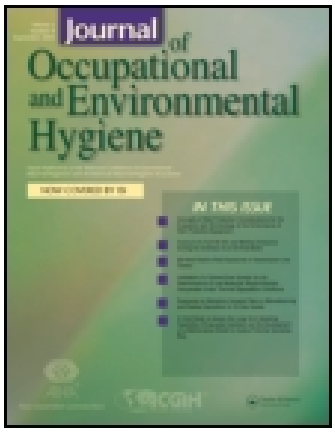

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2011 William P. Yant Award Lecture

Trevor Ogden [a] & Jérôme Lavoué [b]
[a] British Occupational Hygiene Society , Derby , United Kingdom
[b] Déptartment de Santé environnementale et Santé au Travail, Université de Montréal , Montréal , Canada
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2011 William P. Yant Award Lecture
Testing Compliance with Occupational Exposure Limits: Development of the British-Dutch Guidance

Trevor Ogden[1] and Jérôme Lavoué[2]

[1]British Occupational Hygiene Society, Derby, United Kingdom
[2]Déptartment de Santé environnementale et Santé au Travail, Université de Montréal, Montréal, Canada

The Yant Award was established in 1964 to honor the contributions of William P. Yant, the first president of the American Industrial Hygiene Association. It is presented annually for outstanding contributions in industrial hygiene or allied fields to an individual residing outside the United States. The 2011 award recipient is Dr. Trevor Ogden, chief editor of the Annals of Occupational Hygiene.

INTRODUCTION

The British and Dutch occupational hygiene societies (BOHS and NVvA) formed a joint working party to draw up guidance for members on measuring compliance with 8-hr occupational exposure limits (OELs) for airborne substances. The central problem is that regulations typically require that exposure does not exceed a specified value, but exposure tends to vary log-normally, which means that there is no upper cut-off. It is therefore in principle impossible to prove that a sharp-cut OEL will definitely be complied with. In practice, it is common to require that exposure is controlled so that $<5\%$ of exposures exceed the limit, but establishing this is thought to require an amount of measurement, which is often impracticable.

Recent work has shown that using the 70% upper confidence limit of the 95th percentile is an efficient way of distinguishing complying from non-complying exposure distributions; a 2009 French regulation is based on this. The BOHS-NVvA guidance uses this to test compliance of a similarly exposed group (SEG), based on at least nine measurements per SEG. The guidance then requires an analysis of variance to establish whether individual exposure within the SEG varies significantly, using as a criterion that between-worker variance should not exceed 20% of total variance. If it does exceed 20%, individual compliance is tested, the requirement being that there is $<20\%$ probability of any worker within the SEG having $>5\%$ of exposures greater than the OEL. The guidance was published in September 2011.

THE COMPLIANCE PROBLEM

Occupational exposure limits originated in most cases as professional opinions to be applied with discretion by trained professionals. The classic statement of this is in the ACGIH® threshold limit values book, which says (with italics as in the original):

> The values in this book are intended for use in the practice of industrial hygiene as guidelines or recommendations to assist in the control of potential workplace health hazards and for no other use. These values are *not* fine lines between safe and dangerous concentrations and *should not* be used by anyone untrained in the discipline of industrial hygiene.[1]

While OELs remain like this, judging compliance is not a problem. Statistical tools are available, such as AIHA's IH-STAT[2] and Bayesian techniques,[3] and the trained industrial hygienist can use judgment and experience in applying these as part of an overall assessment of risk and control.

If, however, regulations apply limits as sharp cut-offs that must not be exceeded, a problem arises. Exposure usually results from the interaction of many causes, and there is a statistical chance that they will combine to produce exposures several times the average, without this indicating a failure of control. Rappaport and Kupper[4] draw attention to some results of Cope et al.,[5] shown in Figure 1, which illustrate this well. More than 95% of the exposures are $< 50\ \mu g/m^3$, and most are less than a third of this, but there is no clear upper limit to the distribution, and it looks as if more measurements might result in a scatter of values at even higher levels. What limit could this distribution be said to comply with?

Regulators have found exposure limits very useful, and all over the world they have been built into legislation of various sorts, often ignoring the problem illustrated in Figure 1. In the European Union, for example, the Carcinogens Directive[6] says that "Exposure shall not exceed the limit value," and the Chemical Agents Directive[7] similarly places immediate

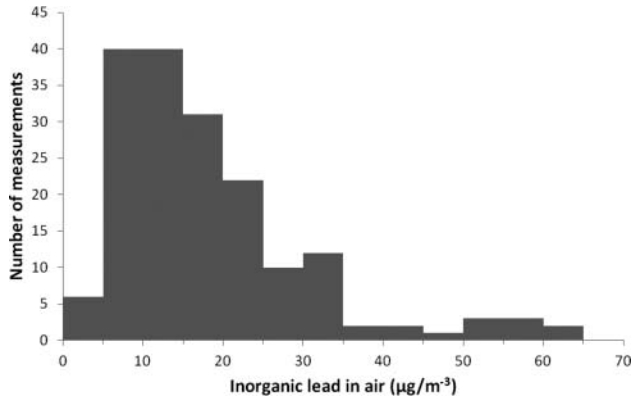

FIGURE 1. Distribution of lead in air exposures measured by Cope et al.[5]

requirements on an employer when a limit has been exceeded, without any discretion as to whether this represents a significant loss of control. This makes for easy enforcement: one valid measurement over the limit demonstrates non-compliance. However, it puts the employer in a difficult position. There may be a series of exposure values well below the limit, but with a distribution like Figure 1 there is no guarantee against the next measurement being much higher. How many measurements below the limit are needed before the employer can reasonably assume that worker exposure complies?

In some cases, enforcers can and do allow some latitude. For example, the permissible exposure limit (PEL) for formaldehyde in the United States is specified as an absolute limit: "The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds . . ."[8] However, the appendix to the standard says that "a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved provided that measurements are conducted using valid sampling strategy and approved analytical methods".[9] This opens up an opportunity for statistical tests of the exposure distribution, to determine the 95th percentile.

Although the European Directives do not officially allow this room for maneuver, hygienists must work with the situation. To give them some authoritative guidance on best professional practice, the British Occupational Hygiene Society (BOHS) and its Dutch equivalent, Nederlandse Vereniging voor Arbeidshygiëne (NVvA), agreed in 2007 to try to draw up guidance for their members on testing compliance. The guidance has now been published.[10] We aim to describe here how this process has developed and what the outcome has been.

RESOURCE CONSTRAINTS VS. STATISTICAL NECESSITY

Historically, professionals have taken a similar line to the appendix to the formaldehyde PEL just quoted. It is enough to demonstrate that there is only a small probability of exceeding the limit. Because exposures are commonly observed to be lognormally distributed, we can use the properties of that distribution to estimate the position of the 95th percentile from a chosen number of measurements. In principle we can then say that our exposure is adequately controlled if <5% of time-weighted exposure measurements are expected to be over the exposure limit, i.e., if the true 95th percentile is <OEL.

In practice, however, a large number of measurements are required to determine the position of the 95th percentile with confidence. The uncertainty is often expressed as the 95% upper tolerance limit (95%UTL), which can be thought of as the 95% upper confidence limit of the 95th percentile, and to be sure that we are complying, perhaps the 95%UTL should be <OEL, rather than the simple 95th percentile estimate. The number of samples required for this is illustrated in Appendix IV of the AIHA exposure strategy manual,[11] taken from the work of Lyles and Kupper.[12] One of the examples is that if the 95th percentile is really two-thirds of the OEL, and the distribution has a geometric standard deviation of 3, then to show that the 95%UTL <OEL will require about 150 measurements.

The AIHA software IHSTAT calculates the UTL as well as the 95th percentile, and a few trials rapidly bring home to the user how the number of results affects the uncertainty.

The fundamental problem is therefore this: to be able to statistically demonstrate compliance with reasonable power and traditional confidence limits usually requires impracticable numbers of samples, especially when the true 95th percentile is more than about 20% to 30% of the OEL. The problem is heightened because there may be several groups of workers in a large workplace to whom the procedure must be applied. Any guidance must somehow try to overcome this problem.

BACKGROUND TO THE BOHS-NVVA GUIDANCE

Why Is New Guidance Needed?

Some pioneering guidance in this field is the NIOSH publication by Leidel et al.,[13] which has been influential worldwide. Its shortcomings became apparent within a few years of publication, and it is now under revision. In Britain, the 1993 BOHS Technical Guide[14] and, more generally, in Europe, the European Standard EN689,[15] have been widely used. In each case, research has made them out of date. Revision or production of new guidance is going to be a continuing task, while the sources of variation of exposure and assessment strategies are active research fields.

The European Standard EN689 is an example of the impact of research. While the standard was being drafted, Kromhout and colleagues[16] were demonstrating the importance of between-worker variability, and this is not taken into account in the standard. Every attempt at a strategy involves breaking the work force into groups that are expected to have the same exposure (similarly exposed groups, SEGs), and, of course, if this is successful the exposure of every worker in the SEG should be represented by the group exposure. However, this is

an ideal, and Kromhout et al. found that in the many groups they studied there could still be important variability between workers. Rappaport and Kupper[4] discuss this in more detail. Exposure limits in the European Directives and, usually, other regulations apply to every worker, so an exposure measurement strategy must take into account the fact that some workers may be exceptionally exposed.

Stages of the BOHS-NVvA Guidance

Revision of a European Standard is a long process involving many interest groups, and although updating of EN689 would clearly be desirable, BOHS and NVvA decided in 2007 that, meanwhile, they should try to give their members guidance by establishing a joint working group under Trevor Ogden and Hans Kromhout as co-chairs.

The joint working group decided at an early stage to use the concept of SEGs and to determine both group and individual compliance using the 95th percentile of a fitted log-normal distribution as described above. The compliance definitions adopted are described later. In this approach they followed Kromhout et al,[17] and in their formulations the group made much use of the work of Hewett[18] and Rappaport and Kupper.[4] A first draft of the proposed BOHS-NVvA guidance was made available on the BOHS website for comment from October to December 2009. Many important comments were made from nine countries, and during the consultation period, an important new French regulation was published[19] that drew attention to the background work published in 2008 by the Institut National de Recherce et de la Sécurité[20] (INRS). Jérôme Lavoué of the University of Montreal made comments that applied this to the proposed BOHS-NVvA guidance and, thereafter, he became a contributor to the work of the group. These developments led to a complete rewriting of the draft, and the final version was placed on the BOHS website in September 2011.[10]

Computer Simulation of Possible Compliance Tests

To explain how the joint working group made its choices, it is helpful to consider what a hygienist does in deciding whether the members of a SEG comply with an exposure limit or not, and how compliance-testing strategies can be evaluated. As discussed above, it is usual to assume that the exposures in a SEG have an underlying log-normal distribution like those in Figure 2, i.e., that if we could take a very large number of measurements, the distribution would look like those in the figure. In practice, the exposure situation is tested by making a few measurements and doing some kind of calculation on those measurements, but as discussed above, establishing that 95%UTL <OEL often requires an impracticable number of measurements.

There is another approach, applied in the French regulation,[19] that goes a long way to overcoming this problem. Consider a log-normal distribution with its 95th percentile at the OEL, i.e., with 5% of the distribution > OEL (Fig 2a). This is a theoretical underlying distribution that just complies by our definition. Of course, when we are measuring in the workplace we do not know in advance whether the underlying distribution is like Figure 2a, which by our definition just complies, or Figure 2b, which does not comply, or like Figure 2c, which easily complies. What we really want to know is not the position of the 95th percentile or the 95%UTL but whether our test is correct in classifying the distribution as compliant or non-compliant, and how confident we can be of that decision. An efficient test will be one that (1) needs a relatively small number of measurements, (2) gives a low chance that a non-compliant distribution like Figure 2b will be declared compliant, and (3) a low chance that a compliant distribution like Figure 2c will be declared non-compliant.

It is possible to use computer simulations to see how this works for a particular test taking "measurements" at random from a compliant or non-compliant distribution, applying the chosen test, and seeing how the probability of a correct decision varies with various parameters, including the number

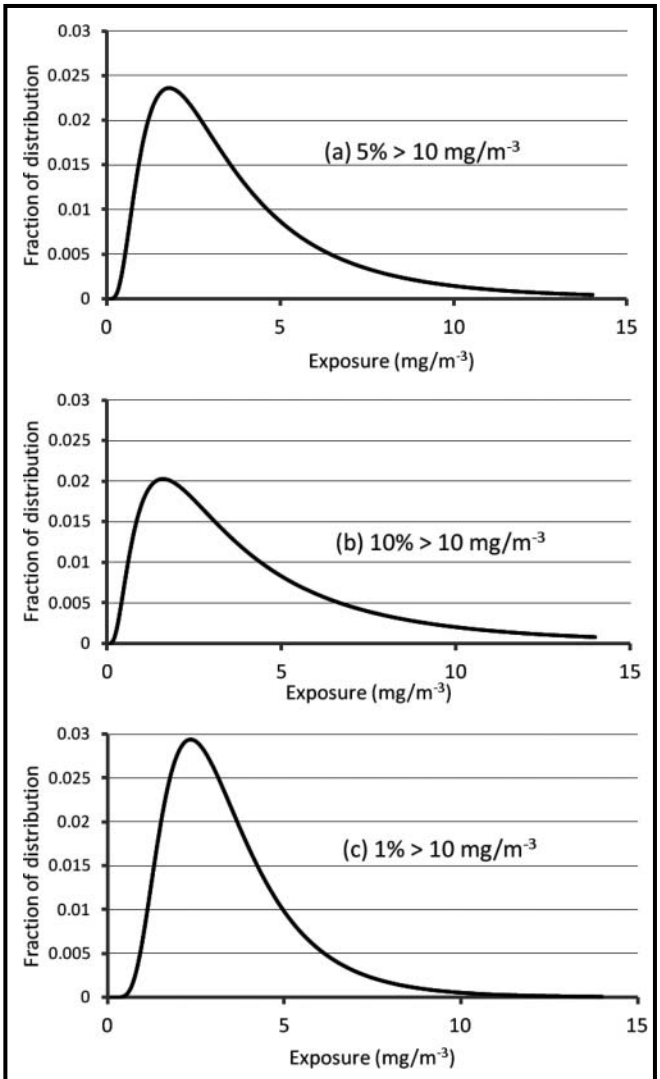

FIGURE 2. Three exposure distributions, idealized as log-normal distributions, with various fractions >10 mg/m^3, taken as the OEL for the purposes of illustration

TABLE I. Probability of a Compliance Decision by Different Tests, for Three Distributions with True Exceedance Fractions of 1%, 5%, and 10% Estimated from Computer Simulations

		Apply the different tests to underlying distributions that have true exceedances equal to:		
		10% (e.g., Figure 2b)	**5% (e.g., Figure 2a)**	**1% (e.g., Figure 2c)**
Results of tests: The probability of the tested distribution being found compliant by:	A perfect test	0%	Just acceptable by definition	100%
	Comparison with the 95th percentile	29%	54%	92%
	Comparison with 95% UTL of 95th percentile	1.5%	5.5%	24%
	Comparison with 70% UTL of 95th percentile	15%	34%	77%

Note: True exceedance fraction = 10% means that 10% of the distribution is >OEL.

of measurements, the true position of the 95th percentile relative to the OEL, and the underlying variability. This kind of simulation has been described by Hewett,[18,21] and applied by INRS in Fiche Méthodologique Métropol A3.[20] Fiche A3 looked not only at the 95%UTL (the upper 95% confidence limit of the 95th percentile) but other degrees of confidence as well. The Fiche tested the UTL (with various confidence values) with various combinations of number of samples and variability of the underlying distribution. It concluded that using the upper 70% or 80% confidence limit of the 95th percentile (70%UTL or 80%UTL) instead of the traditional 95%UTL led to a better balance between the chances of declaring a compliant situation to be non-compliant and a non-compliant situation to be compliant. This work formed the basis of the compliance-testing method specified in the French regulation. Compliance is therefore verified by comparing the 70% upper confidence limit of the 95th percentile with the OEL, i.e., testing if there is >70% chance that <5% of the underlying distribution of exposures >OEL.

Table I illustrates the results of some computer simulations of this type. These values were calculated through simulations performed by Jérôme Lavoué based on the framework proposed by Hewett.[18,21] Similar calculations for a continuum of true exceedance values are presented in INRS Fiche A3,[20] and can be partially replicated with the freeware developed by Hewett[21] (EAS simulator v2.5.1, possible degrees of confidence 90, 95, or 99%). The simulations are of tests each using nine measurements taken randomly from the underlying distribution. The results are virtually unchanged when changing the value of the underlying geometric standard deviation (GSD) from 1.5 to 2.5. If the underlying distribution had 10% of exposures >OEL, a good test would find it unacceptable (because we define 5% as compliant). It can be seen from the table that simply comparing the OEL to the 95th percentile estimate gives a 29% chance of accepting this distribution, but the 70%UTL test gives only 15%. The 95th percentile estimate comparison will accept 92% of distributions with 1%>OEL (which should be accepted), but the 70%UTL accepts 77%. The 95th percentile estimate comparison is therefore more accepting of non-compliant environments, but the 70%UTL test is more likely to reject environments that in fact comply.

On the other hand, using a 95%UTL for comparison with the OEL, while it will ensure very few compliance decisions when the true situation is not compliant, will classify as non-compliant many compliant situations. Which of these alternatives is to be preferred is a matter of judgment, but a 29% chance of declaring an environment compliant if it has >10% of exposures >OEL seems difficult to defend as a professional recommendation if the law says that no exposures should be >OEL, and if we believe that 5% of exposures above the limit might be acceptable in practice. In the other direction, the 95%UTL will lead to waste of resources on control measures because it declares situations with only 1% exceedance to be compliant only 24% of the time.

The outcome of INRS simulations was that the French regulation[19] used the 70% upper confidence limit on the exceedance fraction, and the further work for the joint working group by Lavoué reinforced this, leading to the BOHS-NVvA group adopting the same criterion for its group compliance test, described below.

The French Regulatory Test

The procedure in the French regulation[19] for testing against 8-hr OELs is summarized here, but the reader is referred to the original for details, and for information on short-term OELs. The regulation envisages that compliance in a workplace is tested by an external accredited organization, and Annexes 1 and 2 of the regulation describe the procedure to be used.

SEGs are established in an initial visit. There are then three subsequent visits, spaced out over up to a year, and at each at least three measurements are made per SEG, so that a complete program generates at least nine measurements per SEG. The visits should be planned to cover various times of year and a range of conditions that might affect exposure. Measurement is by personal sampling if technically feasible, and the TWA 8-hr exposure is calculated.

If all three of the measurements at the first visit are <0.1 OEL, the SEG can be regarded as compliant, and not measured again on the second and third visits. If any measurement on any of the visits is >OEL, the SEG is non-compliant, and corrective measures must be taken and the process restarted. At the end of the process, the geometric mean and GSD of the (at least) nine measurements are calculated and used to calculate a factor that is compared with values in a table to decide if the decision is compliance or not, i.e., whether <5% of the distribution exceeds the OEL with 70% confidence. The table gives the critical values for this decision for numbers of measurements from six upward. If the decision is that the SEG complies with the OEL, a program of periodic measurement (reassessment) is started, but no details are specified.

The regulation specifies three spaced visits. The statistical calculations do not depend on this and can be used with the table in the regulations even if the measurements are made in a single campaign. However, spreading the measurements in time reduces the risk of autocorrelation, that is, correlations between one measurement and the next. This might occur if the measurement period does not represent the full range of conditions.

THE BOHS-NVVA GUIDANCE

Group and Individual Compliance

Following its public consultation at the end of 2009, the BOHS-NVvA working group has tried to integrate all these considerations into a compliance test method. It only considered shift-length OELs for airborne substances. Interested readers should consult the full text,[10] but it will be summarized here. Because of the availability of excellent modern works such as the 2006 edition of the AIHA *Strategy for Assessing and Managing Occupational Exposures*,[22] the guidance does not go into details on how to conduct a survey of a workplace or how to select SEGs. The guidance assumes that this is done, and the strategy then has four stages. Stages 1 and 2 follow the French regulation, except that the nine measurements can all be done in the same campaign, not spread out over a year. The process is illustrated in Figure 3:

(1) Conduct a screening test of three measurements taken on members of the SEG picked at random. As in other parts of the test, if there are fewer members of the SEG than the number of measurements required, some workers will have their exposure measured on more than one day. As in the French test, if all three measurements show exposure <0.1 OEL, then compliance is assumed, and if in this or any later part of the process a valid exposure measurement gives a result >OEL, then the SEG is deemed not to comply.

(2) Test the *group compliance* for each SEG, using the approach in the French regulation. The guidance says, "The group complies if, with 70% confidence, <5% of the exposures in the SEG exceed the OEL." This is tested by making at least six further exposure measurements on SEG members, combining these with the three from the screening test, and applying the test taken from the French regulation. So that individual compliance can be tested (Stage 4 below), at least two separate shift measurements and, if possible, at least three are made on each worker selected. If there are more than two workers in the SEG, the exposure of at least three workers is measured. If not all workers are to be measured, those measured are to be picked at random.

(3) Perform an analysis of variance (ANOVA) to see if there are meaningful differences between the exposure patterns of the measured workers. Details of this test are given below. If there are meaningful differences, include Stage 4. If not, the measure of individual compliance is not needed.

(4) Test the *individual compliance* of the SEG. The guidance says, "The SEG complies in terms of individual exposure if there is <20% probability that any individual has >5% of his or her exposures exceeding the OEL." (Another way of expressing this is to say that ≥ 80% of SEG members have ≥ 95% of their exposures <OEL.) This is tested making use of the approach in Appendix A of Paul Hewett's Technical Report on performance-based exposure assessment strategies.[18]

It is expected that the software SPEED (http://www.iras.uu.nl/iras_speed.php), produced by the University of Utrecht Institute of Risk Assessment Sciences, will be updated to deal with the calculations. However, the guidance includes an appendix with a step-by-step example of the calculations using Microsoft Excel.

When Should Individual Compliance Be Determined?

Although substantial inter-worker variability has been found within SEGs,[16] it should not, of course, be significant within a perfectly constructed SEG. The ANOVA at Stage 3 above, conducted on the log-transformed values, provides a test of whether there is enough variability to require calculation of individual compliance in addition to group compliance. A draft of the guidance applied two tests to the results of the ANOVA. One of these was the familiar F test of whether the difference between workers was significant at the 5% level. The other estimated the intra-worker correlation coefficient ρ, which is equal to the proportion of the total variance of the log-transformed data represented by the between-worker

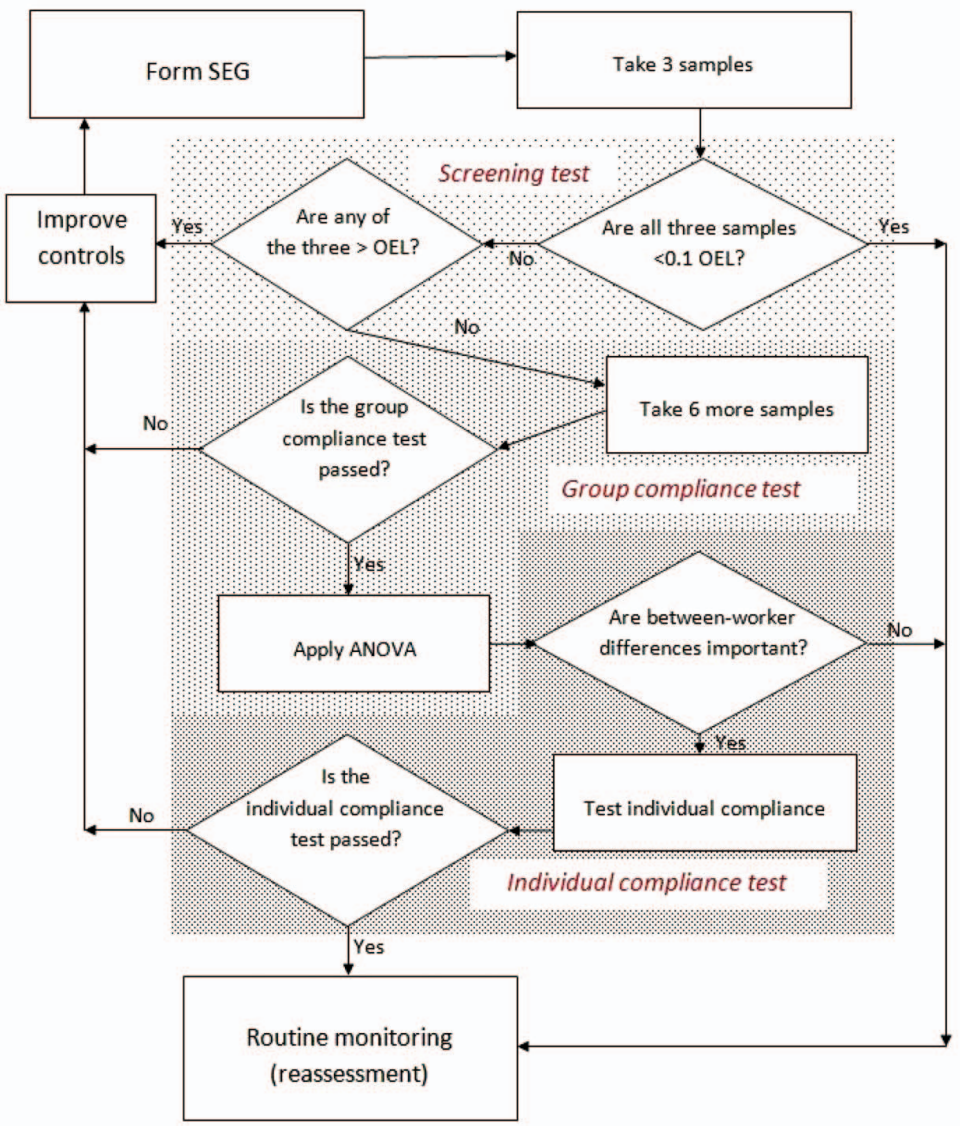

FIGURE 3. Flowchart of the BOHS-NVvA guidance

variance—a high value of ρ means more difference in exposure between workers. Computer simulation used a series of true values of ρ and found that setting the threshold of estimated value of ρ at 0.2 was more powerful than the F test at identifying distribution with big exposure differences between workers. As an illustration, for a true $\rho = 0.3$ the ANOVA F test was significant only about 12% of the time, while the estimated value of ρ was >0.2 about 41% of the time. In consequence, in the final version of the guidance, the F test is omitted. (The simulations assumed three workers with three measurements each and tested 1000 samples in each case taken from distributions with geometric standard deviations equal to 1.5, 2.5, and 3.5. For various true values of ρ, the simulations calculated the proportion of time that the ANOVA F test would be significant and that the estimated value of ρ would be >0.2. The ANOVA test was always found to have less power.)

The 0.2 (20%) threshold for ρ was chosen on the basis of very little information—merely inspection of some examples—and experience may show it to be the wrong threshold. For geometric standard deviations between 2 and 3, this threshold corresponds to values of the Rappaport ratio (the ratio of the 97.5th to the 2.5th percentiles) between 3 and 7.[4]

The Individual Compliance Definition

As already mentioned, the individual compliance criterion is met if there is $<20\%$ probability that any individual has $>5\%$ of his or her exposures exceeding the OEL. This was chosen arbitrarily by the group in the absence of any data. However, putting it as its equivalent, $\geq 80\%$ of SEG members have $\geq 95\%$ of their exposures $<$OEL, it seems a reasonable test of compliance as an addition to the group compliance test. It might be thought that we should require that there should be a zero probability of any worker having $>5\%$ of exposures

>OEL, but because the result is calculated on the basis of a fitted log-normal distribution, the estimated probability is never zero, just as the estimate proportion of exposures >OEL will never be zero.

There are two completely different 20% thresholds in the guidance that should not be confused. The individual exceedance test is undertaken if the inter-worker variance is more than 20% of the total variance ($\rho > 0.2$), and the individual compliance test is met if there is <20% probability of any worker having >5% of exposures >OEL.

Values Below the Level of Quantification (LoQ)

The treatment of values <LoQ in our field of science remains a subject of research, and there is no definitive method,[23,24] and it has not therefore been possible to give one in the guidance. The guidance states that, "Wherever possible, the analytical method and the volume sampled should be chosen to ensure that the LoQ is less than one-tenth the OEL (LoQ < 0.1 OEL)." If LoQ>0.1 OEL, then clearly the screening test (Stage 1 above) cannot be applied. The guidance refers to three discussions of regression methods,[23,25,26] that will probably not, however, help with the individual compliance test. A range of substitutions is suggested, but they could result in biased estimates of the variance and hence false compliance decisions. The guidance says that if any of these methods gives a non-compliance result, that should be taken as the decision.

Reassessment

Reassessment (called "periodic measurements" in the European standard) is the ongoing program of occasional measurement that must be undertaken if the tests show that the SEG complies with the OEL to check that exposure remains under control. Clearly, the intervals should depend on the level of exposure in relation to the OEL, and many other factors. There is no definitive method of deciding the right intervals, and there was a wide range of opinion within the working group, but the guidance suggests some intervals depending on the relation of the geometric mean of the measurements to the OEL.

DISCUSSION

As pointed out at the start, most hygienists would prefer to have OELs as a guide in their assessment of a workplace, and giving legal significance to the OEL raises all sorts of difficulties. The BOHS-NVvA working group hopes that its guidance will be helpful but shares the experience of every other group that has tried to do this: that it is impossible to cover the infinite range of circumstances that may occur. In the end, we can only offer guidance to the experienced hygienist and warn others that applying the method as a recipe book will be dangerous.

Research has made past sets of guidance obsolete, and this will be true of the BOHS-NVvA guidance also. In particular, it will be clear to the reader that some fairly arbitrary choices were made in setting criteria for individual compliance. Research in this field will probably necessitate revision. One active field of recent development that we have not used is Bayesian decision analysis (for example, Logan and Ramachandran's chapter in the AIHA guide[27]). This is becoming a powerful tool in workplace exposure management. However, the group had in mind that we were providing guidance that hygienists could use in justifying their exposure control approaches to a critical enforcement agency, and an approach that had professional judgment as a component might not be persuasive in those circumstances.

For the group compliance method, the INRS research and French regulation have been very helpful, and now that French regulation and British and Dutch professional guidance are very similar, this should provide a good basis for revision of the European standard.

One fortunate thing is that the European directives require effective control as well as compliance with limits. The guidance emphasizes there is no point in putting a lot of attention into compliance with the limits and resources into measurement if practicable control measures are not also being implemented. Where there are numbers like exposure limits, all attention tends to focus on them, but European Union law and professional opinions here agree: measuring compliance with exposure limits is all very well, but it is futile unless it is part of an overall strategy of effective exposure control.

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