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Vincent, James H
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International Occupational Exposure Standards: A Review and Commentary

AUTHOR
James H. Vincent

Department of Environmental and Industrial Health, School of Public Health, University of Michigan, 109 S. Observatory Street, Ann Arbor, MI 48109-2029; jhv@umich.edu

This article is a report of work carried out during visits to Australia, Britain, Norway, and Russia for the purpose of becoming acquainted with the various processes of setting occupational exposure standards in those countries. The article reviews the processes by which occupational exposure standards are developed from country to country, examines the role of the occupational hygiene discipline in their development and implementation, and reflects on the complex philosophical and practical issues that surround them and the prospects for international harmonization.

Keywords: international, occupational exposure limits (OELs), occupational health policy

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The subject of occupational health touches on many disciplines. An occupational health policy is the outcome of political behavior by which individuals or groups of individuals, often representing parties with competing interests, strive to influence an endpoint in the form of occupational health-related legislation and regulation. That general endpoint is based on consensus about the ways in which occupational health is valued in a responsible society. A specific regulation derives from the specific value that society gives to a particular aspect of occupational health, and to the factors that influence it or are influenced by it. If the policy is an envelope that identifies the scope for implementation of the regulation, incorporating all the other factors that society at large needs to take into account, a standard is defined as a measurable reference point consisting of specific guidelines by which the desired objective can be quantified and achieved.

In general, there are different types of standard that may relate to a wide range of aspects of the system of interest, and these may include guidelines for design, operation, performance, etc. One area of occupational health policy concerns the standards by which workplace environments and workplace practices may be properly maintained to avoid occupational sickness and injury arising from occupational exposure to hazardous substances or agents. Occupational hygienists are an important interest group in this scenario. These are people with multidisciplinary scientific training traditionally grounded in the major core subjects of physics, chemistry, biology, and mathematics and statistics, along with toxicology, physiology, epidemiology, environmental health and biostatistics, working alongside—and complementary to—occupational health physicians, toxicologists, and nurses. Whereas these professionals come to occupational health primarily from the scientific perspective, it is, however, a fact of life that much of what is embodied within occupational health standards policy falls outside the scientific domain and into the area of the socioeconomics and sociopolitics. As a result, the dialogue about occupational exposure standards may involve interesting interdisciplinary debate among groups that are (frequently) in competition or find it difficult to communicate with sufficient eloquence across disciplinary boundaries. In turn, therefore, the dynamics of the development and implementation of occupational exposure standards are complex and fraught with many problems.

This article is a report of work carried out during December 1996 to March 1997 that involved trips to Australia, Britain, Norway, and Russia to participate in seminars; extensive discussions with scientists, officials, and policy makers; and meetings of national standards-setting bodies. The purpose of the exercise was to become acquainted with the various processes of setting occupational health exposure standards in the countries visited: to examine similarities and differences and so identify what is generic. The article is in two parts. The first articulates a generic model for an occupational exposure standard, reviews the contrasting standards-setting

APPLIED STUDIES

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philosophies and processes in the countries visited and in the United States, and identifies the roles of the occupational hygiene discipline and community in those countries. The second part springs from both the factual information that was gained during the visits and the many philosophical discussions that took place. It comprises a commentary on what parts of standards setting can be described as "scientific" (and hence potentially generic to all), reasons why there are disagreements among scientists in so many areas, the points where politics and other nonscientific considerations enter the process, the extent to which science is ultimately significant in the way occupational standard setting plays out in reality, and the inevitable changing face of occupational hygiene. Ultimately, it is hoped, discussion of these issues should illuminate the path toward at least some degree of international harmonization of occupational health standards.

A FRAMEWORK FOR OCCUPATIONAL EXPOSURE STANDARDS

In the context of occupational health, the term *hazard* is used by many to refer to an intrinsic property of an agent that reflects its potential to cause harm. On the other hand, *risk* reflects the probability of actual harm under the conditions where the agent is encountered. Although these are not the same, they are frequently confused. For practical purposes, therefore, it is perhaps more helpful to think in terms of the more accessible index, *exposure*, one definition of which might be "the intensity, time-averaged in some appropriate way, of the agent of interest at the relevant interface between the environment and the biological system representing the worker." It is exposure that drives the risk and so is most directly the object of control strategies. So it would appear to be a good basis for a standard.

If the definition given is applied to an airborne chemical that may be inhaled, the "intensity" is then the airborne concentration (say, in milligrams per cubic meter) and the "relevant interface" is the region of the respiratory tract where the agent first comes into contact with the exposed subject at a location where it can influence the outcome of the disease in question. So, for example, for dust exposure in relation to silicosis, a disease of the alveolar region of the lung, the exposure of interest is the concentration of inhaled particles of crystalline silica that are small enough to penetrate down to and deposit in that region. A standard for silica therefore aims to lower exposure to those most relevant silica particles so that the risk of silicosis is minimized. If no silica particles can penetrate down to the alveolar region, that risk becomes zero. More widely, the general definition of exposure applies directly also to other chemical agents that occur in the forms of gases and vapors, as well as biological agents in the form of fungi, bacteria, viruses, etc. Even more widely, it also applies to physical agents (e.g., noise and vibration, ionizing and nonionizing radiations, heat, etc.).

From the definition of exposure comes the concept of an occupational exposure limit (OEL), reflecting the maximum level of exposure that can be accepted (according to whatever definition of *acceptable* is applied). In turn the OEL becomes an important component in an occupational exposure standard. The other important components are exposure measurement and, where appropriate, exposure control. An ideal health-based standard should therefore contain:[1]

(1) Criteria for exposure, which identify the agent and its specific physical, chemical, and/or biological properties relevant to a specific adverse health outcome.

(2) Reference to monitoring instruments and analytical methods with performance characteristics matching the defined exposure criteria.

(3) Reference to a monitoring strategy that sets out to assess exposure in a manner representative of the temporal histories and variability of workers' exposures.

(4) A health-based OEL based on considerations of the effects of exposure at various levels, known incidences of the prevalence of the health outcome in question, and what might be an "acceptable" level of risk.

When the standard is set out in this way, it becomes obvious that, strictly, an OEL cannot be assigned until consideration has been given to the other items listed. This becomes particularly clear for aerosol exposures where the evaluation of the health effect includes not only consideration of the intrinsic toxic properties of the particulate material in question but also its physical properties (i.e., particle size, shape, density), which govern how the particles are transported within the respiratory tract. For such exposures, research has delivered a good understanding of the physical nature of how airborne particles are inhaled and, based on knowledge of nasopharynx and lung physiology, how they penetrate to and are deposited in the various parts of the respiratory tract. From such understanding, particle size-selective criteria have been proposed that in turn may be linked with specific types of health effect. Such criteria provide quantitative guidelines for the design and testing of sampling instruments that can collect particles in a manner appropriate to the health effect of interest. To a large extent we now know how to design and test such instruments. In addition, analytical instrumentation is available that can quantitate the sampled fractions that belong in specific chemical groups. Further, the statistical properties of worker exposure across a wide range of industries have been studied extensively so that contributions to within and between-worker exposure variability are well understood.[2] Therefore, it is fair to say that, for these parts of the standard, there is the potential for wide international agreement based on science.

But, even if we can assert that scientific agreement on these parts of the standard is within reach, the setting of the actual numerical value for the OEL is much more problematical. For a single, relatively well-defined adverse health outcome in a single subject, the principle of the OEL is usually discussed formally by reference to the hypothetical "dose-response" curve, which relates the probability of the outcome arising from a given exposure. Usually this is accompanied by the assumption that the exposure occurs day after day for the complete working life of the subject. Most idealistically, the OEL may be defined by the point in the curve below which the outcome becomes unobservable (the no-observed-adverse effect level, NOAEL). But such a curve may or may not have a threshold in reality; and, even if it does, the threshold may not be observable. Further, for a whole population of such subjects (as is more relevant for an actual occupational exposure standard), the curve becomes bounded by uncertainties arising from intersubject variability in the population in question. In addition, there are further uncertainties that derive from the quality and quantity of the available experimental or observational data. As a result of all these factors, it would therefore appear that the strict NOAEL concept is not in itself very helpful in setting practical OELs. Rather, to be realistic, some judgment is required that allows for the inevitable uncertainty that exists. This is usually achieved by the application of certain language that provides the necessary flexibility. Carter,[3] for example, refers to "the ability to identify, *with reasonable certainty*, a concentration averaged over

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a reference period, at which there is no indication that the substance is *likely* to be injurious to employees if they are exposed by inhalation day after day to that concentration." Here, however, the terms *reasonable certainty* and *likely* imply a degree of uncertainty, which in turn leads to the inevitable question about what is the level of acceptable risk. In a recent article, Fairhurst[4] described an OEL as being derived in practice from (a) reliable data from relevant human populations exposed to known concentrations where there is at least one level showing no clear-cut adverse health effect, and (b) confidence from the general toxicological picture that other possible health effects that are difficult to monitor directly in humans (e.g., mutagenicity, reproductive toxicity, etc.) give no cause for concern. This pragmatic approach seems appropriate for most practical standards-setting purposes. Fairhurst also notes the limitation of the NOAEL concept, and discusses the application of "uncertainty factors" (or "safety margins") to bridge the gap between an actual OEL that standards-setting bodies are obliged to assign in the real world and the hypothetical NOAEL. The uncertainty factor that needs to be applied will be lower the greater the quality and quantity of the available data, and will be lower the more human data are available.

There are other uncertainties or questions that further complicate things. If there is more than one health effect, which should take priority in the setting of the OEL? For animal studies, what is known about interspecies differences and extrapolation to humans? For epidemiological studies, what are the quality and quantity of the exposure data? How do we deal with the mixed exposure that prevails in most practical situations, perhaps involving different elements and/or different compounds of the same element? For such mixtures, there may be biological interactions that are additive, synergistic, or antagonistic in ways not at all well understood.

For some substances, the adverse effect arising from exposure may be less specific (e.g., irritancy), so that the toxicologically based dose-response curve approach may not be an available option. Such cases therefore require a simple, more intuitive interpretation of the available evidence.

From the preceding it is clear that, in the part of the standard where we come to discuss numerical values for OEL, there is scope for wide disagreement even among scientists. The situation is compounded still further by the fact that many of the scientific issues raised cut across scientific disciplinary boundaries, where the languages, paradigms, and basic underlying philosophies can be quite different. This brings us into the realm of "trans-science" where questions can be asked *of* science but not answered by science and so where the authority of science is decreased. In this area, players can stake out a claim over an issue at the interface between disciplines, creating a boundary dispute over what part of the problem is—and what is not—"scientific." In the end, the scientific discussion is itself subject to value judgments, so that even the development of a supposedly scientific OEL is far from being truly objective.

Health-based standards, which have been the subject of all the preceding discussion, represent the ideal by which we would expect to be able to protect the health of all workers. An idealist might argue that nothing less should be accepted. But, in the real world, we have the type of standard that is embodied in public policy and so is enforceable by law. Public policy cannot be determined by scientists alone, but must also involve those who are ultimately accountable to society at large. Other forces come into play so that a regulatory standard inevitably includes not only the scientific argument about how much exposure leads to how much ill-health but also considerations of technical feasibility and socioeconomic and sociopolitical factors. In addition, the contribution of cultural and moral dimensions cannot be ignored. The result is a pragmatic OEL that, hopefully, represents a fair compromise between all the competing factors. For many substances it is inevitable that this may be set at a higher level than the corresponding health-based OEL.

The issues and dilemmas raised in the preceding have no doubt been wrestled with by all standards-setting bodies, and some will be brought out further by reference to the examples given below.

REVIEW OF OCCUPATIONAL EXPOSURE STANDARDS

Most developed, and many developing, countries have OELs embodied in national occupational health policies. But they can vary greatly from country to country, not only in how the OELs themselves are defined but also in how they are developed and applied as part of public policy. Consideration of such differences—as well as similarities—provides an essential part of any discussion that might ultimately be conducted about international harmonization. Many aspects have been reviewed extensively elsewhere, most notably by Cook[5] and more recently in a report sponsored by the Chemical Manufacturers' Association.[6] Each report covers a wide range of countries and jurisdictions. Here a review is presented of a small number of contrasting national standards-setting processes in Australia, Norway, Russia, the United Kingdom, and the United States, based on visits to participate in in-depth individual and group discussions with key players in those countries during the period December 1996 to March 1997. In drawing together what was learned, an attempt is made to evaluate the dynamics of the interactions between the various players in those countries, and in particular the roles of the occupational hygiene discipline and occupational hygienists. Through this, we may examine what can be generalized among systems, and hence what is generic to the standards-setting process.

Health-Based Standards

The first purpose of an occupational health standard is its application as a guideline to be interpreted and used, within the realm of the professional judgment, by the occupational health specialists who are charged with protecting their workforces. A primary source over the past 50 years has been the American Conference of Governmental Industrial Hygienists (ACGIH), as reflected in its annually updated list of OELs, termed threshold limit values (TLVs®),[7] and the supporting documentation and other materials generated by its TLV Committee. Since its first appearance in 1946, the list of TLVs has come to be regarded as an international benchmark for many other standards-setting bodies.

ACGIH specifies 8-hour (workday) time-weighted average exposure concentration levels (TLV-TWAs) to which "*nearly* all workers may be repeatedly exposed, day after day, without adverse effect." For some substances it also specifies 15-minute TWA short-term exposure limits (TLV-STELs) that "should not be exceeded at any time during a working day, even if the 8-hour TWA exposure is within the TLV." For substances with a TLV-TWA but no TLV-STEL, excursion limits are specified. Further, for some substances, ACGIH specifies ceiling levels (TLV-Cs) that "should not be exceeded even instantaneously." Where appropriate, substances are denoted in terms of categories that reflect their

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carcinogenicity and their propensity to be absorbed through the skin.

OELs like those published by ACGIH are derived from science and, within the recognized uncertainties like those mentioned earlier, are generally regarded by most fair-minded observers as being "health-based," at least to the extent that is possible based on the available information. They are derived from the best available occupational hygiene, medical, toxicological, and epidemiological data together with a balanced evaluation of exposure, dose, and response. Here the central body of information is regarded as that contained in the open, peer-reviewed literature. However, material in reports and documents from other useful sources may be considered. In addition, the ACGIH TLV Committee may also receive information, written or in the form of oral presentations, from interested outside groups.

Although ACGIH itself is a premier and respected institution representing specifically the learned and professional occupational hygiene community, the TLV Committee is made up of a voting membership comprising "independent" experts in all relevant fields drawn from the government and academic communities. It may also contain nonvoting members from industry or workers' organizations. Its three subcommittees—miscellaneous organic compounds, dusts and inorganic substances, and compounds containing hydrogen, oxygen, and carbon—consider new substances, or revisit previously considered ones, on the basis of nominations from its membership. Briefly, the main steps in the process are as follows:

(1) A list of substances being considered is published annually in the TLV booklet, and information and data are solicited from all interested parties.

(2) The information is passed on to the appropriate subcommittee where, if it agrees to proceed, one of the individual members is nominated to be responsible for researching and assembling the complete documentation. During preparation of the documentation, the relatively small number of ACGIH full-time staff assigned to the TLV Committee provide mainly administrative support (e.g., conducting literature searches, facilitating committee interactions).

(3) A new TLV is proposed based on the data contained in the documentation, and the TLV Committee votes on whether to proceed. If it is agreed, the proposed new TLV is listed under the Notice of Intended Changes in the next published TLV booklet, where it will remain for at least 1 year, during which time comments and new data may be considered from all interested parties.

(4) At the appropriate time, the TLV Committee may agree to recommend the new TLV to the ACGIH board of directors for voting by the whole ACGIH membership at its annual business meeting. If approved, the new TLV is incorporated into the TLV booklet at the next opportunity.

The ACGIH occupational exposure standards developed in this way are distinctive because they are derived without regard to any specific countries' national policies and legislation. Neither do they take account of technical feasibility or socioeconomic considerations. In their application, it is implicit that the specialists who interpret and use them are sufficiently well educated, in breadth as well as depth, to make the necessary judgments. Perhaps for all these reasons they are widely admired and have traditionally been very influential beyond their original, and still primary, charge. Even so, they have not been free of criticism, there having been some much-publicized scepticism in some quarters about the independence of the TLV process.[8] Nevertheless, the TLVs have been widely applied, to varying degrees and at least as a starting point, in many individual national occupational health policies.

National Regulatory Standards

As already mentioned, beyond ACGIH and other independent bodies that purport to specify truly "health-based" OELs, standards setting within individual national regulatory frameworks usually also involves considerations of technical feasibility and socioeconomic and sociopolitical factors. This, therefore, is where considerable differences can emerge. Four contrasting national models have been studied and provide examples by which to illustrate the differences as well as the similarities. A fifth example, the United States, is included for the purpose of comparison.

United States

Regulatory OELs in the United States are set and enforced, under the 1970 Occupational Health and Safety Act, by the Occupational Safety and Health Administration (OSHA). These OELS have been published since 1971 and have some similarities with the TLVs, where the direct equivalents to the TLV-TWAs are the permissible exposure limits (PELs). As with the TLVs, the primary intention in the first instance is to protect most, but not necessarily all, workers. There are also corresponding short-term, ceiling, and excursion limits. In addition to these, there is for each substance an action limit specifying the conditions under which certain initiatives may be taken within the standard (e.g., by an inspector). Originally, all the OSHA limit values were based directly on a combination of the OELs promulgated by ACGIH (i.e., the TLVs) and the American National Standards Institute (ANSI), although provision was made under the Act to add to and update the list independently. But progress was slow, such that less than 30 such modifications were made during the following 15 or so years. In 1989 OSHA attempted a sweeping update by proposing revised PELs for more than 400 substances in a single rule. However, this was deemed by some as inconsistent with the original Act and, following court action in 1992 (between the trade unions and OSHA), there was a return to the original process. This means that a high proportion of most current PELs presently remain based on the original, now largely outdated, 1968 TLVs that were applied at the outset.

The process by which OSHA sets new PELs is complex and heavily influenced by court rulings and the legal process in general. In summary:

(1) OSHA decides, or is advised (with the help of its advisory committee), that the time has come for a new standard for a given substance, and files its intention with the Office of Management and Budget (OMB).

(2) There follows coordination between relevant agencies and exchanges of comments and opinions, and there may be publication of appropriate notices and a public hearing.

(3) For each substance, expert working groups within OSHA, together with selected external consultants, review all relevant literature and other information, and propose the PEL.

(4) A proposed rule is formally published, and all interested parties may respond by submitting written comments and objections and by requesting a further public hearing.

(5) Based on the comments and the results of the hearing, a decision is made whether to proceed with the standard.

(6) After all the comments have been addressed, and if it is then decided to proceed, the final standard is drafted and reviewed by the United States Department of Labor's Policy Review Board and by OMB.

(7) The rule (embodying the standard) is developed, legal challenges are made and responded to, and eventually the rule becomes law.

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In its preparation of new standards, it is likely that OSHA considers the same basic scientific peer-reviewed literature as that considered by ACGIH and most of the other standards-setting bodies. It also considers studies that have not been peer-reviewed, such as information triggered by the request for written comments. In addition, it takes into account published OELs and other relevant information from bodies in the United States (e.g., ACGIH, the National Institute for Occupational Safety and Health [NIOSH]) and elsewhere (e.g., the International Agency for Research on Cancer, the Nordic Expert Group on Limit Value Documentation [NEG]). Up to this point, the considerations may be said to be scientific, leading to a standard that is health-based. But here the direct similarity with the TLVs ends, because OSHA goes further to take account also of technical achievability for affected industries. Additionally, it carries out economic impact analysis to ensure that the resultant federal regulation will not impose undue burdens on industry. There is special concern for smaller businesses. By these additional steps beyond the setting of the health-based OEL, the PEL that appears in the final regulation may be higher than its corresponding health-based value.

Occupational health standards in the United States are enforced by the OSHA inspectors, who may apply them rigorously, based even on a very small number of samples in an exposure assessment. This means that the variability present in all occupational exposures to airborne contaminants can in turn lead to corresponding variability in how the regulations are applied.

The development and implementation of occupational health standards in the United States today is underpinned by a strong learned and professional occupational hygiene community. It was in the United States that the new discipline of occupational hygiene first emerged as such, and the focal points for scholarly and professional activity there for the past 50 years have been ACGIH and the American Industrial Hygiene Association (AIHA). Whereas in the earlier days, specialists entered occupational hygiene indirectly from other fields, most notably engineering, the new emerging generation comes with primary and advanced training specifically in occupational hygiene itself. Here, a major stimulus for the past 20 years has been the specialized, graduate-level occupational hygiene training available through programs sponsored by NIOSH, in particular at the Educational Resource Centers that NIOSH funds at 15 universities nationwide. The graduates from such programs are highly sought after by industry (as corporate specialist occupational hygienists), government (as inspectors, researchers, and policy makers), and educational institutions. The scale of the national occupational hygiene community in the United States is reflected in the membership of AIHA, which currently runs at close to 12,000. Professional certification of practicing occupational hygiene professionals is achieved through the Certified Industrial Hygienist (CIH) qualification, administered by the American Board of Industrial Hygiene (ABIH). Accreditation of postgraduate training programs is achieved through the Industrial Hygiene Related Accreditation Program of the Accreditation Board of Engineering and Technology. From all the preceding, it is seen that the United States has achieved a highly developed community of learned and professional occupational hygiene specialists. This in turn ensures that occupational health standards in the United States are handled at all levels by appropriately qualified individuals.

United Kingdom

Since 1989, following the enactment of the Control of Substances Hazardous to Health (COSHH) regulations, the framework for setting occupational exposure standards in Britain has centered on the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE). In 1989 the Working Group on the Assessment of Toxic Chemicals (the WATCH Committee) was formed, with a view to providing a forum for a wider scientific discussion of OELs, including a more critical appraisal of "imported" OELs and the development of homegrown ones. WATCH makes recommendations on OELs to the Advisory Committee on Toxic Substances (ACTS) which in turn passes them for action to HSC. For a given substance, WATCH develops a numerical occupational exposure standard (OES), provided that (a) "The available scientific evidence allows for the identification, *with reasonable certainty*, a concentration averaged over a reference period, at which there is no indication that the substance is likely to be injurious to employees if they are exposed by inhalation day after day at that concentration"; (b) excursions about the OES of the type that might be expected to occur in practice are unlikely to result in serious health effects; and (c) the proposed OES can be reasonably complied with by industry. Otherwise, WATCH recommends that a maximum exposure limit (MEL) be developed. In this case, WATCH refers the issue to ACTS, which then becomes the forum for the development of the MEL for the substance in question.

From the preceding it is seen that, while both the OES and MEL may be regulatory OELs, the OES, if it is developed, is considered to be health-based. So the OES is somewhat analogous to the corresponding TLV. By contrast, if the MEL alternative is followed, it embodies substantial considerations of technical feasibility and socioeconomic impact. While it is intended to indicate the exposure level that should never be exceeded, it is explicit that the MEL provides no absolute protection against disease. So it is expressly stated that industry should strive to reduce its workers' exposures as far as is reasonably practicable below the MEL. In general, while it is fair to say that the starting point for British OELs used to be the TLVs, and that many of the OES values currently listed remain the same as the current TLVs, the United Kingdom is working vigorously toward developing an increasing proportion of homegrown occupational exposure standards. The actual process by which OELs are set in Britain is summarized briefly as follows:

(1) WATCH and ACTS prioritize substances requiring work toward OELs. HSE then carries out a comprehensive review of the published and unpublished literature, including not only toxicological and medical data but also relevant current and past exposure data.

(2) For each substance being considered, HSE presents its report (in the form of a "criteria document") to WATCH, including also its own recommendation for what type of OEL is appropriate and, if it is an OES, the numerical value.

(3) WATCH discusses the matter and decides whether the substance under consideration meets all three of the criteria for an OES. If so, the discussion continues on the basis of health effects, and a recommendation for a numerical OES value is passed to ACTS. If ACTS endorses it, it is then subject to public consultation before final endorsement by HSC and adoption. Alternatively, if one or more of the OES criteria are not met, a recommendation for an MEL is passed directly to ACTS without further discussion. ACTS now assumes the responsibility for developing the numerical MEL value.

(4) HSE consults with interested parties in developing a MEL that takes into account not only relevant health information but also socioeconomic and sociopolitical factors and the results of appropriate cost-benefit analysis. HSE then forwards its proposal for an MEL to ACTS.

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(5) Following ACTS agreement, the proposal for an MEL is put to HSC seeking permission for public consultation. Following such consultation, the proposal is again submitted to HSC which, providing the proposal is still supported, recommends it to Parliament for approval.

(6) The proposed MEL is published for public comment and discussion and is ultimately finalized and written into law.

For consideration by WATCH, HSE prepares exhaustive information for the criteria document for each given substance, drawing on its large and highly qualified body of toxicological, medical, occupational hygiene, epidemiological, engineering, and other specialists. The material generated is circulated to the WATCH members before each meeting and is followed up by summary presentations by HSE specialist staff at the meeting itself. WATCH itself has tripartite representation, comprising experts nominated by industry (through the Confederation of British Industry) and trade unions and independent experts nominated by HSE itself. Most are drawn from industry or academe. Although the industry- and union-nominated members are appointed to represent their constituents, in the dynamics of WATCH, the tradition has grown that each expert speaks independently without explicit reference to his or her affiliation or source of nomination. Any potential conflicts of interests are explicitly declared at the outset of the discussion on each given substance. During such discussion, WATCH is prepared to receive presentations from interested outside parties. During its meetings, it also receives presentations on new issues or aspects of standards setting that might be expected to feature in discussions on specific OELs at future meetings. It is worth reiterating that, although most of the discussion at WATCH is learned and scientific, and so may be comparable to that in the ACGIH TLV Committee, the component that addresses current and past exposures (aimed at evaluating the feasibility of any OES that might be recommended) adds an additional layer and, with it, a very strong occupational hygiene component. The overall atmosphere at WATCH is one of collegiality. ACTS is similarly tripartite in its membership, but is necessarily broader—and more overtly political—since it must also provide a balanced reflection of the interests of the various interested parties in areas that go beyond science. HSC itself is also tripartite.

From the preceding, it is seen that consensus is carefully built into each stage of the British standards-setting process. So the likelihood of legal challenges to the actual resultant standards themselves is greatly reduced. This has been borne out in practice. In the enforcement of the actual regulation, the traditional role of the HSE inspector has been to work constructively with, rather than against, the employer. So a degree of flexibility is used in deciding whether, in a given situation, the industry is in or out of compliance with the standard and on what actions need to be taken to correct matters or apply formal sanctions. In this way, implicit recognition is given to the great variability that exists in occupational exposures to airborne contaminants.

Like the United States, the United Kingdom also has a long history in learned and professional occupational hygiene, thus enabling similarly highly informed discussion about occupational health standards and their application. The field was certainly active in Britain in the period immediately after the First World War (and until the Great Depression). For example, in 1918 the Health of Munition Workers Committee, in its Final Report on Industrial Health and Efficiency, reported that "there is apparently an increased appreciation of the importance of the whole question of industrial hygiene." In its conclusions, the committee called for further research (which followed, mostly through the British Medical Research Council) and general application of occupational hygiene. The latter was not taken up until much later. Stimulated by activities on the other side of the Atlantic, the British Occupational Hygiene Society (BOHS) was founded in 1953, and rapidly became the focus for the emerging new occupational hygiene discipline in the United Kingdom. Its current membership now stands at more than 1200. BOHS is a "broad church," incorporating not only specialist occupational hygienists but also occupational physicians and individuals from other disciplines—in fact, anyone whose activities and researches touch on occupational hygiene in any way is eligible for membership. Although in the early years, BOHS was itself involved in developing exposure standards, it has been less active in this area since the appearance of the COSHH regulations in 1989. Now it functions in the national standards-setting process in an important consultative role with the regulatory body, providing expert input and acting as a sounding board to HSE (which in turn is highly receptive to such a relationship). In the 1980s the need was identified for a separate body to represent practicing occupational hygiene professionals specifically. So, in 1981 the Institute of Occupational Hygienists was founded, with its members certified in the practice of occupational hygiene by the British Examining Board in Occupational Hygiene. Although specialized postgraduate training in occupational hygiene has taken place at several universities for many years, there is no coordinated emphasis (and funding) commensurate with the NIOSH program in the United States. Nonetheless, it is clear that the United Kingdom has a large and well-qualified occupational hygiene community that plays an active role at all levels of occupational exposure standards setting, implementation, and enforcement.

Australia

The current framework for occupational exposure standards in Australia is based on the 1985 National Occupational Health and Safety Commission (NOHSC) Act. The commission itself is tripartite, involving industry and employers, trade unions, and government (state/territory and commonwealth). While NOHSC is somewhat akin to the HSC in the British system, the Standards Development Standing Committee (SDSC) is equivalent to ACTS. In turn, the Exposure Standards Expert Working Group (ESEWG) is equivalent to WATCH. Although ESEWG is, like WATCH, a tripartite body made up of members nominated by industry, the trade unions, and government itself, the operating rationale is somewhat different. The aim of ESEWG is to recommend OELs that "according to current knowledge, should neither impair the health of nor cause undue discomfort to *nearly* all workers." There is no qualifying criterion that addresses the feasibility or otherwise of achieving the designated OEL.

Historically, back in 1986, the starting point for Australian OELs was the TLV list. Although the TLVs remain influential today, and indeed many of the numerical OELs currently listed are the same as those in the TLV list, discussion of new or revised OELs involves considerations of those from other countries, including Germany, the Netherlands, and the NEG. Australian OELs are expressed either as 8-hour TWA values or in terms of peak (15-min TWA) values. In summary:

(1) ESEWG identifies the need for new OELs based on recommendations from industry or state/territory agencies, or based on new OEL-development activity in other standards setting organizations.

(2) ESEWG reviews the available relevant national and international information (including summary documentation from other

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countries), based on background papers prepared by specialist staff at the National Occupational Health and Safety Office. Based only on scientific considerations, it may propose a standard (new or revised) to SDSC.

(3) In reviewing the proposed standard, SDSC takes into account feasibility and socioeconomic/political factors. Based on such considerations, it may decide either to approve the OEL proposed by ESEWG or to modify it. NOHSC publishes the resultant OEL and invites comment within 3 months.

(4) ESEWG revises the standard in the light of all the comments received, and this is reconsidered by SDSC prior to endorsement and declaration by NOHSC.

From the preceding it is seen that the Australian approach has certain similarities with both the ACGIH and the British approach. On the one hand, ESEWG operates within a collegiate structure whose representation and overall administration is similar to the British WATCH Committee—that is, government-guided but with the power of decision in the hands of its tripartite membership. On the other hand, it recommends OELs that are closer to the ACGIH philosophy, in particular in its intention to set OELs that protect "nearly all" workers without taking account of technical feasibility or economic impact. In the Australian approach, such matters come up for the first time at SDSC.

[Since this report was prepared some changes have taken place in the Australian procedures for considering OELs. A new group has been established, the Hazardous Substances Subcommittee, which will subsume the work of three previous expert groups on classification, health surveillance, and exposure standards. Australia is now working to create a system by which to prioritize exposure standards development within this new, wider framework.]

Although the Australian OELs derived from this process are "national" standards, they have no force in law unless adopted into the legislation of individual states/territories. So, formally speaking, they are guidance standards only. Nonetheless, experience has shown that they are usually taken up by the individual jurisdictions within the Australian Commonwealth, and are subsequently enforced by individual state/territorial inspectorates. However, there are some cases where states/territories choose to use even lower values, one example being in New South Wales where the OEL for chrysotile asbestos fibers has been set at 0.5 fibers/mL (cf. the national value of 1.0 fiber/mL). Ultimately, the states/territories have the absolute power in the setting and enforcement of occupational exposure standards within their own occupational health policies.

Australia has recognized the occupational hygiene discipline for many years, and has boasted many distinguished scholars and practitioners in the field. The Australian Institute of Occupational Hygienists was founded in 1979, and its membership currently stands at about 350, increasing at about 5% per annum. Many of these members play an active role in the setting of occupational exposure standards and their implementation and enforcement in Australia. Those seeking professional certification usually apply for the ABIH-administered CIH qualification.

Norway

Occupational exposure limits in Norway are developed under the auspices of the Labour Inspection (Arbeidstilsynet, or AT) within the framework of the 1977 Working Environment Act. AT operates within the Ministry of Local Government and Labour but also reports to a separate tripartite board that includes representatives from employers and employees as well as independent members nominated by the government. The first list of OELs was published in 1978, based on the TLVs that prevailed at that time, and has been continuously updated or added to ever since. The process by which they are generated is at present undergoing some significant changes. Until recently it proceeded as outlined in the report of the CMA.[6] That is, for the purpose of developing such standards AT appointed an independent expert working group that evaluated exposure and health-related material compiled from Norwegian workplaces as well as scientific documentation from the NEG, ACGIH, and elsewhere. Although they started from scientific considerations, the resultant OELs were also based strongly on technical feasibility and economic factors. In this process, although scientific, health-based considerations were an important starting point, the working group also explicitly engaged in the discussion of technical feasibility and economic factors and so embodied their effect in the final OELs. Since the resultant OELs were not fully scientific, and so did not purport to represent levels for "safe" working conditions per se, they were therefore referred to as "administrative norms." Philosophically, this terminology avoids the need to deal directly with the difficult concept of a "limit." Therefore, such norms were intended only as guidelines for application by both industry and the inspectors.

Very recently AT initiated a new approach where generation of the OELs is made internal to AT itself. In the process, the external tripartite expert working group has been eliminated. The modified process is now as follows:

(1) AT generates proposals for new OELs, based on input from its partners in the NEG, the National Institute of Occupational Health, the employers' and employees' organizations, and the occupational health learned and professional bodies. It also takes account of other standards-setting groups (including ACGIH).

(2) AT initiates the acquisition of exposure data as required (including new measurements if necessary) for relevant workplaces.

(3) For each substance, a "consequence description" (CD) is prepared by officials within AT, describing the substance, where and how it is used, information on its toxicity and health effects, relevant workplace exposure data, measurement and analytical methods, and—after assessment of the consequences—a proposal for an OEL. Here it is important to note the philosophy that, although an attempt is made to make the resultant OEL as close as possible to the ideal health-based value, it is likely to be higher based on considerations of feasibility derived from inspection of the workplace exposure data.

(4) The CD is sent to interested parties for comment and supplementation, after which AT modifies the documentation as appropriate.

(5) After a further fixed period of hearings for discussion and comment, AT offers the proposal to its tripartite board for approval. If approval is granted, the OEL is published, as before, in the form of a guideline or administrative norm. For the substance in question, the time from initiation of the process to final publication is about 2 years.

This modified system brings the Norwegian approach somewhat closer to that of the United States OSHA, particularly in the way by which the whole OEL development process is carried out and orchestrated within the central government body (AT). However, the process is simpler. This is possible because the intention of the Norwegian system of OELs is less constrained in the legal sense. As already mentioned, the published numerical values are administrative norms to be used as guidelines by both employers and the inspectors for aiding in protecting the workforce. They are not intended to be strictly enforceable limits. The role of the inspectorate is therefore very important if the system of OELs is to be applied properly and in the intended spirit. To achieve this, AT has main offices in each of the 13 districts of Norway, and a

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total of about 50 inspectorate stations with about 350 inspectors in total. These play an important part in communicating the standards to industry, as well as working with industry to prioritize occupational exposure problems, recommend improvements and, where appropriate, impose sanctions. At any given time, the strategy for inspection of workplaces is developed centrally within AT in liaison with its partners, aimed at industries and substances considered to be of current highest priority. For example, primary metals production is currently being given special attention. In the meantime all enterprises, from the smallest to the largest, are required by law to maintain documentation about health and safety procedures, which can be audited at random by the inspectors. Companies identified by AT as having workplaces where workers may be exposed to specific chemical hazards are also required to have access to professional qualified occupational health expertise, either by employing such personnel directly or by a formal arrangement with appropriate consulting companies.

Because of the large number of enterprises, it is not possible for AT to do the detailed inspections itself. Its overall strategy is therefore to be proactive in encouraging enterprises to work systematically toward the achievement of specific goals to comply with laws and regulations. This should include the activities that are necessary for complying with the health and safety regulations, and the enterprises themselves should be able to document how they meet those regulations. Occupational exposure measurements are a natural part of that documentation.

Occupational hygiene as a discipline in its own right has emerged relatively recently in Norway. The Norwegian Occupational Hygiene Society was formed in 1985 and now has more than 300 members, comprising individuals working in the field of occupational hygiene in industry, research and educational institutions, and the inspectorate. Although there are as yet no formal educational degree programs in occupational hygiene, an increasing number of specialized courses are becoming available to individuals training in related disciplines (e.g., engineering, analytical chemistry). Recognizing the importance of the occupational hygiene discipline, Norway has recently started to develop a framework for professional accreditation of occupational hygienists.

In Scandinavia more widely, the Nordic Institute for Advanced Training in Occupational Health (NIVA) is funded by the Nordic Council of Ministers to provide advanced courses and symposia for researchers and professionals in occupational health and safety. In the process, NIVA grants special scholarships to participants from the Baltic countries, Barents Sea region, and the St. Petersburg area. As a result, a strong occupational hygiene culture has emerged in Scandinavia commensurate with that in the other, more prominent countries.

Russia

Russia was one of the countries that led the way in setting occupational exposure standards during the early years, publishing its list of maximum allowable concentrations as early as the 1930s for about 900 substances to which workers may be exposed as gases, vapors, or aerosols. The approach is distinctly different from that applied by other countries and, unlike elsewhere, there is no history of significant influence by the TLVs. The development of OELs in the form of maximum allowable concentrations (MACs) is driven by the concept of the "threshold hazardous effect." That is, for each substance, the MAC is set at the level that would correspond to a tissue burden in exposed subjects representing "the minimum dose which triggers changes beyond the limits of physiological adaptation reactions."[9] Using the numerical MAC values, substances are classified on the basis of their level of hazard: Class 1—MAC value less than 0.1 mg/m^3; Class 2—0.1 to 1.0 mg/m^3; Class 3—1 to 10 mg/m^3; and Class 4—greater than 10 mg/m^3.[5]

The MAC development process is entirely toxicological, without reference to occupational hygiene or epidemiology. It is carried out under the auspices of the Ministry of Health, acting through the Russian Federation Department of Sanitary and Epidemiological Surveillance (DSES). DSES is responsible for a wide range of areas of public health, including infectious diseases, radiation protection, water quality, and food protection, as well as occupational health. The actual development of the MAC values is carried out by toxicologists in research institutions supervised by the Scientific Research Institute of Occupational Health. In summary:

(1) The Ministry of Health, through the DSES, sets priorities and identifies substances requiring new or updated MACs.

(2) For each substance, toxicology and medical experts carry out the necessary literature reviews and conduct new research, leading to a proposed MAC value.

(3) The new MAC is recommended to the DSES, which in turn sends it for review by a commission of experts.

(4) The MAC may be approved or sent back for further consideration and investigation.

(5) When the MAC is eventually approved, it is decreed as a standard by the Ministry of Health, whereupon it becomes effective in law.

In preparing the MACs, the material considered is derived mostly from Russian sources. There is no discussion about prevailing exposure levels in industry, technical feasibility, or economic implications. The development of an MAC for a given substance is based entirely on its potential impact on the health of the worker, to the exclusion of all other considerations. But, even at the level of basic health effects, the criterion for setting an MAC is generally much more stringent than that adopted by other standards-setting bodies.

During the period post-World War II, little information was available about the standards-setting process in the Eastern Bloc countries. This dearth of information was eased somewhat in 1963 when a delegation of six U.S. toxicologists visited the (then) Soviet Union and provided the first reports of such differences.[10,11] In more recent years the level of contact has increased significantly.

The stringency of the MAC values and their underlying rationale raises an important question about enforcement. Implementation is the responsibility of the industrial establishments themselves, but is supervised by the 78 regional centers of the DSES, comprising more than 2600 separate stations, located throughout the country. The implementation itself is achieved through engineering and other means. Licencing is one means of enforcement. Here, sanitary physicians from the DSES inspect each establishment prior to granting a licence, and this is followed up by routine inspections conducted about three to four times per year. The sanitary medical inspectors are accompanied where appropriate by suitably qualified technicians and engineers. It is perhaps fair to note that many of the medical doctors who thus form the official inspectorate have backgrounds that go beyond occupational medicine as it is frequently regarded in other countries. Indeed, many are well-versed in science and engineering commensurate with the requirements of occupational hygiene as it is known in the West.

In the inspection process, the inspectors consider whether industries and workplaces fall into one of three categories: (a) where the MACs are not exceeded and there is no evidence of increased risk to health; (b) where there is some exceedance of the MACs but there is no evidence of increased risk to health; and (c) where

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there is exceedance and there is also evidence of worker ill-health associated with the exposure in question. In principle, penalties can be imposed on companies with workplaces falling into any of these categories, although they are more likely for those in the third. The penalty itself may take the form of plant closure (in the worst case) or fines (more usually). To give some sense of the level of such regulatory activity, in the metropolitan region of St. Petersburg, for example, fines totaling about 1 billion Russian roubles (of the order of 200,000 U.S. dollars) were imposed during 1996. The magnitude of this sum should perhaps be viewed in the context of the very difficult economic climate that currently exists in Russia. That notwithstanding, it is reasonable to conclude that enforcement of the standards based on the very stringent MAC values is not very rigorous.

As already mentioned, the Russian approach to occupational exposure standards is governed very strongly by the disciplines of toxicology (in the setting of the MACs) and medicine (in their implementation and enforcement). This derives from the strong Russian philosophy that focuses on the health and well-being of each and every individual worker. Although the topic of occupational hygiene occurs quite frequently during the general discussion of occupational health with Russian officials and scientists, it does not appear yet to be a well-developed discipline in Russia. So there appear to be no professionals or scholars matching the definition of that discipline as embodied in the traditions that have grown up in the West during the past half-century. As a result, exposure assessment in the modern manner as recognized and applied by occupational hygienists in most other countries does not feature strongly. For example, personal sampling appears to be virtually unheard of.

Until the link between hazard recognition, exposure assessment, and regulatory controls is strengthened, it is hard to envisage how the Russian MACs can be effectively enforced. Perhaps, therefore, when the economic situation allows it, priority might be given to enhancing recognition of the occupational hygiene discipline and developing appropriate training programs to provide the required professional base in Russia. This would complement the outstanding tradition in occupational medicine and toxicology that already exists.

COMMENTARY

The countries selected in the preceding review do not allow for an exhaustive account of international occupational exposure standards setting. But they do provide some contrasting scenarios that help stimulate reflection and highlight some of the issues that will need to be addressed if progress toward international understanding or harmonization about occupational exposure limits is to be advanced.

The Data

In general, the basic core of scientific knowledge for all standards setting is that available in the open literature. In the first instance this may be taken to be the information about health effects from toxicological and epidemiological research, and this appears to be the common thread among most of the standards-setting bodies. For these it is clear that there is considerable mutual awareness of each other's activities, priorities, and thought processes, and that there is considerable interchange of information about the data and their application. In particular, the processes within the TLV Committee are watched closely by almost all other organizations. The basic core data therefore provide an essentially common starting point for the discussions within the various expert working groups involved in setting national OELs. Where departures occur, however, they lie in the data that derive from sources that are not in the international public domain (e.g., from industry research, government reports, etc.). For some substances, such sources have historically been very influential. But they have also sometimes been controversial, especially in cases where bias or selectivity may be suspected or inferred.[8]

In addition to the toxicological and epidemiological database, some standards-setting bodies also go further to apply knowledge about workers' exposures in relevant industries. This is particularly important where feasibility and economic factors are issues to be addressed. Here, it is not so easy to identify what is specific and what is generic. So, although documented exposures to a given substance will have some features that are common within industries and workplaces of the same general type, there will inevitably be wide differences overall. Such differences may be greater between countries, where there may be different working practices, climatic conditions, etc., than within countries. Therefore, the idea of a central core of exposure information is more complicated than for health effects, and needs to be applied only by expert occupational hygienists and generally treated with caution.

One country that emerges as distinct, based on the preceding discussion, is Russia. In a system that is carried over from the days of the former Soviet Union, the database from which to derive OELs is markedly different, comprising mainly toxicological information reported almost entirely internally. This is driven by the markedly different philosophical approach to standards in Russia. At the same time, such data are not so widely available to other countries, through difficulties in language and dissemination. Data relating to workers' exposures are not readily available. Indeed, based on the observations noted earlier, they may currently be very sparse.

The Underlying Rationale for OELs

As outlined earlier, OELs should ideally be contained within a framework that also addresses exposure criteria, properties, and methodologies. The various national models studied follow this approach to a greater or lesser extent. In general, most countries recognize the need to have well-defined exposure measurement methodologies to support their systems of OELs, and follow some features of the ideal model. For aerosol exposures, for example, some bodies—including ACGIH and the British HSE—have already moved toward adopting the internationally agreed, scientifically based, particle size-selective criteria that also imply recognition of the need for specific types of instrumentation and sampling methods. Other countries, including Australia and Norway, seem receptive to the same approach. Russia, however, has not yet reached the point where such issues are being discussed.

Even for OELs set on the basis of the same scientific data, there are differences in how the OEL is set. The first may derive from divergent opinions about which health endpoint should drive the OEL or about what level or prevalence of ill-health is considered acceptable. Such differences are value-driven, dependent on variations in emotional response to certain types of ill-health, and variations in attitude to risk associated with certain substances. These in turn depend on local cultures and perceptions and cannot be quantified.

If the scientific discussion leading to even a health-based OEL is subject to considerable differences at a number of levels, then opening up the process to consideration of questions beyond

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health effects leads to further amplification of the differences. Now a completely different set of criteria and values comes into play. They are driven by the question of feasibility. Although feasibility relates to whether a given OEL is practically achievable using known or available technology, there is the underlying rationale related to the cost of achieving a given OEL versus the cost of loss of life or quality of life, and to the local and national need for a given industry to continue to operate and be profitable (and the resultant cost to society were it not to do so). At the societal or cultural level, it relates to individuals' and society's perceptions of the relative value of risk versus the need for employment and their attitudes toward the role of government in regulating industry and work, and to the ability of the government to set and enforce OELs within the machinery of the given regulatory framework and ethical climate. The issue then becomes part of the wider political discussion. Comparison of the British and U.S. approaches to occupational exposure standards illustrates how such issues can lead to differences. As noted in the CMA report,[6] the British process, based on consensus among industry, workers' unions, and independent experts and backed up by a strong, respected, and demonstrably impartial civil service, develops standards that are recommended to Parliament, which in turn can incorporate them into an existing regulatory framework. The goodwill engendered by this consensus-based process means that the possibility of legal actions to challenge occupational health standards is largely deflected. The same approach would not be possible in the United States because Congress does not have power of final approval over regulatory actions by an executive agency such as OSHA. In addition, culturally, the U.S. approach is greatly influenced by adversarial legal processes.

Although there are considerable differences in the types of OEL that are set by individual bodies, and the ways in which they are set, there does appear to be some common ground. Perhaps the most striking part is the fact that so many bodies depended strongly on the TLVs in the early years, and that the influence still remains strong today. The role of ACGIH was particularly important at the beginning in establishing a process by which (a) published—and sometimes unpublished—data on health effects and exposures, in humans and in animals, could be documented, evaluated, and discussed in a multidisciplinary peer group; (b) dose-response relationships identified; and (c) health-based OELs arrived at. Although many of the individual national bodies have striven over the years to reexamine the old data (and to include new data) to develop their own OELs independently, progress has been relatively slow. So progress in developing completely home-grown OELs has been slow in most countries and, in view of the effort required to carry out the full process for any given substance, it is likely to remain so. As a result, most of the OELs listed by many individual bodies remain numerically the same as the corresponding ones listed by ACGIH. The differences, where they occur, are for the relatively small number of "difficult" substances that have continued to generate interest by virtue of ongoing public concerns about associated occupational ill-health (e.g., crystalline silica, asbestos and other fibrous dusts, benzene and other solvents, etc.).

The Role of Science and of Scientific Experts

Science plays a strong role in the approach to health-based occupational exposure standards. But it is clear that, even there, irreconcilable differences can arise in the way the data are interpreted and applied. In the real world, where data and information are not complete, the real "truth" does not exist. The version of the truth depends on the question that is posed. But even that is subject to the uncertainty present in the available data. So supposedly scientific occupational exposure standards are inevitably subject to nonscientific value judgments. Unfortunately, this picture of science does not fit the picture held by society at large, which likes to believe that science can resolve complex issues by identifying exactly what is true and what is not true. The effect of uncertainty in the process of scientific judgment is frequently not grasped. So, when science fails to provide definitive answers, public mistrust is engendered. This is when policy makers, the people who represent society and interface with scientists on scientific issues of public concern, and are the ones who are ultimately responsible for actions in the public domain, lose confidence in the ability of science to be useful in policy. Then single-agenda, science-based pressure groups get into the act and, in so doing, often undermine further the trust of the public in science. Paradoxically, when scientists try to overcome these difficulties by being more open, the more the divisions between them become apparent, and the feeling of public mistrust becomes even greater. Such scepticism may be derived from earlier mistakes, real or perceived. Here, the media plays an important role in influencing public opinion on such matters, not always constructively. In this somewhat confused climate, the populace tends not to take kindly to the appearance of having the opinions of an elite group of scientific experts impose its views in influencing the lives of others. With all this in mind, it is not difficult to comprehend why the role of science in the setting of occupational exposure standards ultimately tends to become secondary to the host of nonscientific factors.

What about those experts? Who is "independent" in the standards-setting process? All the experts will inevitably come with some sort of affiliation (i.e., to industry government, organized labor, academia, etc.), and each will, of course, proclaim his or her "independence," and indeed they may actually believe themselves to be independent. But independence is something that not only needs to be the case in reality but must also be perceived to be so by all interested particles. But this is virtually impossible. The government scientist will tend to be seen by others to be suspicious of the motives of industry. Industry scientists will tend to be perceived by government and workers' representatives as holding back on contributions that might be viewed as negative to industry. Traditional "independent experts," usually academics, are not free of such perceptions since most of them will have, at one time or another, have received support from or worked closely with either government or industry (or both). This after all is how they were able to gain the first-hand knowledge and experience that made them into "experts." Ironically, therefore, suspicion of the motives of such "independent experts" may come from all sides. There is no escape. With this in mind, the concept of "independence" perhaps needs to be reconsidered. It implies the ability to win complete trust from all other parties. It therefore has to be accepted that lack of independence, even if only perceived (and not necessarily real), means that there will be mistrust. Recognizing this, it might be suggested that respect may be substituted for trust.[12] In this scenario, it might be said, the more highly the expert is respected then, irrespective of the question of independence, the greater his or her contribution will be valued. Perhaps the best that can be hoped for in this complex scenario is that all the experts in some way set out to strive for the common good.

Funtowicz and Ravetz have commented interestingly on the dynamics of multidisciplinary scientific expert groups like those engaged in the development of occupational exposure standards,

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and note that "Multidisciplinary teams . . . generally become a collection of specialists playing safe by abstaining from criticism of others' research results. A questioner can all too easily be driven off and humiliated by an aggressive defence; and so in the absence of a common understanding on the issues of uncertainty and quality, it is futile for an expert to attempt to stray onto another's turf. Since policy-related research involves complex systems which have been approached from a plurality of disciplinary perspectives, this systematic weakness of multidisciplinary projects must be resolved, if effectiveness is to be achieved and progress to be made."[13] They go on to note that the need to communicate uncertainty properly is therefore no less for such groups than for inexpert lay groups.

Scientists and the Other Players

Norseth[14] has written about the moral and ethical "dilemma" confronting those involved in the setting of occupational exposure standards. He has discussed the question of who decides what is acceptable risk, and to whom, and the communication of information about risk by scientific experts and policy makers to the people who are actually the ones at risk. The definition of what is acceptable varies depending on the perspective of who is doing the defining. The different critical roles and modes of the participants in this process have been set out by Clark and Majone.[15] On the one hand, scientists will define what is acceptable in terms of rational explanations of the nature of risk, how risk compares between risk factors, and considerations of probability. They can articulate the extent to which their perspective is close to "the truth," and are frequently frustrated at the difficulty with which such seemingly simple concepts are grasped by others. On the other hand, it is the policy makers that define acceptability in terms of what they believe is good for—and intelligible to—society as a whole. They would like to claim to be the ones who maintain vigilance with respect to accepted ethical standards in society at large. However, they, in turn, become frustrated at the idealism of some scientists. Meanwhile, public interest groups, representing the exposed people and so the ones actually at risk, are most immediately concerned with the nature of the conclusions of both scientists and policy makers, and wish to see the issues handled with fairness and balance. They are frequently confused by, and so mistrust, both scientists and policy makers.

The Future for OELs

In this review of occupational exposure standards, it is important to note that the number of substances for which OELs exist is relatively small within any standards-setting body or jurisdiction. For example, the TLV list deals with fewer than 900 substances. Compare this with the 100,000 or so separate chemicals listed by the European Inventory of Existing Chemical Substances as being traded among countries. It may be that, for many of these, the amounts traded and the numbers of workers who become exposed are relatively small. It is also true that, based on manufactures' hazard data sheets, a relatively small proportion may be considered toxic to exposed humans, with a much higher proportion considered to be harmful to the general environment.[16] But all such substances present finite potential risks to workers who become exposed to them routinely. So those workers need to be protected. In the light of all the preceding, however, it is clearly impracticable that all such substances could individually be assigned OELs. The cost and effort would be prohibitive. This presents a dilemma to the standards setters. Can it be said that the existing TLV list, for example, represents the exposures that occur in most workplaces involving most workers? Probably not. Perhaps, therefore, it reflects the substances for which there are the most toxicological and/or epidemiological data—or, dare it be said, where there is pressure arising from the greatest economic priority.

Some governmental and institutional occupational hygiene specialists are starting to express the opinion that the existing system of OELs has less impact on the occupational environment than had been thought previously. Recent research sponsored in Britain by HSE has revealed that, although current OELs are quite well-understood and applied in large industries, most notably those who employ professional occupational hygienists, they are much less well-recognized in small- and medium-sized enterprises (SMEs).[17,18] Such companies rarely employ their own professional hygienists, rarely conduct exposure assessments, and are rarely visited by an inspector. In short, the overall level of awareness of OELs and their importance in protecting workers' health is probably much lower than we would like to believe. It would not be surprising to find similar trends in other countries.

How does such knowledge influence how we think about the future for OELs? Or about substances for which there are no OELs? Some say that a rethinking of the approach to occupational exposure standards might be appropriate. One suggestion moves the emphasis of compliance evaluation from explicit exposure assessment (as is required by the current approach) to engineering control. In principle, this might be achieved by reference to information contained in the material safety data sheets (MSDSs) provided by the manufacturers of the chemicals that are used by industry. Such safety data sheets are required under international laws governing classification, packaging, and labeling. By combining MSDS information about the nature of—and the potential hazard associated with—a given material with knowledge about how the material is being used in the industrial process, the level of exposure may be classified as falling within a proscribed health-related band. Once the exposure is thus classified, a hierarchy of technical exposure control measures can be specified, ranging from general exhaust ventilation, to local exhaust ventilation, partial and full enclosure and finally, as the last resort, personal protective equipment. Thus, in principle all substances for which there is an MSDS can be dealt with in this way. A somewhat similar philosophy is seen in the hazard-rating approach used by the pharmaceuticals industry and in biohazard laboratories. Many agents encountered in such situations are generally considered to be too hazardous, both to workers and to the environment and even in very small concentrations, for us to rely on monitoring methods to ensure compliance. Sceptics might argue that this control-based approach is qualitative at best, and so crude in comparison with the more quantitative traditional approach based on exposure assessment in relation to OELs. But its supporters might reply that there is already very great uncertainty, maybe as much uncertainty, in the present system of OELs, both in their development and in their application. Of course, any such new approach would need to be validated with respect to the existing approach for a wide range of industrial scenarios. Then, once validated, the OELs themselves would be moved into the background. Subsequently, in the enforcement of new standards based on the new approach, the inspectorate would be charged with evaluating the control systems in place rather than requiring explicit exposure assessment to be carried out, as the current approach calls for. It is argued that this would be more effective than the present approach for protecting the majority of workers, especially those in SMEs. Meanwhile, of course, larger concerns with professional occupational hygiene expertise readily at hand, may opt to continue to work

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within the current OEL-based system, at least for substances where OELs exist.

Changing Occupational Hygiene

In a famous book, quoted and applied in many fields beyond science, Kuhn[19] has written about the nature of science and argued that, although new theories may be more complex that the ones they replace, they are not actually any closer to the "real truth." Rather than the steady acquisition of knowledge moving ever closer to this truth, the history of science is seen to be represented by periods where one or other model—or "paradigm"—holds sway interspersed by intermittent "revolutions" in which the model accepted by the scientific community in question is changed dramatically. Since Kuhn, the importance of this concept of revolutionary paradigm shifts has been noted with respect to many fields, both within and outside science. The field of occupational hygiene, and occupational exposure standards setting in particular, spans both science and public policy, and it too may be said to be subject to the same sort of dynamics. Here, the current paradigm for occupational health standards may be said to be the OEL approach that focuses on exposure measurement. This in turn underpins much of current occupational hygiene thinking and training. So it occupies much of what is discussed and agreed between—and practiced and taught by—occupational hygiene professionals and scholars. New approaches like those advanced above therefore represent paradigm shifts that can have far-reaching implications to those working in the field. To some, they might seem to represent a challenge to the occupational hygiene community at large and to the exposure-based philosophy it has come to accept. So it is likely to be resisted. On the one hand, it is possible that a new approach will eventually emerge where the emphasis of occupational exposure standards is shifted to technical control measures, and this may indeed be embraced by the occupational hygiene community. On the other hand, despite the persuasiveness of the arguments presented, the suggested changes in approach may be successfully resisted by the "establishment" and the old approach may survive and so continue. The balance is in the nature of intellectual revolution alluded to by Kuhn.

Meanwhile, revolutionary change is frequently uncomfortable to, or is perceived to be uncomfortable by, those affected. Evolutionary change is easier. In the public policy field, this is referred to as "incrementalism."[20-22] In this approach, participants often limit themselves to considering changes close to the status quo, based on the argument that restricting the effort to "politically" feasible changes conserves scarce time and energy, making the best use of available knowledge. As a result, the short- and long-term effects are easier to predict and the possibility of large errors is small. Within this approach, however, if a problem is perceived to be sufficiently severe by some participants, those participants may break out and press for more radical change. This is similar to the approach discussed by Heclo and Wildavsky[23] in relation to the field of public administration, in particular relating to the governance of public expenditure. They note that change tends to happen only "at the margins," where for significant change the burden of proof is on the proposer and not on those preserving the status quo. Heclo and Wildavsky, however, were describing the system in Britain pre-Thatcher, and experience would suggest that the strength of their argument has been whittled down by events since. But it would seem to apply still within the large bureaucracies in countries like Russia. In the context of occupational exposure standards, changes in the criteria for exposure assessment and in individual OELs may be viewed as incremental. By contrast, as already alluded to, a wholesale switch from an exposure assessment-based policy (to which the OELs are central) to one based on control technology might be seen as revolutionary.

Such ideas from other domains of public policy seem appropriate to the ways in which we think about change in occupational health standards. In the international area of occupational exposure standards, any degree of international harmonization will inevitably require changes in the mind-sets of all national standards-setting bodies. The ability to accommodate such change depends on the nature and the history of the organizations in question. Of the national standards-setting bodies studied, for example, the United Kingdom, Australia, and Norway would appear to be more ready to propose and adopt new approaches than, say, the United States and Russia. As far as occupational health policy is concerned, the latter two are characterized by older and much larger bureaucracies. In Russia in particular, resistance to change may stem from the fact that the framework and machinery currently in place have been there for very many years (since the 1930s) and so have become institutionalized and largely unchanged despite the great central political changes that have taken place in that country in the 1990s.

The readiness to make changes, especially radical changes, is linked with the willingness of officials to be prepared to expose themselves to the risk associated with the possible failure of that policy. This is particularly problematic for publicly accountable policy makers, to an extent that is likely to vary greatly between cultures. Jeremy Vincent[24] recently reviewed the general concept of this type of risk among administrative managers in the private and public sectors and noted that managers in the private sector are more likely to embrace radical changes while, in contrast, "public servants may feel unwilling to take potential risks due to the twin potential pitfalls of falling under the glare of public scrutiny or being prey to governmental intervention." In relation to occupational health standards, there may be the tendency for some policy makers to be conservative (that is, to tend toward "incrementalism") when it comes to adopting radical new approaches to occupational health standards or changes commensurate with the requirements of international harmonization. The greatest inertia is therefore likely to come from policy makers and not from the scientists.

INTERNATIONAL HARMONIZATION

In summary from the above, systems for developing health-based OELs have some generic features that are common to all standards-setting bodies, including basic core data sets and rationales frequently based on the processes established by ACGIH and other pioneering institutions. This in itself provides a potential platform for international harmonization of standards, at least within the majority of countries. Harmonization of anything stems from the desire to rationalize—that is, to intellectualize or to give a rational explanation. This is in the nature of science and so is especially attractive to scientists. For occupational exposure standards, therefore, it follows that the international harmonization movement comes from the scientists working in the field of occupational health. A major driving force is the internationalization of the occupational health sciences and professions, most notably through such bodies as the International Occupational Hygiene Association. A major justification is the increasing harmonization of other aspects of world trade and industry. It is recognized that occupational health standards do differ from country to country.

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Such differences can be very marked, especially between the so-called "developed" nations and the "developing" nations (where standards tend to be less stringent, or at least less stringently applied). This is undoubtedly an issue for trade and international business, where there is the widespread perception that some multinational corporations have seen economic advantage in transferring portions of their operations to developing countries where the cost of occupational health is perceived as being lower.

The idea of international harmonization of occupational exposure standards is not new, and the search for international mutual understanding is a well-trodden path. In 1963, for example, Stokinger[25] published a short list of "internationally agreed" OELs. In the years since, especially encouraging progress has already been achieved in certain parts of the standards-setting process. In 1991, for example, Zielhuis et al.[26] outlined how harmonization of the criteria documents might be achieved. These are the cornerstones on which to base the discussion of individual OELs for each and every substance. For the specific case of aerosol exposures, there has been a long history of harmonization of supporting standards by which health-related aerosol fractions are defined for the purpose of exposure assessment. This goes back to the early 1950s when the first definition of the fine "respirable" fraction of particles was proposed and later agreed to internationally.[27-29] More recently, wide international agreement has been achieved on a more comprehensive system of particle size-selective criteria for inhalable, thoracic, and respirable fractions on which more rational OELs can be based for substances that appear as aerosols.[7,30,31]

For occupational exposure standards more generally, the scope for harmonization may range from (a) full harmonization among countries, with common sets of criteria, exposure assessment methods, and strategies and OELs; (b) intermediate harmonization, with common criteria and methods and a common primary database, but with local OELs based on national considerations and priorities; and (c) rudimentary harmonization, with better understanding among countries about all the factors that underpin the local OELs. Based on the discussions undertaken during the present study, the prospects for the first option would appear to be remote. As Norseth[14] points out, "international harmonization of exposure limits is impossible, even if collaboration on biomedical and toxicological criteria is highly recommended. However seeing the limitations of such collaboration in setting actual numbers for acceptable exposure is important. In view of the vast differences in technological development and social welfare in various countries, such harmonization may not even be a good solution for improving the working environment for all workers." The second and third possibilities would therefore appear to be more "incremental"—and so less threatening—to individual national interests, and so provide more promising routes toward achieving the goal of reducing, if not eliminating, differences among countries.

CONCLUDING REMARKS

In summary, a study has been conducted of a small number of national processes for establishing occupational exposure standards. This comprised detailed discussions with scientists and officials in the countries chosen outside the United States, including the United Kingdom, Australia, Norway, and Russia. Not surprisingly, similarities and differences have been found where, of the sample studied, the Russian approach is the most distinctive, being based on a totally different philosophy by which the occupational exposure limit is defined and how the resultant system of OELs is applied in reality. In general, science is seen to play a strong role at the front end of the standards-setting process, guiding the decision to place the numerical value of the OEL itself into a range where it can, when implemented, truly protect worker health. However, even for standards supposedly based entirely on science, the uncertainties in data and difficulties in interpreting complex multidisciplinary scenarios mean that value judgments play a significant role. These are influenced not only by scientific disagreement but also by national emotional and cultural responses to different types of exposure and health outcomes. But further, for standards that are incorporated into public policy for implementation in the real world, a wide range of other factors comes into play, including questions of engineering and technical feasibility as well as socioeconomic, sociopolitical, ethical, and legal perspectives. In the end the standard may be influenced even more greatly by the latter group of considerations. This is where the greatest differences may occur between countries, and so where the greatest challenge arises with respect to international harmonization of standards. It is likely, therefore, that such harmonization may ultimately be limited to those parts of the standards-setting process that can be defined and discussed in terms of science, and this might, in the end, be a small part of the whole.

Meanwhile, the discussion about the nature of occupational exposure standards leads to consideration of the future of the OELs that underpin current approaches in most countries. Occupational hygienists, identified as an important learned and professional group in the whole area of occupational health standards, are starting to question whether the current approach is truly effective in protecting the health of the majority of the work forces in their countries. The changing demographics of working populations is one significant factor. As a result, new ways of thinking about occupational health standards are beginning to emerge. As the discussion of these proceeds into the twenty-first century, the need becomes even more clear for the continued development worldwide of a strong occupational hygiene community, bridging the gaps between occupational medical doctors and toxicologists on the one hand and engineers on the other. Countries with strong such communities and opportunities for advanced education and training should continue to maintain and grow those strengths. Countries with less strong occupational hygiene cultures should be encouraged to invest in greater efforts in that direction.

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REFERENCES

1. **Vincent, J.H.:** *Aerosol Science for Industrial Hygienists.* Oxford, U.K.: Pergamon Press, Elsevier Science, 1995.
2. **Rappaport, S.M.:** Assessment of long-term exposures to toxic substances in air. *Ann. Occup. Hyg. 35*:61–121 (1991).
3. **Carter, J.T.:** Indicative criteria for the new occupational exposure limits under COSHH. *Ann. Occup. Hyg. 33*:651–652 (1989).
4. **Fairhurst, S.:** The uncertainty factor in the setting of occupational exposure standards. *Ann. Occup. Hyg. 39*:375–385 (1995).
5. **Cook, W.A.:** *Occupational Exposure Limits—Worldwide.* Fairfax, VA: American Industrial Hygiene Association, 1987.
6. **Chemical Manufacturers' Association (CMA):** *An International Review of Procedures for Establishing Occupational Exposure Limits.* Fairfax, VA: American Industrial Hygiene Association, 1996.
7. **American Conference of Governmental Industrial Hygienists (ACGIH):** *Threshold Limit Values for Chemical Substances and Physical Agents, and Biological Exposure Indices (1996-1997).* Cincinnati, OH: ACGIH, 1996.
8. **Castleman, B.I., and G.E. Ziem:** Corporate influence on threshold limit values. *Am. J. Ind. Med. 13*:531–559 (1988).
9. **Sanotsky, I.V., Y.S. Kagan, G.N. Krasovsky, V.T. Mazaev, and N.G. Ivanov:** Thresholds of harmful health effects of chemicals on animals and man; prediction of safe exposure levels. In *Toxicometry of Environmental Chemical Pollutants* A.A. Kasparov and I.V. Sanotsky (eds.). New York: United Nations Environment Program, 1986. pp. 301–336.
10. **Magnuson, H.J., D.W. Fassett, H.W. Gerarde, V.K. Rowe, H.F. Smyth, and H.E. Stokinger:** Industrial toxicology in the Soviet Union: theoretical and applied. *Am. Ind. Hyg. Assoc. J. 25*:185–197 (1964).
11. **Magnuson, H.J.:** Soviet and American standards for industrial health. *Arch. Environ. Health 10*:543–545 (1965).
12. **Ravetz, J.R.:** "Beyond Scientific Certainty in Risk Management." Comments made at the Chief Scientist's Seminar, Health and Safety Executive, London, U.K., January, 1997.
13. **Funtowicz, S.O., and J.R. Ravetz:** *Uncertainty and Quality in Science for Policy.* Dordrecht, The Netherlands: Kluwer Academic Publishers, 1990.
14. **Norseth, T.:** Exposure limits: an ethical dilemma. In *Advances in Modern Environmental Toxicology*, M.A. Mehlman and A. Upton (eds.). Princeton, NJ: Princeton Scientific Publishing Co., Inc., 1994.
15. **Clark, W.C., and G. Majone:** The critical appraisal of scientific inquiries with policy implications. *Sci. Technol. Human Values 10*:6–19 (1985).
16. **Oldershaw, P.:** "A Changing Picture of Chemical Control." [Unpublished paper] Bootle, Merseyside: U.K. Health and Safety Executive, 1996.
17. **Topping, M.D., C.R. Williams, and J.M. Devine:** "Industry's Perception and Use of Occupational Exposure Limits." Paper presented at the 1997 Conference of the British Occupational Hygiene Society, Warwick, U.K., April 15–18, 1997.
18. **United Kingdom Health and Safety Executive (HSE):** *Industry's Perception and Use of Occupational Exposure Limits* (Contract Research Report No. 144) London: HSE Books, Her Majesty's Stationery Office, 1997.
19. **Kuhn, T.S.:** *The Structure of Scientific Revolutions*, 2nd ed. Chicago: University of Chicago Press, 1970.
20. **Lindblom, C.E.:** The science of muddling through. *Pub. Admin. Rev. 19*:79–88 (1959).
21. **Lindblom, C.E.:** Still muddling, not yet through. *Pub. Admin. Rev. 39*:517–526 (1979).
22. **Lindblom, C.E., and E.J. Woodhouse:** *The Policy-Making Process*, 3rd ed. Englewood Cliffs, NJ: Prentice-Hall, 1993.
23. **Heclo, H., and A. Wildavsky:** *The Private Government of Public Money*, 2nd ed. London: Macmillan, 1981.
24. **Vincent, Jeremy:** Managing risk in public services: a review of the international literature. *Int. J. Pub. Sector Manag. 9*:57–64 (1996).
25. **Stokinger, H.E.:** International threshold limit values—1963. *Am. Ind. Hyg. Assoc. J. 24*:469–474 (1963).
26. **Zielhuis, R.L., P.C. Noordam, C.L. Maas, J.J. Kolk, and H.P.A. Illing:** Harmonisation of criteria documents for standard setting in occupational health: a report of a workshop. *Reg. Toxicol. Pharmacol. 13*:241–262 (1991).
27. **British Medical Research Council (BMRC):** "Recommendations of the BMRC panels relating to selective sampling" from the minutes of a joint meeting of Panels 1, 2, and 3, March 4, 1952.
28. **Hamilton, R.J., and W.H. Walton:** The selective sampling of respirable dust. In *Inhaled Particles and Vapours*, C.N. Davies, ed. Oxford, U.K.: Pergamon Press, 1961. pp. 465–475.
29. **Orenstein, A.J. (ed.):** Recommendations adopted by the Pneumoconiosis Conference. In *Proceedings of the Pneumoconiosis Conference* (Johannesburg). London: Churchill, 1960. pp. 619–621.
30. **International Organization for Standardization (ISO):** "Air quality—particle size fraction definitions for health-related sampling" [Technical Report ISO/TR/7708-1983 (E)]. Geneva: ISO, 1983 (revised 1992).
31. **Comité Européen de Normalisation (CEN):** "Workplace atmospheres: size fraction definitions for measurement of airborne particles in the workplace" (CEN Standard EN 481). Geneva: CEN, 1992.

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