In many cases, scientific documentation left much to be desired, but a time came when the scientist had to stop studying a problem and do something practical about it. Most of the health standards on the books today originated as educated guesses that had to be made to protect workers from disastrous effects. Refinements were made on the early standards as experience accumulated, but they were also largely guesswork. Later, organizations setting voluntary standards put some order into the setting of occupational exposure limits.

THE CONCEPTS OF HEALTH STANDARDS AND OCCUPATIONAL EXPOSURE LIMITS

For the purposes of this paper, I am approximately equating health standards and occupational exposure limits. A health standard is a limit on the presence in workroom air or in the body fluids of a toxic substance for which standardized sampling methods and analytic procedures have been specified. Health standards for prevention of occupational dermatitis and for controls of certain health hazards in the construction industry are seldom quantifiable in terms of mg/m^3 or parts per million; these standards are procedural and are similar to safety standards or codes of practice. Both safety standards and health standards have the connotation of being enforceable.

As for occupational exposure limits, the concept on which they are based is simple—that a toxic substance can be reduced to such a low concentration that it has no effect on health. This idea is reminiscent of the medical proverb, "A small amount of poison neither harms nor kills." In practice there are so many knotty problems to standard setting that it is a wonder that there is any consensus at all. For example, the spectrum of health effects is great, ranging from subtle psychological, physiological, and enzymatic changes at one end; through nuisance effects and the overt signs and symptoms we ordinarily recognize as occupational diseases; to excesses like cancer and the degenerative diseases and the shortening of life at the other end. A dose-response curve can be established for each part of the spectrum. Which one is to be used in setting the standard? In this country, we have attempted to draw the line before nuisance effects and overt signs and symptoms appear. In the future, more attention will have to be paid to precursor enzymatic changes and to changes in reaction time that could cause accidents. I do not think we will even get down to the fine point of using blink rates in setting health standards.

The most absolute protection against harmful substances would be to ban their use, but this measure would have profound economic consequences. The concept of occupational exposure standards therefore represents an attempt "to reconcile two requirements: continued use of certain chemical substances and safeguarding the health of the workers." This compromise concept is a direct quotation from a 1970 International Labor Organization publication, *Permissible Levels of Toxic Substances in the Working Environment.*[1] Anyone who stated that he would be willing to compromise the health of the American worker would be looked on as inhumane. Anyone who said that practicability demanded sacrificing a certain percentage of the working population would be accused of playing God. But before anyone reacts to the concept of setting occupational exposure standards, he should be aware that most of the materials for which new or improved standards are being considered are substances that have been in everyday use for many years, have considerable economic importance, and must now be controlled because of a chronic or latent effect that was not suspected when they were introduced.

Standard setters do sometimes make small compromises. Because of technological difficulties and hypersusceptibility, health protection afforded by occupational exposure limits is seldom absolute. For example, the industrial hygiene standard for chrysotile asbestos dust recommended by the Committee on Hygiene Standards of the British Occupational Hygiene Society purports to protect 99% of exposed workers from developing asbestosis.[2] The present 90 dBA noise standard is similar in that it protects about 99% of exposed workers, according to British criteria.[3] The Occupational Safety and Health Act (Section 2(b)(7)) provides for medical criteria that will assure, insofar as practicable, that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience.[4] This is a worthy objective, and it will be our guideline in setting health standards.

Problems of Standard Setting

In setting health standards, I anticipate two very knotty problems. One is hypersusceptibility and the other is the reconciliation of limits for workroom air with stricter ambient air quality limits. Under hypersusceptibility are included biologic variation and enzymatic aberrations, malnutrition, pregnancy, allergic hypersensitivity, and various other medical conditions. Do we lower the established workroom air limits that protect 99% of the workers or do we find screening tests to detect the small percentage of workers who are unusually susceptible? Actually, we will do both. Age, sex, and underlying disease all play a role in susceptibility. One of the earliest effects of carbon monoxide exposure is to increase the cardiac output—a potentially dangerous exposure for workers with cardiac problems. Female workers in general are less tolerant to heat stress than are male workers. Aging decreases physical capacity, reducing it by one-third by age sixty. In addition to studies on feasibility and research on hypersusceptibility, we will also have to look into the problem of multiple exposures. For example, heat exposure increases susceptibility to many airborne contaminants such as carbon dioxide and lead, producing a synergistic effect.

Ambient air limits for air pollution control and industrial hygiene limits for workroom air appear to be incompatible. For example, how can we permit occupational exposure to carbon monoxide of fifty parts per million for eight hours, time-weighted average, when the ambient air limit is a ten parts per million ceiling for an eight-hour period? Both industrial hygiene and air pollution limits recognize that people can be exposed to low concentrations of carbon monoxide without harmful effect. Some of the difference between the two types of limits can be explained on the basis of population differences. Compared to the general population, the employed population is much healthier. Ambient air limits are stricter because they must protect the very young, the very old, and the sick. Actually, these two types of limits were set by different groups of people, at different times, using somewhat different criteria. In the future, more attention will have to be given to correlation or reconciliation of these two types of limits.

Historical Background of Standard Setting

I have avoided mentioning threshold limit values (TLV) or maximum admissible concentrations (MAC) until now. The abbreviations mean different things to different countries and even in this country, within their originating organizations, the definitions have changed. As pointed out in the ILO publication,[1] there are generally two kinds of permissible limits:

1. Maximum admissible concentrations (MAC): absolute limits that should not be exceeded during any part of the working day. In other words, fluctuations are permitted, but they must occur below a ceiling. The C values of the American Conference of Governmental Industrial Hygienists (ACGIH) and most of the MAC's of the American National Standards Institute (ANSI) would be included in this category. The C listings are used for substances which produce intolerable irritation; chronic or irreversible tissue change; and narcosis of sufficient degree to increase accident proneness, impair self-rescue, or materially reduce work efficiency.

2. Threshold limit values (TLV): a time-weighted average in which fluctuations are permitted above the average, provided there are equal area excursions below the average. Some limitations are also imposed on the height of the excursion, depending on the toxicity of the substance.

Who devised the first list of permissible limits? According to the ILO, the USSR the first in 1933, followed by the Commonwealth of Massachusetts in 1937, and Germany in 1938.[1] The Z-37 Committee of ASA (now ANSI) began publishing exposure standards in 1941, using the term "Maximal acceptable concentrations." Originally, the Z-37 Committee's MAC was defined as a time-weighted average, but in 1963 the Committee redefined MAC to give it its present meaning of a ceiling below which all fluctuations should occur.[5]

The precursor of ACGIH's TLV Committee was established in 1941. A table of limits for 45 substances had been prepared in 1943 by the United States Public Health Service, but it was not until 1946 that the first list containing 144 recommended maximal allowable concentrations was adopted by ACGIH and published.[1] Although the term MAC was used, it referred to a time-weighted average concentration, not a maximal ceiling value. The name was subsequently change to TLV, and Dr. Lawrence Fairhall, a Public Health Service toxicologist, has been given credit for the term.[6]

Occupational exposure standards were originally based on short-term animal studies. For example, the first carbon monoxide limit was determined at the

Munich Hygienic Institute in 1883 based on exposures of twelve rabbits and two hens over a three-day period.[5] The next improvement in developing criteria for standards was the recognition of the need to study the occupational exposures of workers. Many of the classic limits, such as the basic quartz dust limit, were developed from Public Health Service studies in the granite and other dusty industries.

Current Practice

Today we recognize many data sources in developing occupational exposure standards. For example, there should be short-term animal studies designed to provide information on the LD 50; acute toxicity by three routes—ingestion, inhalation, and percutaneous absorption; irritation of the eyes and skin; and skin sensitization. Long-term animal studies are designed to solve such problems as neoplasms and chronic toxicity, especially in the lungs, liver, and bone marrow.

Because animal toxicity data are not directly translatable to man, it is sometimes necessary to conduct short-term human exposure studies to answer questions about discomfort, irritation, and sensitization. Long-term epidemiologic studies are necessary to answer questions about chronic effects or neoplasia, and all too frequently there are no occupational groups that have had low levels of exposure.

In selecting a limit based on health effects, a safety factor is frequently introduced, varying with the seriousness of the response. A sampling instrument and analytic method are specified and become an integral part of the hygienic limit. The last step in selecting a limit is a feasibility study to see if control measures are available. Questions are always raised about economic impact, and it is also necessary to estimate the cost of controls.

Some concern has been expressed about the greater stringency and impracticability of the Soviet ideological standards for workroom air quality. The Soviets use more sensitive indicators of physiological and psychological response than we do in setting their industrial hygiene limits; regardless of the values set, the optimum value and goal to be sought is zero concentration.[7, 8] In a comparison of USSR and ACGIH limits made recently by the ILO,[1] there was close agreement for 24 industrial and/or agricultural chemicals, but there was considerable variation for a comparatively large number of other toxic substances. Attempts have been made to reconcile the differences between the USSR and ACGIH limits, but without success, since the Russians have not published their documentation in a single document as the ACGIH has done. Documentation of 77 MAC values in Czechoslovakia has recently been compiled and translated,[9] but this document, little more than a summary of the literature, has been of little help.

In closing, I would like to say a few words about the present United States limits for respirable coal dust and to compare the division of standard setting responsibility under the Federal Coal Mine Health and Safety Act of 1969 and that under the Occupational Safety and Health Act of 1970. The present standard for coal mine dust (3 mg/m^3) specified initially in the Coal Mine Health and Safety Act was developed by the Public Health Service in the fall of 1968, prior to the Farmington, West Virginia, coal mine disaster. It was based on epidemiologic studies by the United Kingdom's National Coal Board, the results of which indicated a linear relationship between mass of respirable coal dust and x-ray progression of disease, and on limited feasibility studies by the Federal Bureau of Mines. The feasibility of a 3 mg/m^3 standard was later confirmed by ventilation experiments initiated by the Federal Bureau of Mines.[10] The National Coal Board has prepared a more recent statistical analysis of their epidemiologic data, in connection with a new dust standard for British coal mines.[11]

The Federal Coal Mine Health and Safety Act gave the Department of Health, Education, and Welfare the responsibility for setting health standards for coal miners. This separation of standard setting from enforcement is commendable in that the enforcement agency is not setting the health standards they are to enforce; but on the other hand, the researchers are not as familiar with the practical problem of enforcement. The division of responsibilities under the Occupational Safety and Health Act is slightly different in that HEW has responsibility for both health and safety research and develops the criteria on which standards are set by the Department of Labor. The Act gives the Secretary of Labor the responsibility for determining the priorities for standard setting, but requires that he give due regard to the recommendations of the Secretary of HEW. The working relationship between the two Departments has been excellent and I think we have developed a true team approach to the problem of standard setting.

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DISCUSSION

Merle Bundy, *Moderator*

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DR. SANSONE (*University of Pittsburgh, Pittsburgh, Pa.*): I believe Dr. Jacobson said that the percentage of mines in your study that were in compliance went from 18 to 71%, from June, 1970 to June, 1971. I think it would shed some light on the other papers concerning themselves with dust control if we could be told what operational procedures were used to bring about this compliance in three-quarters of the mines.

MR. MURRAY JACOBSON: Let me correct the date. Our initial survey date was 1968–1969. The only two things that were used were those which were available, water and ventilation.

DR. SANSONE: If that is the case, let me ask a further question. Would you estimate the prospects for those mines that are not in compliance to come into compliance with the proper use of water and ventilation?

MR. JACOBSON: As far as the 3-mg-per-cubic-meter standard, which will exist until December 30, 1972, is concerned, there is no reason why any of these mines, with the exception of one type of mining, should not reach it. The exception may be the longwall system, where there is inadequate experience. I'll hesitate to say that 100% can reach 2 mg/cubic meter, but I see no reason why they couldn't reach 3 mg.

DR. JAN LIEBEN (*Philadelphia, Pa.*): I'm very much impressed with this success story which you have given us, and I wonder what safeguards you use to make sure that the samples reported are representative of the conditions under which the miner actually works.

MR. JACOBSON: I can only say the samples are representative of the conditions that the men worked under the day they were sampled. We have something else. "Technical Progress Report No. 32" brought up to date all the information we had up until the end of March this year. This was compared with the inspection data. They were remarkably close. The results show what can be done if somebody holds a club to you and says you do it or else.

DR. LIEBEN: What I really wanted to know is what method was used to make sure that the samples are taken at a certain time, at a certain place, under certain circumstances:

MR. JACOBSON: The law states that the operator has a responsibility to take these samples in the manner which we have prescribed. We have trained over 4,000 people in the procedures for sampling and evaluating respirable coal mine dust. They are not in the weighing area but in the operation and calibration of the samplers. We run a continuous quality control on the manufacturers who make the cassettes, NIOSH approves the performance of the personal samplers, and there are spot inspections. Of course, this is spot surveillance, not a continuous surveillance program. Yet, surprisingly, the data are fairly close to what we found under a total surveillance program, when we were there all the time.

DR. HARRY HEIMANN (*Mount Sinai School of Medicine, New York, N.Y.*):

Mr. Jacobson, would you tell us of the size distribution of the respirable size particles that were collected?

MR. JACOBSON: There is pre-size selection of the instrument itself. One unit has an upper limit of 7 microns aerodynamic equivalent diameter, and the other has a 10-micron upper aerodynamic equivalent diameter. At the operator's position, we're primarily talking about approximately 1 micron geometric mean diameter by count, and somewhere between 2–2½ geometric standard deviation, determined the same way. This is at the continuous miner's position.

DR. PAUL DESSAUER: Mr. Jacobson, do we have any information relative to compliance concerning how much the production cost of a ton of coal was increased?

MR. JACOBSON: No. Dr. White, I was surprised that you found no ash material. Our normal ash content on respirable samples will run anywhere from 20–45% ash. This can be anything, including the rock dust or limestone. The fact that you found none in particular samples may be that only a limited number of samples have been studied.

DR. E. W. WHITE: We did find ash mineral particles, although infrequently, perhaps one particle in 200–500. Of course, any given coal particle itself has an inherent ash content.

This was our finding with regard to the 0.5-micron or larger fraction. The instrumentation as we had set it up did not have proper dwell time for particles smaller than 0.5 microns for reliable chemical tagging. This can be rectified by slowing it down, which we're now doing. We're quite certain we can work down to 0.1–0.2 microns for the tagging.

I interpret our data to perhaps imply that the ash particles that must be there are in the minus-0.5-micron size fraction.

DR. CARL MAGGIORE (*Mt. Sinai School of Medicine, New York, N.Y.*): What is the smallest particle that you're able to identify and what particular mineral phases are you able to identify unambiguously? What sort of confidence would you give to your identification of those mineral phases?

DR. WHITE: As the initial recordings were made, we didn't have confidence in chemical identification below 0.5 microns. Now we're quite certain of being able to say, with confidence, that a given element is present as a major constituent at 0.1–0.2 microns.

If just calcium is found, we assume it's a calcite, probably a rock dust fragment. If only iron is found, then we assume it is an iron oxide. If just silica is present, we're likely safe in calling it a silica particle. In order for it to be any of the minerals other than free silica, there would have to be calcium or potassium or aluminium.

DR. MAGGIORE: One further question: In our probe work, we've looked at the problem of the visibility of small particles, particularly particles less than a tenth of a micron. Our experience has been that if, instead of looking at the secondary electron signal, which is dependent basically on the topography of the specimen, one looks at the transmitted electron signals, the smaller particles are much easier to detect.

DR. ROBERT W. FREEDMAN (*Bureau of Mines, Pittsburgh, Pa.*): I generally think in terms of quantitative analysis. What is the prognosis of this type of analysis in terms of weight per hour? What part of a milligram or picogram could you analyze in an hour? For example, there are, let us say, 10^9 spherical or cubic particles per milligram. How many of those do you think you can scan in a given time?

DR. WHITE: I can scan, on a number basis, several thousand. By the same token, of course, although we have the problem of being sure that our sampling is representative, you also sample only so many liters per day, yielding a few milligrams of the total tonnage of dust produced in a mine. I don't see that our sampling problem is any different from yours.

DR. FREEDMAN: We're able to check the larger samples by various methods. We know that if you sample a milligram of dust in the respirable range, that's rather representative. If one talks of picograms, I'm not so sure.

DR. WHITE: We can take multiple samples from the same samples, subsamples, to check the precision of the method.

DR. IRVING J. SELIKOFF: Epidemiologists have a request to make of the physical scientists. Perhaps it ought to be addressed to the Bureau of Mines. We are making a decision to expose a new generation of miners in this country to what we believe is going to be a safe dust level. We're certainly going to decrease the mass of dust a great deal, but I don't know if we're going to decrease the number of inhaled particles very much. I would hope that in these next years people like Dr. White be supported very strongly by the Bureau of Mines, so that we might monitor the fine dust qualitatively and quantitatively, as he has done. It would be well to develop a body of experience very rapidly, so that we will be able to judge what happens to the mining population that is now to be exposed.

DR. IAN WEBSTER: Mr. Chairman, this is one of the discussions that as a medical officer one doesn't know whether one should take part in or not. Industrial hygienists are rather suspicious of medical officers in South Africa, and I debated as to whether I should take part. I would like to tell Dr. Selikoff that this paper is one of the most significant papers that we've heard at this conference. It was, however, at variance with what we heard about pathology. Your high dust count was 1.15–2.0 mg per cubic meter. Yet, in the United States you're causing far more coal workers' pneumoconiosis than we are in South Africa at say an average of 7 mg per cubic meter. Why?

You say that 40% of your miners wear respirators. We mine at 500–600 feet. We can't get the miners to wear respirators—not even 2% of our miners wear respirators. You mentioned that respirators leak. Respirators shouldn't leak, if one has an industrial hygiene program that sees to it that the respirator fits. The respirator must be individual, must be one that fits on to the mouthpiece or on to the facepiece, with a special shape for each particular type of face. It must be one that is tested every time a person goes underground. And even then, you will never get a person to use it for eight hours.

You say that you are worried about the type of respirator, whether a 75%-efficient respirator or a 99%-efficient respirator. This is a worry all over the world. I would opt for a less efficient respirator worn for a reasonable length of time than a 99%-efficient respirator worn for a short time.

DR. PARKER REIST: Perhaps I failed to make myself clear. We were not trying to show the incidence of pneumoconiosis in this particular paper. We chose a mine that happened to be convenient. It demonstrated one particular type of mining. We wanted to study what the effective protection factors of respirators would be. We didn't think it necessary to pick a mine that had very high dust levels to demonstrate this. We were interested in what sort of protection effective factor a man could expect when wearing a respirator.

DR. LORIN KERR (*United Mine Workers, Washington, D.C.*): Also, in reference to the question that was asked, the amount of pneumoconiosis being reported in the country is a reflection of dust levels prior to the enactment of the law, which did not go into effect until December 30, 1969, with the dust work being done in June of 1970.

However, there are two questions I would like to ask. Did you talk to the men on or off the job? Second, did any of the men, when you were talking to them, indicate that if the dust levels were down to the point where they should be, the masks would not be necessary except in extreme instances?

MR. HOMER E. HARRIS (*Eastern Associated Coal Corp., Pittsburgh, Pa.*): If dust levels get down low enough, would the people wear respirators? A number of people told us that there would be a need in the future. They simply said yes, we're going to need respirators, and we are going to need them for a long time to come.

Did we interview men on or off the job? Generally, we talked to the men as they reported for work, before they went underground, but in most cases we did not talk to them in the presence of the supervisory personnel. In some cases, we went underground and talked to the men while they were working there.

Now, in answer to Dr. Webster: At the time this particular survey was made, all of the sections were in compliance.

DR. J. S. MCLINTOCK: I found this paper most interesting for quite another reason. We have respirators in Britain that are reputedly 95% effective in the laboratory. When mining engineers hear that these respirators are 95% effective and water spray only 75–60–50% effective, there is a very great tendency for them to overemphasize the use of respirators. We have not yet done studies comparable to those of the speakers, but if personal experience and hearsay evidence are any guide, the human nature of miners in Britain and in America is exactly the same. We don't find any greater usage than during about 20–30% of the working time at most.

MR. HARRIS: I think it's very important to emphasize that even though perhaps a rather substantial number of people make use of respirators, it is on an intermittent basis. We think the estimates of the time the men wear them is high. Furthermore, I think we should emphasize the fact that there is inconvenience and discomfort associated with all the presently available units, so people are just not going to wear them continuously.

QUESTION TO DR. KEY: Few in the field of Occupational Health or Public Health take issue with the philosophy of standard setting. But in taking a sample, there are often gross errors, at all times, errors in sampling, errors in analytical procedure. Can we then set a single number standard, recognizing the fact that we cannot, with any high degree of accuracy, determine the concentration of a particular contaminent in the air, exactly.

DR. MARCUS KEY: Would you be willing to add up all the errors, the errors of the sampling method, the errors inherent in the dispersion of the dust cloud, the errors in the weighing method? And add this to the limit and use it as a ceiling value? If the limit is 3 and the sum total of all the errors was 1½, would you mind having a ceiling value of 4½ mg per cubic meter for a single sample, in addition to using a time-weighted average?

COMMENT: In the case of dust, we can consider a range; in the case of coal dust, plus or minus a half a milligram, without creating any great problems. In terms of the gases and vapors, fewer data are available, but I think we can establish a range, in recognition of the normal errors that occur in sampling and analysis of the particular samples.