

An Industrial Hygienist's Perspective On Generic Standards

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Although our past approach to standard-setting was appropriate for the time, history has taught us that the *framework* for standards is remarkably similar and that the 1990s warrant primary concentration on generic standards without abandoning a *mechanism* for supplementary substance-specific requirements where appropriate.

Pitfalls are undeniably associated with generic standards, but the advantages far outweigh the disadvantages. The precedents recently established by regulation, which I will briefly discuss, have created an opportune climate.

Of immediate and urgent importance is the need for a generic monitoring standard. Certainly the required elements of such a standard have become clear, and certainly it is defensible to support the right of workers who are significantly exposed to toxic materials to know what their exposure is.

Three historical endeavors come to mind when I think of generic standards: the joint OSHA/NIOSH Standards Completion Program, the OSHA Generic Carcinogen Policy, and the OSHA Hazard Communication Rule. The first two, although they failed, were probably ahead of their time and should be looked at again with today's hindsight. The Hazard Communication Rule set the stage for generic standards in the 1990s. I would like to discuss each of these briefly.

OSHA/NIOSH STANDARDS COMPLETION PROGRAM

In the mid-1970s, NIOSH and OSHA jointly undertook a massive multimillion dollar effort entitled the Standards Completion Program, intended to meet the mandate of the Occupational Safety and Health Act (Public Law 91-596, Sections 6 and 8) to provide requirements to protect employees beyond simply a Permissible Exposure Limit (PEL) when the potential for overexposure to chemical substances existed. The effort attempted to push through to promulgation expanded standards for groups of similar substances, but it was doomed to failure because the substance-specific approach hopelessly overloaded OSHA. The legacy of this effort was the logic used to formulate the expanded requirements. What we should consider for the 1990s is promulgation of a modern version of this logic as a complement to specific numbers.

By logic, I mean the decision process that systematically leads to a specific requirement. If the decision process can clearly be spelled out in regulations, or even not so clearly spelled out guidelines can be published, we will have achieved our objective.

The OSHA/NIOSH Standards Completion Program resulted in a comprehensive framework for standards—definitions, the concept of an action level, and all of the elements considered a part of expanded health standards that are promulgated today, including exposure monitoring, use of respirators and other personal protective equipment, sanitation, training, medical surveillance, record keeping, and use of nonmandatory appendices.

OSHA GENERIC CARCINOGEN POLICY

In the late 1970s an ambitious effort was undertaken by OSHA to develop a generic policy for carcinogens.² The effort captured the attention of all regulatory agencies as well as the broad public health community. A record 250,000 pages of extensive public hearings were produced. The effort, which remains perhaps the best example of an attempt to put into place a generic approach considering scientific uncertainty, unfortunately was never finalized. The policy prescribed the logic to be used to determine if a substance was to be considered a carcinogen, and the specific requirements to be contained in regulations for those substances meeting the criteria. It was reasoned that if agreement could be reached on the generic issues, they would not need to be reargued each time a substance was considered for regulation. The idea of reaching such agreement could be extended to the criteria for defining a "toxic" substance or a "significant exposure level."

OSHA HAZARD COMMUNICATION RULE

The OSHA Hazard Communication Rule (29CFR 1910.1200) broke significant new ground by requiring employers to identify and maintain a list of all "toxic materials" known to be present in their workplace and to inform workers of the hazards. The Rule defined what was meant by "toxic" (i.e., one positive study conducted in accordance with established scientific principles; oral LD₅₀ < 50 mg/kg, rats; dermal LD₅₀ < 200 mg/kg, rabbits; inhalation LC₅₀ < 200 ppm or < 2 mg/liter, rats), but it did not specifically provide or reference any one listing or address what constituted a significant exposure level.

These attempts at generic standards lacked at least two fundamental concepts that should be considered in the future. First, there was no recognition of or requirement for a "qualified" or "competent" person with a mandated occupational safety and health responsibility to identify and quantify exposures and to develop a management plan for controlling exposures to toxic materials. Second, there was no recognition that employers who use toxic materials in significant quantities should have a basic occupational health program. I find it interesting that the precedents for these two missing regulatory ingredients can be found in recent EPA legislation.

THE ASBESTOS HAZARD EMERGENCY RESPONSE ACT (AHERA)

On October 22, 1986, President Reagan signed Public Law 99-519, the Asbestos Hazard Emergency Response Act of 1986 (AHERA).

AHERA amended the Toxic Substances Control Act (TSCA) to require the Environmental Protection Agency (EPA) to promulgate regulations requiring

every school district to conduct inspections for asbestos-containing material in all school buildings, and to develop management plans and appropriate response actions, using accredited individuals, to deal with asbestos-containing materials in schools.

AHERA established a Model Accreditation Plan specifying in great detail the amount and content of training that individuals involved in asbestos abatement activities in schools must receive. Workers, contractors, supervisors, project designers, inspectors, and management planners all must be accredited for the type of work they perform. Further "awareness training" is required for all custodial and maintenance personnel with additional requirements for those who come in contact with asbestos-containing materials.

Using accredited individuals, school districts must inspect every school building for the presence of asbestos-containing material, must develop a management plan for each school building, must develop an ongoing operations and maintenance program for any school building where asbestos exists, and must reinspect buildings with asbestos at least every 3 years. Specific requirements are established for determining whether materials contain asbestos as well as for air sampling in an attempt to ensure that air levels are not increased as a result of abatement actions.

There are lessons to be learned from the AHERA legislation. Although it currently applies only to public and private schools, kindergarten through grade 12, legislation has already been introduced that extends it to all public buildings. The next logical step is to look beyond asbestos to all toxic materials.

Fundamental to taking this next step and to developing generic standards in general is the well-recognized and controversial need to define what is meant by "toxic" and "significant exposure." I simply propose that on a regular basis NIOSH publish a listing of recognized safe exposure levels. I call your attention to Section 20(a)(6) of the OSHA Act (Public Law 91-596) which mandated NIOSH . . . "to publish . . . at least annually a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur." NIOSH has addressed this mandate by publishing the Registry of Toxic Effects of Chemical Substances (RTECS), which identifies those compounds having recognized safe exposure levels. What is needed is merely a sublisting of RTECs, which would become a standard guidance document for employers. I define "recognized" as referring to established organizations, principally OSHA, NIOSH, and ACGIH, who establish or recommend exposure limits.

I further propose that "significant exposure" be defined as exposure in excess of one half the *lowest* recognized safe exposure level that occurs either under normal conditions or in a foreseeable emergency. These levels could be referred to as action levels. The idea of action level triggering monitoring, medical and employee information, and training requirements is not new, having originated as previously mentioned in the Standards Completion Program and having become an expected ingredient of modern standards.

I next propose that generic standards of the 1990s require the use of "competent" persons. OSHA, in its new Asbestos Construction Standard (29 CFR 1926.58, effective July 21, 1986), for the first time in its history, introduced the requirement for a competent person, defining him or her as "one who is capable of identifying existing asbestos in the workplace and who has the authority to take prompt corrective action to eliminate [asbestos]." The duties of the competent person [were defined to] "include at least the following: establishing the negative-pressure enclosure, ensuring its integrity, and controlling entry to and exit from

the enclosure; supervising any employee exposure monitoring required by the standards; ensuring that all employees working within such an enclosure wear the appropriate personal protective equipment, are trained in the use of appropriate methods of exposure control, and the use of hygiene facilities and decontamination procedures specified in the standard; and ensuring that engineering controls in use are in proper operating condition and are functioning properly (p. 22756).” The standard further explains that “the competent person will generally be a Certified Industrial Hygienist, an industrial hygienist with training and experience in the handling of asbestos, or a person who has such training and experience as a result of on-the-job training and experience (p. 22780).” . . . “The competent person shall be trained in all aspects of asbestos . . . abatement, the contents of [the] standard, the identification of asbestos . . . and their removal procedures, and other practices for reducing the hazard, such training shall be obtained in a comprehensive course, such as a course conducted by an EPA Asbestos Training Center, or an equivalent course (p. 22757).”

RECOMMENDATIONS

If the definition of toxic substance and significant exposure, and the need for a competent person defined to be an industrial hygienist are accepted, I can conclude with a recommended generic standard involving six elements, which for political expediency, may be considered independently. These six elements are: (1) initial determination; (2) employee-exposure monitoring; (3) medical surveillance; (4) sanitation; (5) training and education; and (6) the management plan.

Initial Determination

I am convinced that many, if not most, overexposures to toxic materials that are occurring in the workplace are unrecognized by employers and employees. Each employer should be required to conduct an initial inspection of his or her workplace, using a competent person, to determine if exposures in excess of action levels are present. This initial determination may not require air sampling, but it may be based on objective data supported in writing by a competent person. The only burden on employers at this point, beyond that already required by the Hazard Communication Rule, would be to assess the potential for exposure in excess of action levels. If employees are likely to be exposed in excess of action levels, then the remaining five “preventive health” elements would be required.

Employee-Exposure Monitoring

When exposures are in excess of action levels, periodic monitoring by competent persons “at such frequency and pattern to represent with reasonable accuracy the levels of exposure of employees” should be required. In no case should sampling intervals be greater than 6 months. If periodic monitoring reveals that exposures are below action levels, the employer should be allowed to discontinue monitoring until there is reason to suspect that exposures may be increased above action levels as with a change in production, process, control equipment, personnel, or work practice.

The requirements for an initial determination with subsequent employee-exposure monitoring, when warranted, could be combined into a generic monitoring standard. Such a standard, in my opinion, is long overdue and urgently needed.

Medical Surveillance

Medical examinations should be made available at no charge to employees exposed in excess of action levels. The current proposed high-risk occupational disease and prevention legislation provides for medical examinations of high-risk employees. However, periodic medical examinations should be routine for all workers exposed to significant levels of toxic materials. Examinations could be performed by a physician's assistant, nurse practitioner, or other health professional, acting under the direction of a physician, to reduce the burden on existing medical facilities.

Sanitation

Laundering of contaminated employee work clothing should be required when a toxic material may cause acute or chronic illness due to resulting exposure if the employee wears the contaminated clothing home. The definition of toxic could be the same as that used in the Hazard Communication Rule.

Employees exposed to toxic materials should be provided showers.

Training and Education

Employees should be informed of the nature and possible effects that could result from overexposure to toxic materials consistent with the OSHA Hazard Communication Rule.

Management Plan

Employers should be required to develop and maintain a management plan for controlling exposures to toxic materials in their workplace. One essential element of such a plan should be the long recognized principle that engineering controls should be implemented wherever and whenever feasible to reduce employee exposure, before reliance on respiratory protection is permitted.

I propose that employers who have exposures in excess of recognized safe exposure levels, but not in excess of PELs (accepting that a PEL may not exist), should not be *required* to take corrective action to reduce exposure unless they are in excess of established PELs. The conservative tendency, however, would be to control exposures below recognized safe exposure levels, to avoid liability, and even further below action levels, to avoid the requirements of the generic standard discussed earlier. We all know that the fear of liability often forces compliance with recommended levels and accepted state-of-the-art good work practices.

Accreditation of Competent Persons

NIOSH could establish minimal criteria for competent persons. As a minimum, these persons should be trained industrial hygienists. Perhaps multiple levels of accreditation should be considered, with larger programs required to be under the supervision of a board-certified industrial hygienist. Smaller employers would not require these individuals on a full-time basis, but they could contract for their services from consulting firms. NIOSH could approve training programs and serve a quality control function.

Implementation

It could be argued effectively that this proposal would overwhelm our current resources in occupational health, particularly industrial hygiene. It would seem reasonable to provide a phase-in plan, requiring initial compliance of larger employers with timetables for smaller employers.

CONCLUSIONS

Regulatory activity in the 1990s should first reassess, refocus, and broaden current approaches by defining what is meant by significant exposure. Once this is accomplished, a generic standard (or standards) should be proposed that relies on a competent person and that involves the requirements for the following:

1. Initial inspection of all workplaces to determine the presence of toxic materials consistent with the requirements of the OSHA Hazard Communication Rule and further the potential for significant exposure;
2. Periodic exposure monitoring of workers in excess of action levels (i.e., one-half the recognized safe exposure levels);
3. Medical surveillance for all employees exposed significantly (i.e., in excess of action levels) to toxic substances;
4. Sanitation, including laundering of contaminated work clothing and providing shower facilities;
5. Training and education, on a regular basis, of all employees who are significantly exposed; and
6. A management plan for controlling exposures to toxic materials, incorporating the basic requirement that engineering controls must be implemented, in preference to personal protective equipment, wherever feasible to reduce exposure.

It is neither unreasonable nor indefensible to require that employers who have employees exposed to recognized toxic materials identify that exposure, quantify it, provide basic medical surveillance to ensure workers are protected, and to inform workers of the nature and magnitude of their exposures. It could be conceded that a requirement to control levels below Permissible Exposure Levels, which have been carefully evaluated and considered as part of a formal extensive rule-making procedure, may place an unjustified burden on employers and put organizations who recommend safe exposure levels in an inappropriate regulatory position. Thus, required Permissible Exposure Levels could continue to be promulgated, but far more expediently. The time is opportune to move forward to promulgate generic standards to achieve these objectives.

SUMMARY

OSHA and EPA regulations promulgated to date contain the necessary framework to consider generic standards in the 1990s. Missing in OSHA standards has been the requirement for a competent person to define and manage an occupational health program and the requirement for all employers who have toxic materials with significant exposures to have a basic occupational health program. Certainly we have evolved to a point where every worker significantly exposed to toxic materials has a right to know what that exposure is.

Fundamental to generic standards is the need to define what is meant by toxic substance and significant exposure level. It is suggested that NIOSH maintain a list of recognized safe exposure levels that have been recommended by credible organizations including NIOSH.

It is suggested that action levels be defined as one-half the lowest recognized safe exposure level. It is proposed that all employers be required to conduct an initial inspection of their workplace, using competent persons, to determine if exposures exceed action levels. This is only one step beyond the requirements of the OSHA Hazard Communication Rule which requires that employers identify and maintain a list of all hazardous materials known to be present in the workplace and to inform workers of the hazards.

If exposure levels are found in excess of action levels, then the basic elements of current standards would be required, including regular employee-exposure monitoring, medical surveillance, sanitation, training and education, and a management plan.

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