British Occupational Hygiene Society

Nederlandse Vereniging voor Arbeidshygiëne

Testing Compliance with Occupational Exposure Limits for Airborne Substances

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Preface: What is this document for?

When repeat measurements are made of exposures to airborne substances in the workplace, it often happens that most results are within a fairly narrow range, but a few results scatter on the high side, sometime four or five times the median or even higher, for no clear reason. This is not due to a failure of control, but happens because there is a statistical chance that the many factors which determine exposure sometimes combine in a way which produces an outlying result. It is a problem partly because occupational exposure limits (OELs) are defined as sharp cut-offs, values which must not be exceeded, taking no account of occasional outliers. (Section 2.5 discusses how regulations define "compliance".) So the law theoretically expects exposure to be controlled below a fixed threshold, when in reality even well-controlled exposure cannot be made to behave like this – outliers inevitably occur. In practice, properly trained enforcers usually take into account accepted good practice and look beyond the simple numbers to the reality of control.

There are also other complications in estimating exposure in relation to OELs. Various attempts have been made to provide guidance in this difficult problem, such as the pioneering NIOSH document Leidel et al (1977), BOHS Technical Guide 11 (BOHS, 1993), and the European Standard EN 689 (CEN, 2018, formerly 1995). Each of these has fairly soon become out of date because of advances in understanding of how exposure behaves, and improved strategies for dealing with this.

This document aims to give guidance to occupational hygienists and others **on measurement strategies for determining compliance with occupational exposure limits**. **It does not give general guidance on conducting a survey of exposure in the workplace** - Chapter 1 refers to documents that do that. It aims to be a guide to good practice on measuring compliance with an OEL in the light of present knowledge, taking into account the variability of the exposures of individuals and groups. It is assumed that you will not use this document unless you have already surveyed the workplace and decided that you should to do a proper test of whether any exposures exceed the OEL.

The layout of the guidance is as follows. Chapter 1 briefly indicates where to find information on conducting a survey of exposure in the workplace. The rest of the document is about what to do if as a result of the survey you decide that exposure may exceed an OEL. Chapter 2 outlines the problem of exposure variation and how it relates to legal definitions of exposure limits, and Chapter 3 and Appendix 1 describe a recommended assessment and data treatment method. Chapter 4 outlines simpler evaluation methods and their strengths and shortcomings. It comes out clearly in Chapter 3 that getting reliable answer on compliance with an exposure limit requires more measurement than many hygienists are used to. The most important part of the guidance is therefore the Introduction, which aims to put compliance testing in its proper place in achieving good control of risk, which is the hygienist's proper job and the aim of good legislation.

This guidance has been produced by a working group of the British and Dutch occupational hygiene societies (BOHS and NVvA). The two societies make this publicly available in the belief that this represents good professional practice. However, the societies accept no liability for any consequences of its use. The user is responsible for ensuring that risk from airborne substances is controlled as the law requires.

In the public consultation on a draft, many other people made major and valuable comments which led to this revised version, and the working group thanks them. Also, particularly important contributions came from Andrew Garrod (formerly of the British Health and Safety Executive), Jérôme Lavoué (of the University of Montreal), Huib Arts, and Margreet Sturm.

From past experience, this document is likely to require fairly frequent revision to cope with improved understanding of the statistics of workplace exposure and the best strategy for measurement. We hope however that it will be useful contribution at the moment and a good basis for future development.

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This document has been reviewed in the light of the 2018 EN689 revision and to make minor editorial changes including the update of references and website URLs.

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Most important – read this first

This guidance is about measuring compliance with exposure limits for airborne substances, but it is ESSENTIAL that this is only considered in a wider context of assessing and controlling risk. In the European Union, the law requires this – the Chemical Agents Directive (EU, 1998) and the Carcinogens Directive (EU, 2004) both require effective control as well as compliance with limits – and national regulations in the member states implement these requirements.

If you are a hygienist, remember that proving that an exposure limit is probably complied with is likely to be expensive and time-consuming, There is no point in doing it unless the occupational hygiene methods of control are also applied – the law requires this as well as compliance with the exposure limit, and applying this guidance without also applying good control practice may be wasted time and effort.

If you are an employer or someone concerned about a workplace, have the principles of good practice been applied? For example, here are some of the principles taken from guidance on the British Control of Substances Hazardous to Health Regulations (HSE, 2005).

- Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.
- Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures.
- Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.
- Check and review regularly all elements of control measures for their continuing effectiveness.
- Inform and train all employees on the hazards and risks from the substances they work with, and use of control measures.
- Ensure that the control measures for substances do not introduce some other sort of risk.

Applying these principles properly is often a skilled business. National occupational hygiene associations will usually advise on where to find competent help. For a list of associations, see the International Occupational Hygiene Association website http://www.ioha.net/ . In the UK the British Occupational Hygiene Society maintains a list of consultancies with qualified and experienced occupational hygienists who can advise on this, at https://bohs.link/Occupational-hygiene-services, and in the Netherlands contact NVvA at nvva@arbeidshygiene.nl. Using a consultant may be much cheaper and more successful than installing expensive and possibly ineffective control equipment.

An enforcement agency will usually look at the whole of the control procedures together. Applying this guidance will enable the employer or hygienist to demonstrate that exposure limits are

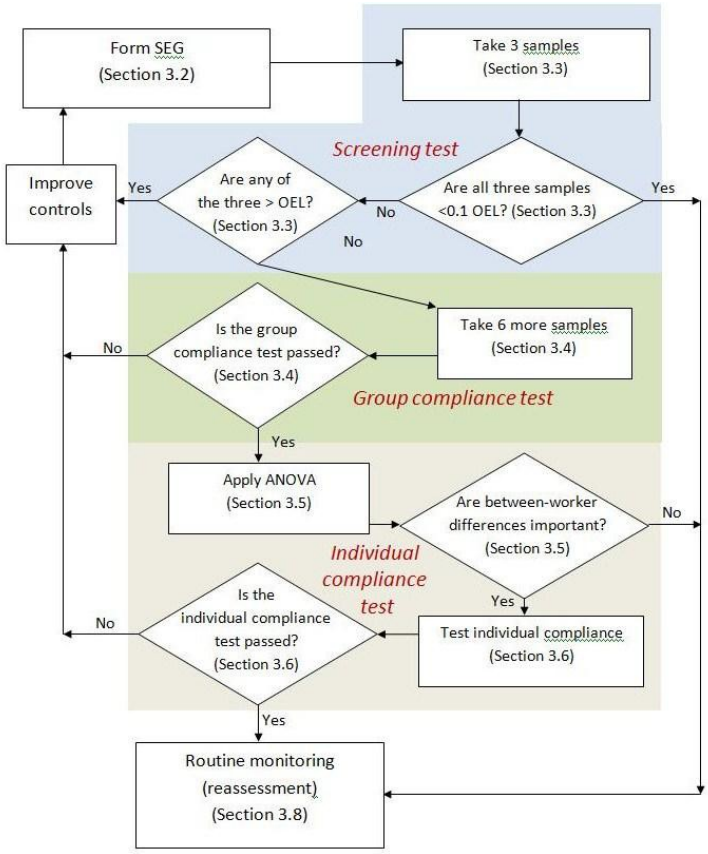
probably complied with, but, as well as looking at the numbers, an enforcer is likely to ask: (1) are engineering methods working?; (2) are engineering controls and other procedures maintained?; (3) are there weaknesses in the way good practice is complied with? As explained in this guidance, statistical fluctuations may lead to occasional measurements above the exposure limits even under good overall control, but an enforcer will generally pay more attention to the answers to these questions about good control than to statistical outliers.

This guidance is about finding out whether exposures comply with exposure limits. The guidance shows that doing this thoroughly enough to be fairly certain of the answer requires much more measurement than is usually done in a quick hygiene survey. **There is no point in doing this unless proper attention is also paid to good control practice.**

Summary

The aim is to provide hygienists and employers with guidance on testing compliance with 8-hr occupational exposure limits (OELs) for airborne substances. It is assumed that a general workplace survey has been done, resulting in a need to test exposure against an OEL.

The problem is that OELs are usually defined as sharp boundaries that must not be exceeded, but the variability of exposure means that occasional high results occur even where the exposure is generally well controlled. The guidance assumes that an OEL may be regarded as complied with if the probability of exposure exceeding the OEL is <5%, always remembering that European law requires that effective control measures are applied whether or not the OEL is complied with.



The method has five steps.
(1) Divide the workforce into similarly exposed groups (SEGs).
(2) Take 3 representative personal exposure measurements from random workers in the SEG. If all three exposures are <0.1xOEL, it can be assumed that the OEL is complied with. If at this stage or any later one any result is >OEL, the OEL is not complied with.
(3) Do a *group compliance* test. Take at least 6 more samples from the SEG, at least 2 per worker from workers picked at random. Use all 9 (or more) samples to apply a test which establishes, with 70% confidence, that there is <5% probability of any random exposure in the SEG being >OEL.
(4) Do an analysis of variance on the 9 (or more) results to establish whether the between-worker variance is >0.2 x total variance. If it is, then step 5 must be added.
(5) Analyse the 9 (or more) results to do an *individual compliance* test. There should be <20% probability that any individual in the SEG has >5% of exposures > OEL.

If the OEL is not complied with, further control measures should be applied. If the OEL is complied with, a periodic monitoring programme should be started, with frequency depending on the test results.

An appendix gives examples of the necessary calculations in Microsoft Excel.

Three shortcut methods and their limitations are discussed.

Chapter 1.
Preliminary considerations

1.1 The initial evaluation of the workplace

This guidance starts from the assumption that a general evaluation of exposure has been done and measurements are now required to determine whether exposure exceeds the OEL. The methods presented in this document therefore come at the end of a substantial process, which is likely to include:

- obtaining a general overview of the workplace and its layout, the tasks carried out and the control measures in place (and whether more control is reasonably practicable);
- considering how these processes vary, perhaps from shift to shift and operator to operator, and how this might affect exposures;
- consideration of what health and safety precautions are involved in carrying out the evaluation;
- walk-through surveys with direct-reading instruments;
- refinement of estimated exposures using models such as Stoffenmanager https://stoffenmanager.com/ ;
- consideration of what occupational exposure limits (OELs) apply and whether they may be exceeded (in which case this guidance can be applied);
- consideration of what periodic monitoring might be required;
- communication to management and workforce.

This guidance does not deal with these issues. Most are explained fully in guidance on assessing and managing exposure published by the American Industrial Hygiene Association (AIHA, 2006). A modern text on occupational hygiene should also be consulted, such as Cherrie et al (2010), which gives wide-ranging guidance on assessment and control, including detailed checklists on carrying out a workplace survey. Since the AIHA guidance was published, Hewett et al (2006) and Ramachandran (2008) have described a way of using a few measurements to improve exposure management. This is summarised in section 4.3 below.

It is important that people carrying out the assessment are professionally competent to do so – the organisations referred to in the Introduction may be consulted for advice on this.

If as a result of this general evaluation of workplace exposure it is considered that OELs may be exceeded, the guidance in the rest of this document may be used to determine if this is likely to be true, but this guidance assumes that the above initial evaluation has been done.

What OELs apply will depend on the country where exposure occurs. The larger countries in Europe will all have their own lists, which will incorporate European limits. GESTIS https://www.dguv.de/ifa/gestis/gestis-internationale-grenzwerte-fuer-chemische-substanzen-limit-values-for-chemical-agents/index-2.jsp gives a consolidated list of OELs from various major jurisdictions.

As explained in Section 3.2, the information gained in the survey should be useful in forming similarly exposed groups (SEGs) at the stage of determining compliance with the OELs.

1.2 Measurement methods

An important preliminary step in measurement is selection of the sampling and analytical method. The IFA https://amcaw.ifa.dguv.de/ lists validated sampling and analytical methods from European countries for 123 substances. Another important source is the US National Institute for Occupational Safety and Health (NIOSH) Manual of Analytical Methods http://www.cdc.gov/niosh/nmam/ . These sources outline validated regimes of sampling and laboratory analysis for quantifying exposure concentrations of the hazardous substance through inhalation. However, where no methods exist e.g. in the case of a new or novel substance, it might be necessary to develop and validate an in-house method.

AIHA (2006) and Cherrie et al. (2010) give advice on how to take samples, and some of the analytical methods just mentioned give advice on sampling. More technical details on assessment of airborne contaminants are given by Ramachandran (2005). National OEL lists should define the period to which the OELs apply, and should give instructions on how the exposure should be calculated for comparison with the OEL. Further details are given in Chapter 3.

Usually samples will need to be sent to a laboratory for analysis. In all cases there will be a lower limit to the amount of the substance that the analytical technique can detect and what can be quantified, and a competent laboratory must be able to tell you what this is. When divided by the volume of air from which the substance was collected, the analytical quantification limit gives a limit of quantification (LoQ) of concentration of the substance in the air. 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). The treatment of measurements below the LoQ is discussed in section 3.7

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Chapter 2.
The problem of variability, and the place of this guidance

2.1 Variability of exposure

Anyone who has measured exposures in a workplace will be aware that the exposure varies, whatever measurement period is chosen and whatever is done to keep conditions constant. The variation is usually much greater than can be accounted for by analytical error. Fig 1 shows a typical case, based on measurements made in the weaving sheds of a cotton mill (Ogden et al, 1993). The results peak at relatively low exposures, with one or two results at several times the most frequent exposure.

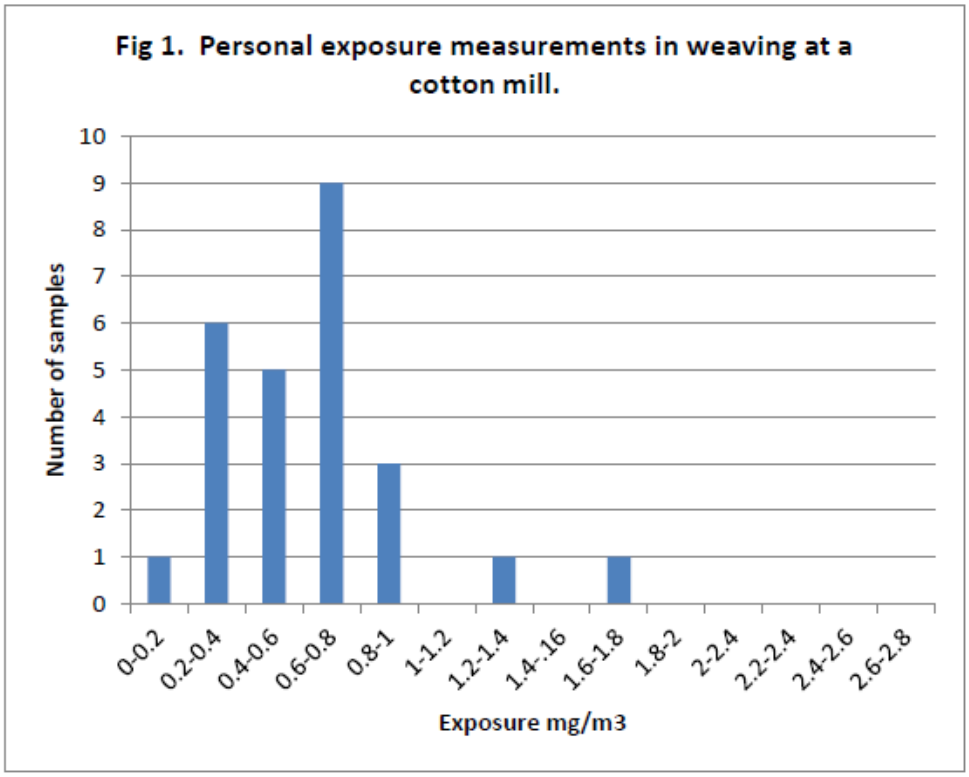
This kind of distribution can usually be fitted well by a log-normal curve.[1] Fig 2 shows such a curve fitted to the data in Fig 1. Because there is a limited number of exposure measurements in Fig 1 (26 altogether) the fit is rough, but if we were to make more and more measurements in this environment under the same conditions, Fig 1 would become a smoother curve and would probably look more and more like Fig 2 as the number of measurements increased. The usefulness of fitting the curve is that it enables us to estimate various parameters of this environment (and their likely errors) that we could only get exactly by taking a very large number of measurements. The curve shown in Fig 2 was fitted to the Fig 1 data using a spreadsheet IHSTAT™ which is made available by the American Industrial Hygiene Association (AIHA). More details of this and other software are given in Section 2.2 below.

Fig 2 shows several interesting features. The mean exposure estimated from the curve is marked as "est AM" and in this case is 0.62 mg/m^3 . (IHSTAT calculates values to three decimal places, but we round this to two in this chapter, although even this precision will often be unjustified.) Because of the variability of the results and the limited number of measurements, there is some uncertainty on this, and the confidence limits on the mean are shown (LCL and UCL). IHSTAT estimates that we can be 95% certain that if we took a very large number of measurements in this environment, the mean would be between 0.52 and 0.79 mg/m^3. The curve further predicts that 95% of measurements would be less than 1.38 mg/m^3. However, this 95th percentile is not known very precisely unless there is a very large number of measurements, and all we can say from these 26 is that we can be 95% certain that the true value of the 95th percentile is less than 1.98 mg/m^3. These values and others are all tabulated on IHSTAT when we input these data. All of this assumes that the measured exposures are log-normally distributed, but this is usually found to be the case.

IHSTAT enables us to input an occupational exposure limit for comparison with the data, and for illustration purposes we have supposed that the OEL is 1.7 mg/m^3. The programme estimates that 2.2% of the fitted log-normal curve lies above this value. From Fig 1 it can be seen that one of our 26 results (3.8%) was above this value, but clearly it could by chance easily have been 0 or 2 results, and

[1] This is related to the familiar bell-shaped normal curve – if the horizontal axes in Figs 1 and 2 were plotted as the logarithms of the concentration, the distribution would look like a normal curve.

if the distribution is really lognormal then the fitted curve gives a better estimate of what is likely to happen at the 95th percentile than our unprocessed measurements.



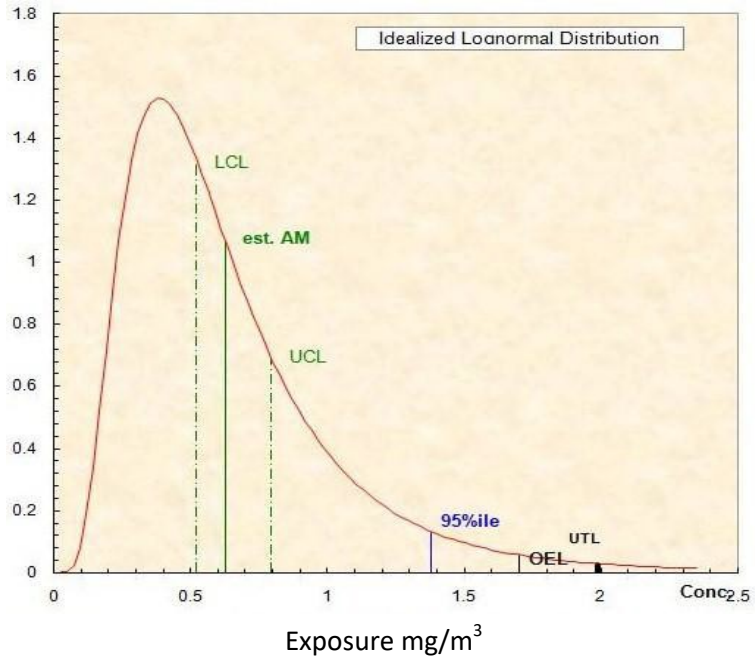


Fig 2. Log-normal curve fitted to the data in Fig 1 using the AIHA tool IHSTAT™

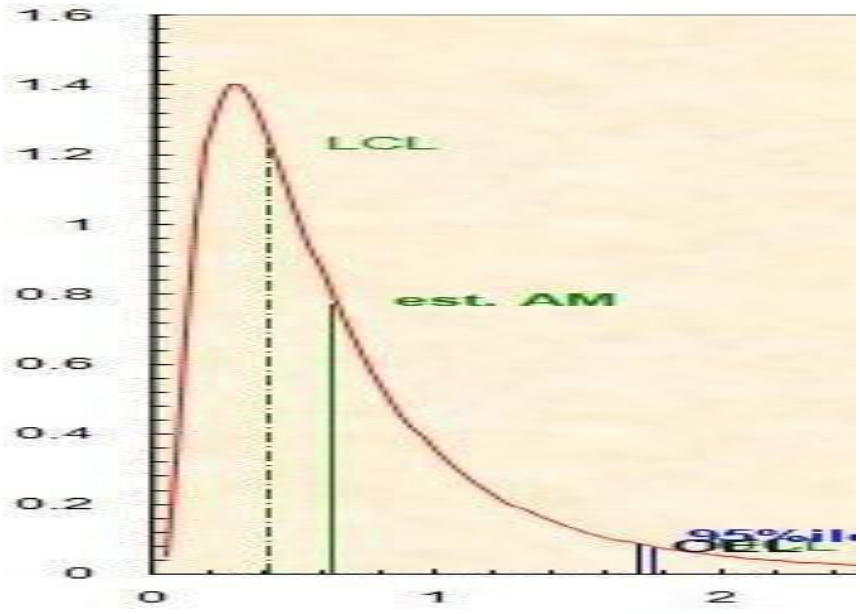
2.2 Some evaluation software

IHSTAT™, the software used in Section 2.1, is made available by AIHA at https://www.aiha.org/public-resources/consumer-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools/ihstat-macro-free-version. This is also illustrated in section 2.3, and we acknowledge AIHA's kind permission to use this copyright material. IHSTAT is a trade mark of AIHA. However, there are several other pieces of software available, which may have useful advantages, and if you analyse data of this type we encourage you to also look at these. A long-established example which has recently been updated is HYGINIST, downloadable from http://www.tsac.nl/downen.html. Another example produced by Paul Hewett is IHDataAnalyst, available fromhttps://www.easinc.co/ihda-software/ . Perhaps the most comprehensive is AltrexChimie, produced in France by the Institut National de Recherche et de Sécurité, downloadable free from https://altrex.inrs.fr/AltrexChimie/Common?pageName=accueil&h=005755. In Altrex Chimie it is permissible to enter the data in any order with, for example, who was sampled and on what day. It handles values below the Limit of Quantification (LoQ), and it produces graphs that can be pasted into a report, and has other useful features. It is in French, but the tutorial in the Help folder is fairly easy to follow for users with a basic knowledge of the language.
In addition, BWStat (downloadable from https://www.bsoh.be/?q=nl/bwstat) is free of charge software to estimate the GM and GSD to be applied to test compliance.

2.3 How many measurements?

Although we have seen that 26 measurements are too few to characterize exposure exactly, it is often thought to be impracticable to take anything like this number. What would happen if we only took say a quarter of this number?

Fig 3 shows the curve fitted by IHSTAT to 7 results taken at random from the set of 26 used in Figs 1 and 2. The arithmetic mean estimated from the curve is now 0.63 mg/m^3, which is very close to the earlier value of 0.62. The confidence limits on this mean are however much wider than before – 0.40 to 1.77 mg/m^3 – compared to 0.52 and 0.79 mg/m^3. In fact the main effect of using a small number of measurements is that the estimates of parameters are much less certain. The best estimate of the 95th percentile is 1.77 mg/m^3, compared with 1.38 before, but the uncertainty of this number is hopeless – all that we can say is that we are 95% certain that the 95th percentile lies below 6.9 mg/m^3. We think that the 95th percentile is just above the exposure limit of 1.7 mg/m^3, but it may be four times that. (IHSTAT drew the curve large enough to include 6.9 mg/m^3 on the horizontal axis. To make Fig 3 comparable with Fig 2, we just took the bottom section of the curve, and stretched; this is why the lettering appears distorted.) This illustrates that measuring compliance with an OEL requires a lot more measurement than generally assumed. We will discuss how compliance is defined in section 2.5, but first we must mention the importance of individual variation.



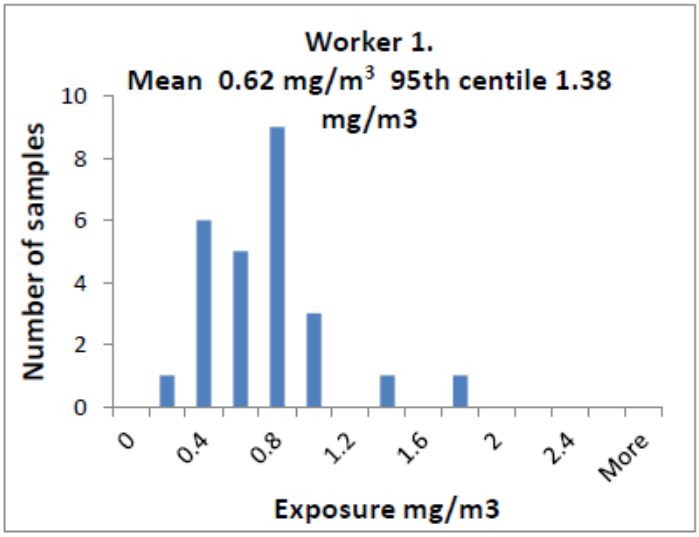
Exposure mg/m^3

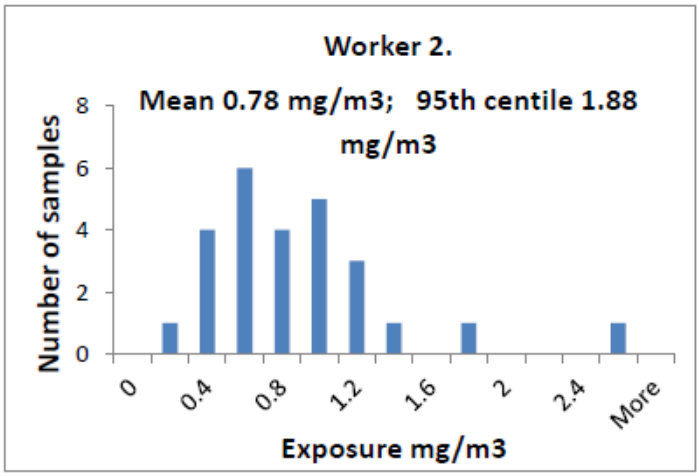
Fig 3. The lognormal distribution fitted by IHSTAT to seven measurements taken at random from the 26 used to produce Fig 2

2.4 The problems of between-worker and within-worker variability

An important complication is that two workers doing the same job will not have the same exposure, because of minor differences in work pattern or equipment. This phenomenon, known as between-worker variability, means that measurements of one worker's exposure cannot simply be assumed to apply to others doing nominally the same job. Of course, the hygienist will wish to correct any evident faults which increase exposure, but experience shows that even after this is done between-worker variability is sometimes not eliminated. Fig 4 illustrates the sort of difference that may occur. Rather more obviously, exposure varies from shift to shift, giving rise to within-worker variability. When they can be separated, both types of variation tend to follow lognormal patterns, and together they will give overall variation like that illustrated in Fig 1.

The usual procedure in assessing exposure where more than one worker is involved is to divide the workforce into similarly exposed groups (SEGs) (see section 3.2), and in some way or other to try to take samples which are representative of the group and representative of the work done. But because of between-worker variability, care must be used in applying a tool like IHSTAT to the whole group. The 95th percentile of the whole group may underestimate or overestimate the percentile for individual workers. These problems have been extensively investigated, especially in the past 20 years, and details are given in standard texts (e.g., Kromhout et al 2005; Ramachandran, 2005; Rappaport and Kupper, 2008). They must be taken into account in any compliance-testing procedure.





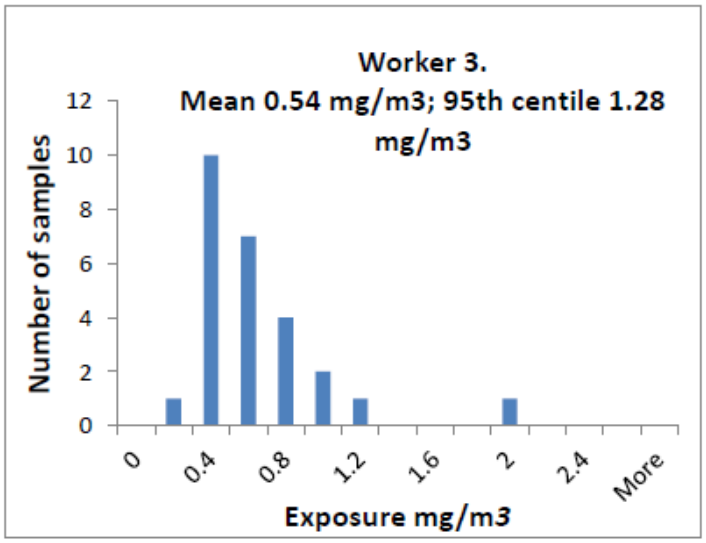


Fig 4. Simulated exposures of three workers in the same occupational group

2.5 The problem of compliance

The central problem of compliance testing is illustrated by Figs 1, 2, and 4. A few measurements will determine the usual exposure, but some results occur which are three or more times the usual value, sometimes for no obvious reason, and in theory the upper limit to the distribution can be very high. Workplace regulations usually apply OELs as absolute limits, with no excursions allowed: examples are the Chemical Agents Directive (EU, 1998), the Carcinogens Directive (EU, 2004), and, in Britain, the COSHH Regulations (HSE, 2005). So if several measurements are below the exposure limit, how can an employer be sure that the next one will not be above it and show non-compliance?

Defining OELs as sharp cut-offs has two bad consequences. First, it makes it impossible in principle for an employer to establish a monitoring programme which will prove that the exposure limit will always be complied with, however often it has happened in the past. Second, it is a disincentive to monitoring exposure. If a couple of measurements show compliance, then it seems better to stop at that point and not risk a higher result next time. When OELs were first defined they were not applied in this way, but current EU regulations treat them as sharp cut-offs, and we must cope with this.

OELs apply to all workers, not just to a group, so any monitoring programme must take into account between-worker variability. It is not permissible to offset low exposure of one worker against high exposure of another: all must comply.

2.6 The approach in this guidance

Faced with the variability problem outlined above, professionals have often regarded it as satisfactory to show that the 95th percentile of the exposure distribution is probably below the OEL. This sometimes gets regulatory backing. For example, although the Permissible Exposure Limit (PEL) for formaldehyde in the United States is an absolute limit, the US Occupational Safety and Health Administration 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” (OSHA, 2011). We are unaware of any such statement in Europe, but, as explained in the Introduction, enforcement authorities will usually look at exposure limits in the context of control practice, looking at a monitoring record alongside the questions: (1) are engineering methods working?; (2) are engineering controls and other procedures maintained?; (3) are there weaknesses in the way good practice is complied with?

This guidance therefore generally tests the 95th percentile. It does not take away the legal obligation that an OEL must not be exceeded. However, it aims to give hygienists and employers a way of demonstrating that there is a low probability of non-compliance, without requiring disproportionate resources. The records of a programme like this can be put alongside answers to the three questions above as evidence of compliance with good practice.

Chapter 3.
Recommended method of measuring compliance

3.1 Principles

The method in this chapter should only be applied and considered along with good control practice, as outlined in the Introduction to this guidance.

Almost all workplace occupational exposure limits (OELs) are defined as either 8-hr mean levels or short-term (usually 15 minutes) levels, and apply to personal exposure, ie exposure measured with equipment carried by the worker which samples contaminants from air near the nose and mouth. The procedures in this chapter describe how to compare measurements with 8-hr (shift) OELs.

Sources such as Cherrie et al. (2010) and AIHA (2006) describe how to take valid samples. For comparison with the OEL, all significant exposure periods during the shift should be included in the sample. For comparison with the OEL, the amount of the material collected should be divided by the volume of air that would have been collected if the sampling had continued for 8 hr. More details and examples of this sort of calculation are given in Annex B of EN 689 (CEN, 2018, formerly 1995). References to exposure measurements in this chapter mean shift-length average exposures calculated in this way.

As explained in chapter 2, compliance tests are often applied to similarly exposed groups (SEGs), but workers who are doing the same job are often unexpectedly found to have different exposure patterns. In this guidance we therefore test the SEG for compliance with the OEL, and, if there is evidence that different SEG members have different exposures, we test individual compliance. The two measures used are as follows.

Group compliance. The group complies if, with 70% confidence, <5% of the exposures in the SEG exceed the OEL.

Individual compliance. 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.

The method has five stages: selection of similarly exposed groups (section 3.2), a screening test (3.3), a group compliance test (3.4), and an individual compliance test (3.6) if an analysis of variance (3.5) shows that differences between individual exposure patterns makes this desirable. Fig 5 is a flowchart illustrating the process. Calculation methods are illustrated in Appendix 1.

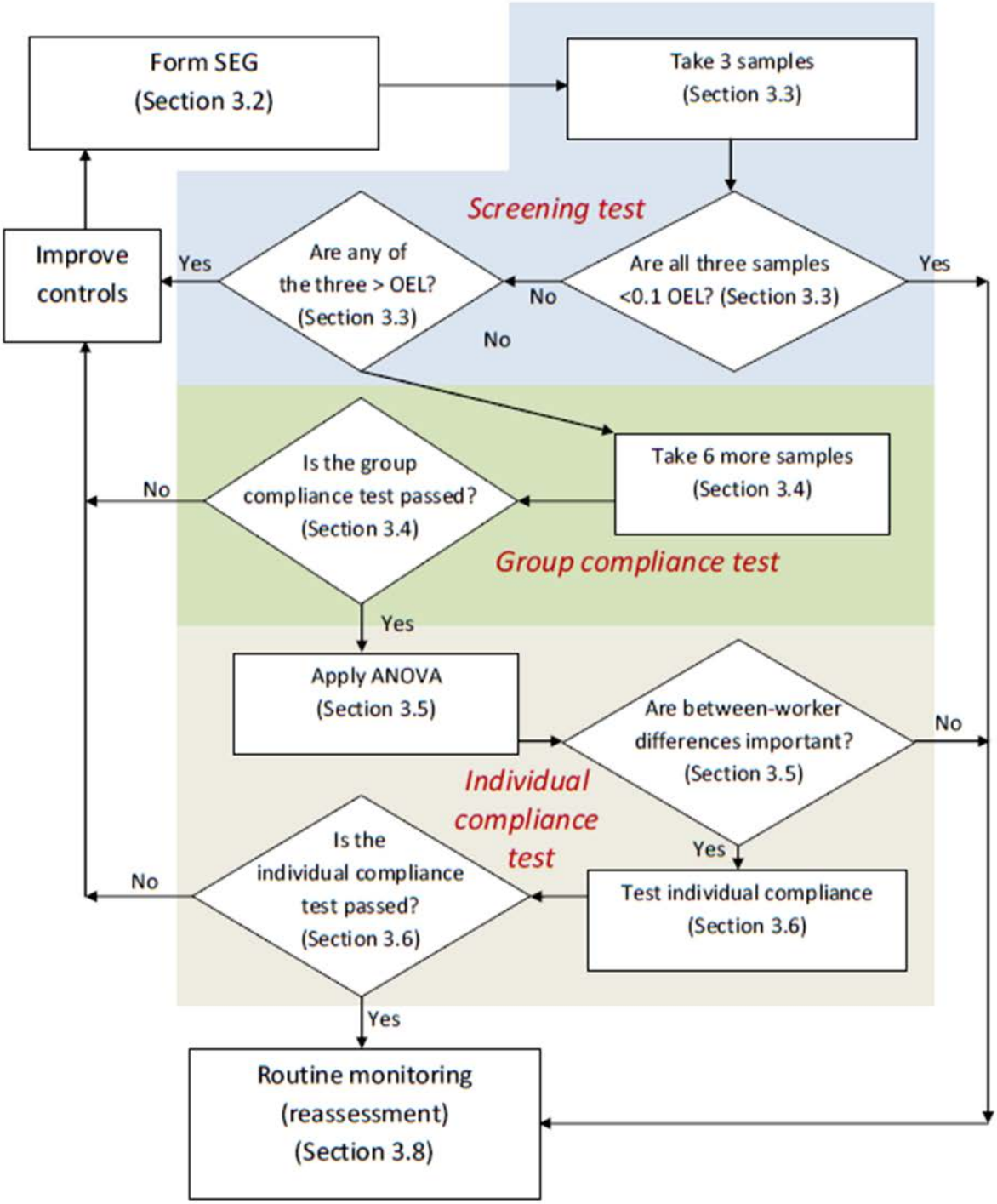


Fig 5. Flowchart of the process

3.2 Selection of similarly exposed groups (SEGs)

OELs apply to every worker, but where different workers are carrying out the same task in the same way, it is usual to limit the number of samples to be taken by dividing the workforce into similarly exposed groups (SEGs), and to make measurements on only some of the members of each group. Mulhausen and Damiano (2006) define a SEG as "A group of workers having the same general exposure profile for an agent because of the similarity of the materials and processes with which they work, and the similarity of the way they perform the task(s)." Clearly, allocating workers to a SEG will require careful examination of these three factors – the materials, the processes, and the ways of working. Using job titles to allocate workers to a SEG will almost certainly be insufficient. As explained in Chapter 1 above, a decision to test compliance with OELs using this guidance should involve a detailed initial survey, and the information gained in the survey will be useful in forming SEGs. If a person performs different tasks in different shifts, they he or she should be allocated to more than one SEG. Mulhausen and Damiano discuss SEG construction in detail, including difficult cases such as non-routine and non-repetitive tasks, and we recommend that their account is consulted in case of doubt.

If it is clear that if one or more people who are doing a task are known to be doing it in a different way from others, then by definition they should not be included in the same SEG as the others. It may be appropriate to put someone in a one-person SEG and proceed to compliance testing, or to conduct a preliminary examination to see which method of work produces least exposure and then to consider appropriate staff training.

When exposure measurements within a SEG are available, perhaps after the compliance testing process, it is possible to test whether the allocation of workers to a SEG was successful, using analysis of variance techniques. A feature of the AltrexChimie software, mentioned in Section 2.2, is that it will do this and report whether inter-worker differences are significant (Section 2.4). It also permits the user to test whether members of a SEG are really "similarly exposed" by permitting the user to set a geometric standard deviation judged to be acceptable for a SEG and to test if the group meets it.

3.3 Screening test

If LoQ > 0.1 x OEL (see section 1.2) it will not be possible to apply the screening test – the evaluation should go straight to the group compliance test (Section 3.4).

For the screening test, take three shift-length exposure measurements on workers selected at random from the SEG. If there are fewer than three workers in the SEG, the measurements will have to be spread over more than one shift, and one or more workers measured twice.

If all three results are <0.1 x OEL, then compliance with the OEL can be assumed to be satisfactory, and no further measurements are required immediately. However, routine repeat surveys should be planned (called reassessment by AIHA (2006) and periodic measurements by EN 689 (CEN, 2018, formerly 1995)) - see section 3.8 for further details of this.

If any of the three measurements exceeds the OEL, and there is no clear reason why the measurement is invalid, then clearly there is non-compliance and the programme may be

terminated. However, if there are reasons to believe that the result is invalid for some reasons, it should be discarded and the group compliance test should be done.

This screening test is taken with slight modification from Annex 1 of the French regulatory scheme (France, 2009), which has been validated by the Institut National de Recherche et de Sécurité (see INRS, 2008).

3.4 Group compliance test

The group compliance and individual compliance tests require the following exposure measurements from each SEG tested:
a minimum of 9 (or more if convenient) measurements;
at least 2 samples and if possible at least 3 shift measurements from each worker selected;
if there are > 2 workers in the SEG, measure exposure of at least 3 workers;
if not all workers are to be measured, select those measured at random.
If the 3 screening test measurements are still valid, they may be used again in the group and individual tests, with more measurements to make up the minimum of 9. Similarly, if other valid samples are available, for example as part of a long-term monitoring programme, they may be used.

Compliance has often been estimated by comparing the 95th percentile of the exposure distribution with the OEL (section 2.6). To be certain that this is true would require a very large number of samples to be taken. Work by the Institut National de Recherche et de Sécurité in France (INRS, 2008), and by Jérôme Lavoué of the University of Montreal (Lavoué, to be published), has shown that the test can be applied with a modest number of samples if we require 70% confidence that less than 5% of the exposures are above the OEL. This gives a balance between probability of declaring non-compliant a distribution which would prove compliant if a large number of samples were taken, and declaring compliant a distribution which would prove non-compliant if there were a large number of samples.

The test is applied as follows

Calculate the geometric mean M_G and the geometric standard deviation s_G of all of the exposure measurements in the SEG. If the n individual shift exposure levels are a_1, a_2, a_3,...a_n, these are

$$\log M_G = (\log a_1 + \log a_2 + \log a_3 \ldots + \log a_n)/n \qquad \text{(equation 1)}$$

$$\log s_G = \sqrt{\{ [(\log a_1 - \log M_G)^2 + (\log a_2 - \log M_G)^2 + (\log a_3 - \log M_G)^2 \ldots + (\log a_n - \log M_G)^2] / (n-1) \}} \qquad (2)$$

These can be worked out using a scientific calculator; or the method in Appendix 1 can be applied.

We then calculate the parameter U (also shown in Appendix 1)

$$U = [\log (OEL) - \log M_G] / \log s_G \qquad (3)$$

U is then compared with the limiting values given in Table 1. If U is less than the limiting value for the number of exposures given, the OEL is not complied with.

Table 1. Limiting values of U. The OEL is not complied with if U calculated from equation (3) is less than the limiting value given here. Limiting values of U for other sample numbers are given in Annex 2 of France (2009).

Number of exposure measurements	Limiting value of U
9	2.035
10	2.005
11	1.981
12	1.961
13	1.944
14	1.929
15	1.917

If the OEL is complied with by the group compliance test, it is necessary to perform an analysis of variance (section 3.5) to decide whether individual compliance should be tested.

(The group compliance test is taken from France (2009). It assumes that the exposures are log-normally distributed, and uses the estimates of the geometric mean and the geometric standard deviation to test whether we can be sure, with 70% confidence, that less than 5% of the exposures are above the OEL.)

3.5 Analysis of variance (ANOVA)

The total variation of exposure in the SEG is composed of temporal variation of each individual worker's exposure about that individual's mean and the variation in mean exposure between workers. If the between-worker variation makes an important contribution to the total variation it is necessary to test individual compliance (as defined in section 3.1).

We compare the between-worker variance with the total variance using a standard analysis of variance ANOVA procedure. This is explained in any statistics textbook, such as Wonnacott and Wonnacott (1990). Appendix 1 illustrates calculation using Microsoft Excel. If the between-worker variance is equal to or more than 20% of the total variance, then the individual compliance test in section 3.6 should be applied.

(Computer simulations by Jérôme Lavoué of the University of Montreal, made available to the working group, have found that if the SEG passes the group compliance test in section 3.4, and the between-worker variance is less than 20% of the total variance, then the individual compliance test will also be passed, so there will be no need to perform that test (Lavoué, to be published). ANOVA

can be used to test whether the between-worker contribution to variance is significant at the 5% level, but Lavoué's simulations have found that this does not add anything to the 20% test.)

3.6 Individual compliance test

If it were possible to construct SEGs perfectly, there would of course be no difference between exposure patterns of the members of the SEG, and the group compliance test would effectively test the exposure patterns of individual members of the SEG. However, differences can be subtle and only emerge in a sampling programme, so the results must be examined to see if differences have emerged, by testing individual compliance.

The individual compliance test may be omitted if the results of the analysis of variance in section 3.5 show that the between-worker variance is <20% of the total variance. If this condition is met then it can be assumed that the exposure patterns of the members of the SEG are sufficiently similar for the results of the group compliance test to be enough to characterize exposure. Otherwise, individual compliance should be calculated.

As defined in section 3.1, individual compliance requires <20% probability that any individual has >5% of his or her exposures exceeding the OEL. We estimate this by calculating the parameter

$$H = [\log (OEL) - (\log M_G + 1.645 s_w)] / s_b \qquad (4)$$

from Hewett (2005), Appendix A, and then calculating the fraction of the distribution which lies above this value. By our definition (section 3.1) our individual compliance criterion is met if this fraction is <0.2.

This procedure assumes that the logarithms of the exposures of each worker are normally distributed (ie that their exposures are log-normally distributed) and that the geometric means of the exposures of the individual workers are also log-normally distributed. S_w^2 and s_b^2 are respectively the within-and between-worker variances of the distributions of logged values. The calculation of this is illustrated in Appendix 1 to this guidance, using Microsoft Excel.

It might be thought that we need to be sure that no workers are in this position, not just <20%, but because the test is actually applied to log-normal distributions fitted to the exposure measurements, the result of this calculation is never zero. Another way of expressing our individual compliance criterion is that >80% of the SEG members have at least 95% of their exposures < OEL.

It should be noted that in sections 3.5 and 3.6 we have applied two completely different tests involving 20% thresholds, which should not be confused. In section 3.5 we said that individual compliance should be tested if between-worker variance > 20%, and in this section we have said that <20% of individuals should have >5% of exposures >OEL.

Other measures have been used as measures of compliance, for example the probability of overexposure (Kromhout et al., 2005), defined as the chance that a random worker's long-term mean exceeds the OEL. This has a logic in health terms for substances whose effect is due to long-term cumulative exposure, but because almost all workplace OELs are defined in terms of 8-hr or 15-min exposure, we have not used overexposure here.

3.7 Treatment of values < LoQ

Every attempt should be made to use analytical methods and sample volumes that keep the LoQ < 0.1 x OEL. If this is done, the tests in sections 3.3 to 3.6 can be applied without adjustment. However, with some substances it may prove impossible to keep the LoQ this low.

The treatment of values < LoQ in statistical analysis of sampling results is controversial, and is still an active field of research (Helsel, 2005 and 2010), so it is not possible to firmly recommend one method. A simple method is given below. But in general, if any way of treating values <LoQ discussed by Helsel or another reputable source gives a non-compliance decision, non-compliance is the decision.

Regression methods are available which use the distribution of results >LoQ to estimate the distribution <LoQ, for example applied by HYGINIST and AltrexChimie (see section 2.2). Methods for censored samples from lognormal populations combined with goodness-of-fit tests (eg Schneider, 1986) can be used for the group compliance test (section 3.4). The unbiased censored approach is included in e.g. HYGINIST. For the individual compliance test (section 3.6) a sound treatment of values < LoQ does not exists at the moment.

If no better test is available, the following is suggested, but it has not been fully validated. If more than 10% of the exposure values are < LoQ, the calculations in sections 3.4 and 3.6 should be carried out three times, with < LoQ values treated this way:
(1) substitute all <LoQ values by 0.25xLoQ;
(2) substitute them all by the LoQ;
(3) substitute half of them by 0.25xLoQ and half by LoQ.
If all three approaches lead to a compliance decision, this can be accepted, but if any give non-compliance, non-compliance is the decision.

It is not recommended simply to substitute LoQ/2 or LoQ/√2 for each value below the LoQ (Helsel 2010).

3.8 Reassessment

A survey which establishes that the OELs are complied with should be followed by occasional reassessment, and if possible a programme for this should be planned and agreed with management or the responsible authority at the end of the initial survey. Such a programme is called “periodic measurements” by EN 689 (CEN, 2018, formerly 1995) and “reassessment” by AIHA (2006).

A reassessment programme should have the general aim of ensuring that control remains satisfactory, and checking compliance with the OEL will be part of this. The programme should therefore take into account changes in the factors affecting exposure, including changes in process, substances, ways of organising work such as shift patterns, and substantial changes in personnel. However, those involved may be unaware of changes affecting exposure, such as gradual deterioration in ventilation equipment, or subtle changes in ways of working, so there should be an agreed programme to reassess compliance with the OEL even in the absence of obvious change.

The interval for reassessment depends mainly on professional judgement if there are no obvious signs of change, and will depend upon the industry and the processes involved. AIHA (2006), CEN (1995), and France (2009) all make somewhat different recommendations, and from these the following intervals for reassessing compliance with OELs should be considered. The geometric mean (GM) is calculated for the results obtained in sections 3.3 and 3.4, plus any later relevant results.

GM <0.1 OEL	2 yr
0.1 OEL < GM < 0.25 x OEL	1 yr
0.25 OEL <GM< 0.5 OEL	6 months
0.5 OEL <GM	3 months

However, these intervals should be interpreted taking into account the following.

- Effective control measures should be applied by those responsible for the workplace at all times, bearing in mind that in Europe and many other jurisdictions the law requires effective control as well as compliance with OELs. Those responsible for the workplace must therefore be aware of the relevant important measures.
- The intervals will depend on the hazard: extra care should be taken if carcinogens, mutagens, or reproductively toxic materials are present, or if for there are substances for which there is risk of serious or permanent injury at levels only a little way above the OEL.
- On the other hand longer intervals between reassessing compliance with the OELs may be justified if the workplace is under supervision of a professional hygienist, and there are stable continuous processes with high levels of engineering control and well defined working processes with high quality control regimes, with change concentrated mainly in well defined periods such as controlled maintenance.

These uncertainties underline the importance of the use of qualified and experienced occupational hygienists in making this sort of judgement (see Introduction).

3.9 Use of the results

As discussed in Section 2.5, the law (and good hygiene practice) requires that exposure should be kept low, not just below the OEL. But if the OEL is not complied with by the tests in sections 3.4 and 3.6, then prompt remedial action is required. If the group compliance test fails, then attention should be given to the exposure of the whole SEG, perhaps by redesign of work practices or improvement of engineering control measures. If the individual compliance test fails, then attention may have to be given to the work practices, equipment, or local control equipment for individual workers.

In the individual compliance case, the individuals with high individual exposures will need to be identified. If several samples have already been taken on individuals, then it may be clear by inspection where the problems lie. If it is not this obvious, then an individual's results can be entered into suitable evaluation software (section 2.2) to estimate where his or her 95^{th} percentile lies in relation to the OEL. Section 3.4 only requires a minimum of 2 and if possible 3 samples per worker, and if the individual compliance test fails then more sampling will be required to investigate further individual exposure.

The hygienist may also wish to look again at sources of exposure and efficiency of control measures, using direct-reading instruments for example. However, discussion of control measures is beyond the scope of this guidance – see the summary in the Introduction to this document.

Chapter 4.
Shortcuts and their limitations

4.1 Shortcut 1: Take a few samples from the most exposed worker and use evaluation software

Advantage

Evaluation software (see section 2.2) can be used to very roughly quantify the exposure in relation to the OEL from a small number of samples.

Limitation

This depends on identifying the most-exposed workers, and failing to do so means that the approach gives false confidence. The approach does not give the overall picture that is obtained by calculating the group and individual compliances. Moreover any conclusions about relation of individual exposures to the OEL are very uncertain unless many measurements are taken, in which case the shortcut loses its point.

Outline

It is of course possible simply to take a small number of samples and enter them into software such as IHSTAT or HYGINIST – see section 2.2. This can be done without going through the process in chapter 3. Bearing in mind that OELs apply to all workers, the highest-exposed workers in a SEG should be identified and included, perhaps using a direct-reading instrument to see where the strongest sources are. Then the software can be used to estimate the distribution of exposures for each worker who might be at significant risk of exceeding the OEL. But the above limitations make the results very uncertain.

4.2 Shortcut 2. Taking a few samples and seeing if they are < OEL/3

Advantage

The principle appears in the previous version of the G409 guidance from the British Health and Safety Executive (HSE, 2006). Provided that a dozen or more samples are taken on the most exposed workers, that the results are lognormally distributed, and that at least three quarters are below one-third of the OEL, the method will work.

Limitations

Although this rule was seen as helpful when published, later work shows that it is not a shortcut, because to give a reasonably reliable result it needs as many samples as the more statistically valid tests in Chapter 3. As with shortcut 1, it depends on identifying the most-exposed workers, and failing to do so means that the approach gives false confidence. The approach does not give the overall picture that is obtained by calculating the group and individual compliances.

Outline

From the point of view of dealing with enforcement authorities, this approach has the practical advantage of being mentioned in the previous version of the British Health and Safety Executive's COSHH Essentials G409 guidance sheet on air sampling, which advises employers, "If the results for a given task are below one third of the exposure limit, your controls are probably good enough" (HSE, 2006). At first sight this looks like a useful rule of thumb. It is true that if the exposures are lognormally distributed with a geometric standard deviation (GSD) of 2.5, then if 75% of exposures are less than one-third of the OEL only about 3% will be above the OEL. (A GSD of 2.5 is close to the median found by Kromhout et al. (1993), for SEGs defined by workplace and job title. More precisely-defined SEGs would have lower GSDs and a smaller percentage above the OEL if this rule were applied.)

The flaw with HSE (2006) is that it gives no guidance on how many samples should be taken, and the monitoring-averse employer may take as few as possible. Three results of say 0.1, 0.2, and 0.3 give poor confidence of compliance with an OEL of 1.0. Putting these figures in IHSTAT (see section 2.2) shows that there is more than a 30% chance that 5% of the distribution lies above the OEL. IHSTAT can be used to explore the effect of more samples, and by the time a dozen samples have been obtained with three-quarters below one-third of the OEL, then there is a high degree of confidence that the OEL is complied with. This assumes that the log-normal assumption is met and that the most exposed workers have been identified and that it is their exposure that is measured.

But if that many samples are taken, it is no longer a shortcut: the tests in Chapter 3 can be used.

4.3 Shortcut 3. AIHA and Bayes

Advantage

Potentially a powerful approach to exposure surveys, and likely to be a very useful tool in managing workplaces to comply with OELs.

Limitation

Decisions depend to a certain extent on the hygienist's professional judgement, which an enforcer might not accept.

Outline

Hewett et al (2006) and Ramachandran (2008) have described a method of applying Bayesian statistics to the American Industrial Hygiene Association (AIHA) exposure classification system. It is a major development in the approach to control in relation to OELs, but as it stands it does not seem to give us a method of quantifying compliance.

The approach is based on exposure classifications illustrated in the Table.

Exposure category	*Statistical interpretation*
Cat 1	95th percentile < 0.01 x OEL
Cat 2	0.01 x OEL < 95th percentile < 0.1 x OEL
Cat 3	0. 1 x OEL < 95th percentile < 0.5 x OEL
Cat 4	0.5 x OEL < 95th percentile < OEL
Cat 5	95th percentile > OEL

(95th percentile means the upper 95th percentile of the exposure distribution)

The method involves the hygienist using professional judgment and experience to estimate the fraction of exposures which would be expected to fall in each category (the *prior distribution*), and then taking some measurements and putting them in the categories to form a *likelihood distribution*. Software is available which combines these using Bayesian methods to form a *posterior distribution*. If the professional judgement is good, this method of testing and refinement by measurements should give a good picture of reality with relatively few measurements. Also, Logan et al (2009) have shown that the professional judgement can be improved by systematic feedback of results.

Applied as described by Ramachandran (2008), and combined with examination of control practice as outlined in the Introduction, this may be a powerful method of approaching exposure in the workplace. Also, if the outcome of this process is, say, < 5% of the posterior distribution in Category 5, then we can have reasonable confidence that the OEL is complied with. The problem for our purpose is that an enforcer may not regard professional judgement as acceptable evidence, and without this component the method becomes similar to Shortcut 1 above. However, in a preliminary review of exposures this could be an efficient method of establishing which SEGs are likely to have difficulty complying with the OEL.

For those who wish to try it, IHDataAnalyst can be downloaded from the Exposure Assessment Solutions website https://www.easinc.co/ihda-software/ . The free Student 2020 version is not for professional use and therefore you may have to pay for IHDataAnalyst V1. The free version is not supported and no liability is accepted, and the user does so at their own risk. This applies also to the following instructions.

- Go to https://www.easinc.co/ihda-software/ and click the software downloads link either to download IHDataAnalyst – Student 2020, or to purchase and then download IHDataAnalyst V1. You have to register.

- When you have installed and open the programme, a window opens. Click the BDA Initial Rating tab, check "Custom Professional Judgement Prior", and you can then enter in the boxes the estimated probabilities of exposures being the above AIHA categories.

- Then, when measurements are available, go to the Data tab, enter an OEL, and, in the Conc column, enter the measured exposures.

- Then click the BDA Charts tab. This displays (top) the prior distribution that you estimated, (middle) the likelihood distribution calculated by the programme from the data you entered, and (bottom) the Bayesian combination of these as the posterior distribution.

Appendix 1. Calculations for the group and individual compliance tests

This Appendix gives calculation methods for the group and individual compliance tests, as described in Section 3.4 to 3.6.

A1.1 SPEED

The Institute of Risk Assessment Sciences at the University of Utrecht and collaborators have developed a programme called SPEED which does the sort of calculations necessary. This is available from http://www.iras.uu.nl/iras_speed.php . At the time of writing, the only available version is based on earlier versions of Microsoft Excel, and does not work with later versions. A new version of SPEED is being written, which is based on R, and this should make it independent of the version of Excel or Windows.

When the new version of SPEED becomes available, it is expected to be easier to operate than the Excel version given below, and being simpler to operate there should be less chance of making a mistake. However, most hygienists or employers will have Excel, or the OpenOffice equivalent, and many organisations are reluctant to allow third-party software. An Excel route to the calculation is therefore given. This will also enable those interested to see how the parameters are derived.

A1.2 Excel method

The example that follows was developed using Microsoft Excel 2007 and Microsoft Windows Vista, but it runs unchanged on Excel 2010 and Windows 7. Free downloadable software BWStat (https://www.bsoh.be/?q=nl/bwstat) contains the example outlined below.

A1.2.1 Entering the values

As an example we have considered a SEG of three workers, who have their personal exposures to cotton dust measured. The (fictional) results are shown in Fig A1. Two of the workers were measured four times but Chloe was not working in the SEG on Tuesday and Wednesday, so there are only two measurements for her. The measurements will only represent the exposure if there is no systematic variation of exposure with the day of the week, and the measurements must be representative of the usual exposure if the results are to be valid.

If any of the results are below the level of quantification LoQ, see section 3.7.

So the first step is to type in the data on a spreadsheet workbook. Fig A1 shows the example we will use.

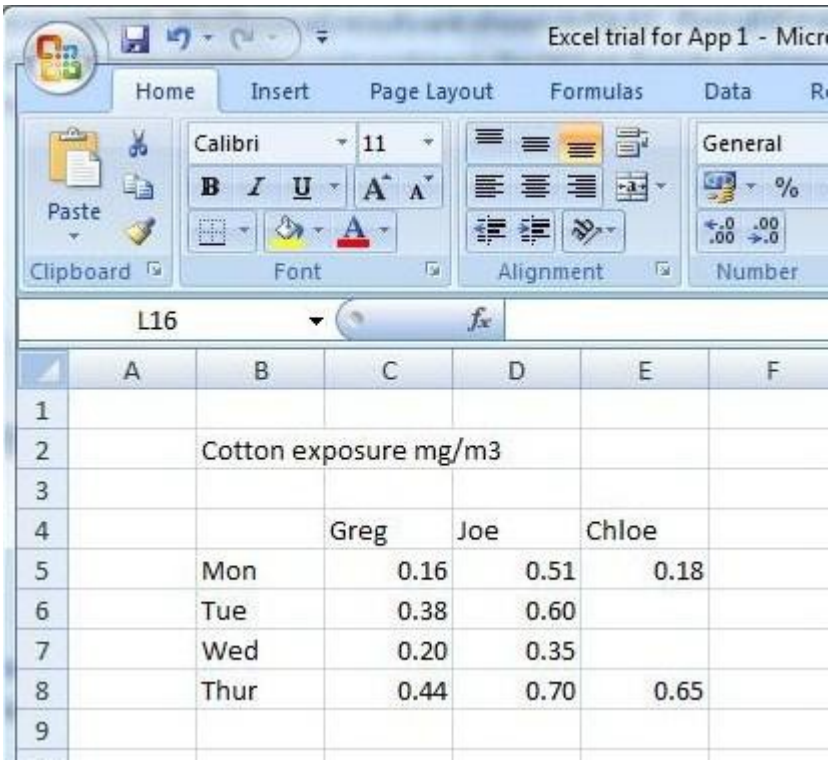


Fig A1. The data – personal exposures to cotton dust for three staff.

The next step is to calculate the natural logarithm of each of these values. As explained in the main text, the data are assumed to be lognormally distributed, so we have to work with the logged values, because the analysis works with values that are normally distributed. The process is shown in Fig A2. We have prepared headings for the table of the log values to the right of the original data, and now use an Excel maths function, typing =LN(C5) in cell H5. This produces in H5 the natural log of the value in cell C5.

Throughout this appendix, we will be using natural logarithms, designated LN in Excel, not logarithms to the base 10. For brevity, we often refer to the logarithm of a value as the logged value. The number of decimal places displayed in each cell depends on setting under the Home tab, and in the example cells H5 to J8 are set to display two decimal places, but Excel stores numbers to many more decimal places and uses them in calculation.[2]

[2] After the Figs in this Appendix were made, it was found that simulated measurements had been entered in cells D7, D8, and E8 to more decimal places than the two displayed here. This means that if the reader tries to reproduce this example, some of the calculations will give different numbers in the third or later decimal places from those in the Figs. This has no effect, but is mentioned in case it causes confusion.

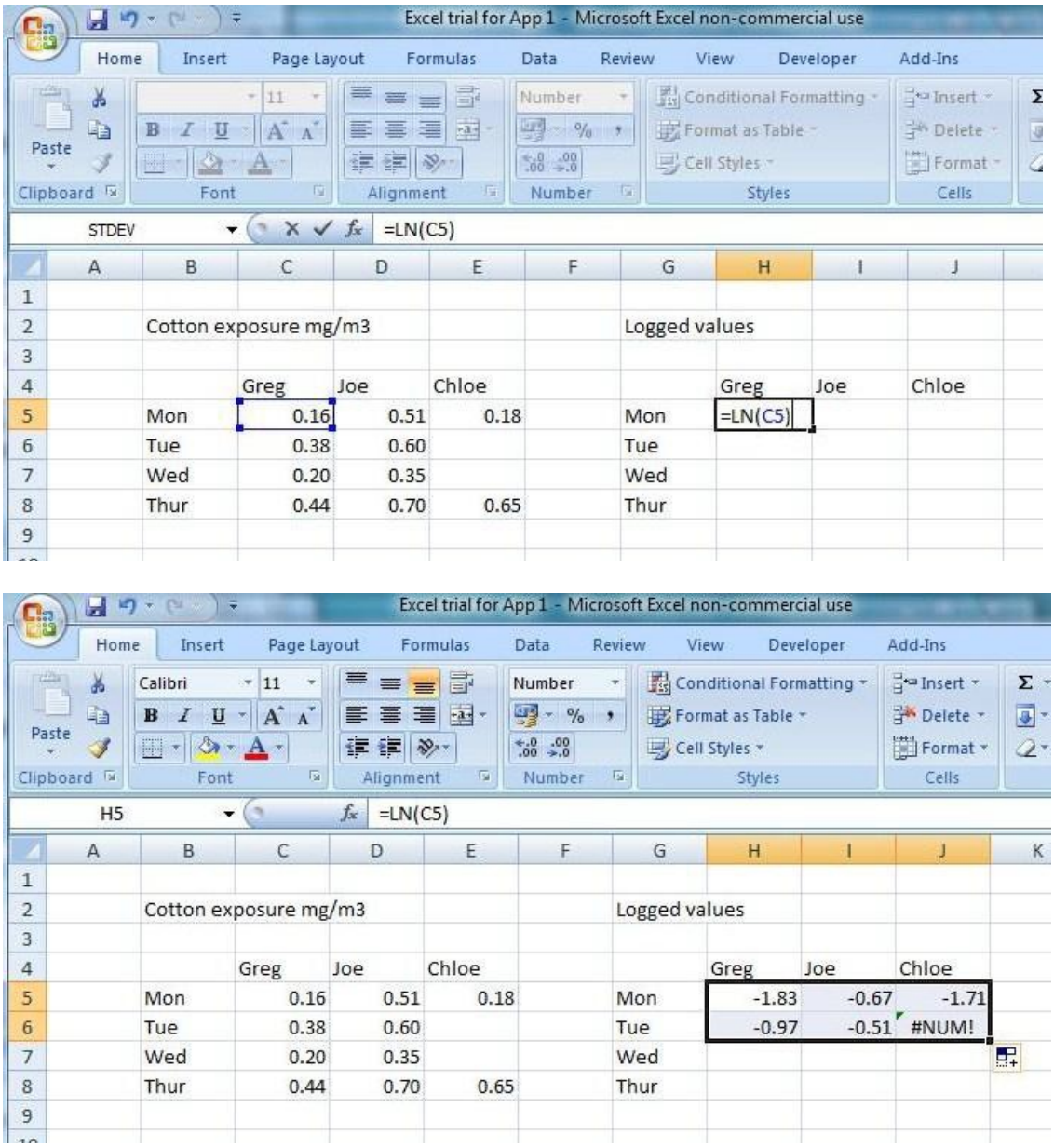


Fig A2. Two stages in the calculation of the log-transformed values.

We then click on cell H5, and move the cursor to the bottom right hand corner of this cell, when the cursor should change to a thin black cross. Hold down the left button of the mouse and drag the cross over to the bottom right-hand corner of cell J5 (Chloe on Monday) and then down to the bottom right-hand corner of cell J8 (Chloe on Thursday). Fig A2b shows this process half completed. This should fill cells H5 to J8 with the natural logarithms of the original cotton exposures in cells C5 to E8. It is necessary to delete the error signs in J6 and J7, which appear because the log of zero cannot be calculated. The completed table is shown in Fig A3.

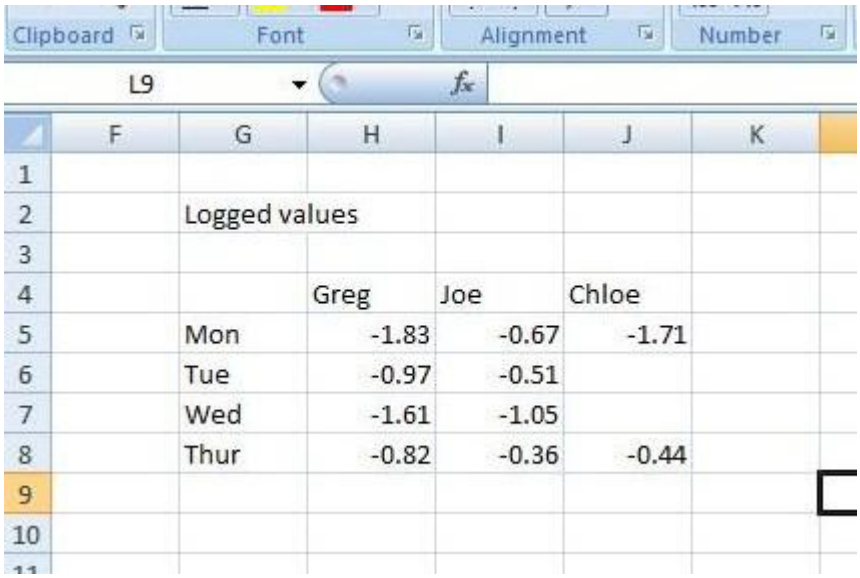


Fig A3. The table of Log values completed

A1.2.2. Group compliance calculation

We can now use these logged values to test group compliance, as explained in Section 3.4 of the main text. The first step is to calculate the logs of the geometric mean M_G and the geometric standard deviation s_G as defined by equations 1 and 2 in section 3.4. In practice we can do this using two of the functions built into Excel. In Fig A4 we have started to put log M_G in cell H10, by typing in that cell

=average(

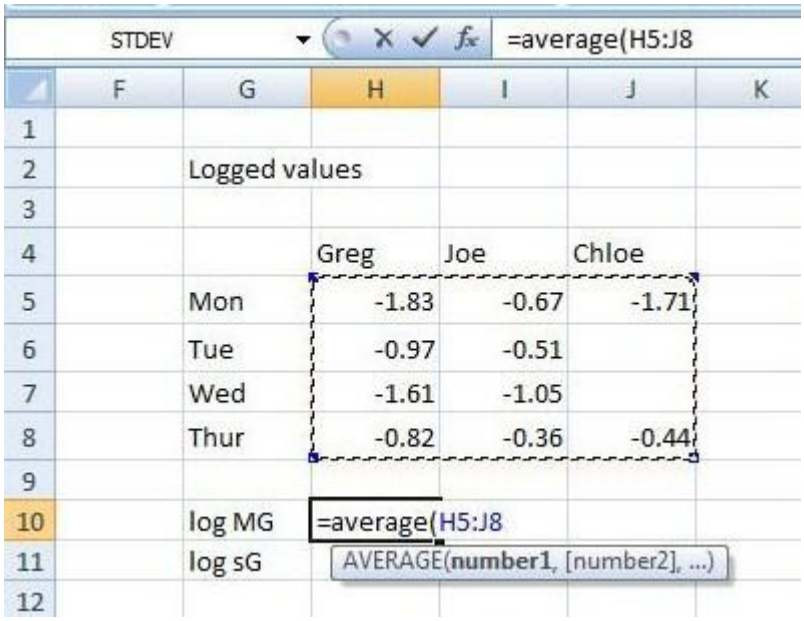


Fig A4. Calculation of log M_G

which calls up the Excel averaging function, and using the mouse to select the cells H5 to J8, which contain the values we want to average. If we then hit the return key the average of these logged values is put into cell H10, as required. We have also typed reminder labels into G10 and G11 for the functions we are calculating. The log of the geometric mean, which we have just calculated, is equal to the mean of the logged exposure values. This follows from the definition of the geometric mean.

As shown in Section 3.4 equation 2, log s_G is the standard deviation of the logged values, and we put that in cell H11 by typing
=stdev(
in that cell and again selecting cells H5 to J8 and hitting return. The outcome is shown in Fig A5.

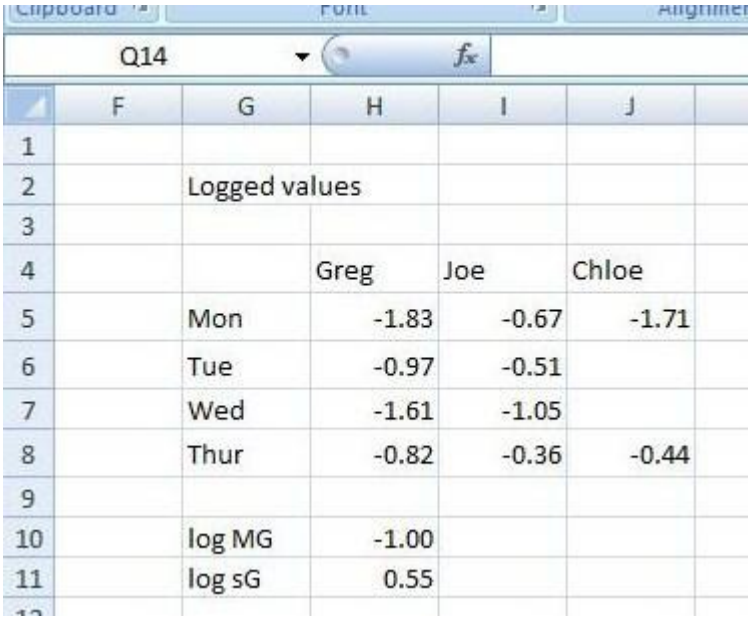


Fig A5. Log M_G and log s_G calculated

We are now in a position to test group compliance by the procedure in Section 3.4 in the main text. As in Section 2.1, we will assume for the purposes of illustration that the applicable OEL is 1.7 mg/m^3, and we will put this value in cell K10 with a label in J10 to remind us (Fig A6). (1.7 mg/m^3 is an arbitrary choice, and as far as we know this OEL is not use for cotton dust anywhere.) We will apply equation (3) in Section 3.4 to calculate the parameter U, and we will use the calculation ability of Excel to put it in cell H12, calling up the values of log M_G and log s_G from cells H10 and H11, and the OEL from K10. Fig A6a shows the calculation in progress and Fig A6b shows it complete.

Fig A6b shows that in this example U = 2.80. Referring to Table 1 in Section 3.4, it will be seen that by the group compliance test the OEL is regarded as complied with if U > 2.005 for 10 exposure measurements. Clearly there is compliance in this case. Comparing the postulated OEL of 1.7 mg/m^3 with the (unlogged) exposure values in Fig A1, this is not surprising. With these exposure results, the OEL has to fall to 1.1 before U falls below 2.005 and a non-compliance decision is reached. Again comparing 1.1 with the exposure values in Fig A1, it is not obvious that a statistically-valid procedure would give this result.

Having reached a compliance decision by the group compliance test, we now have to perform an analysis of variance to test individual compliance.

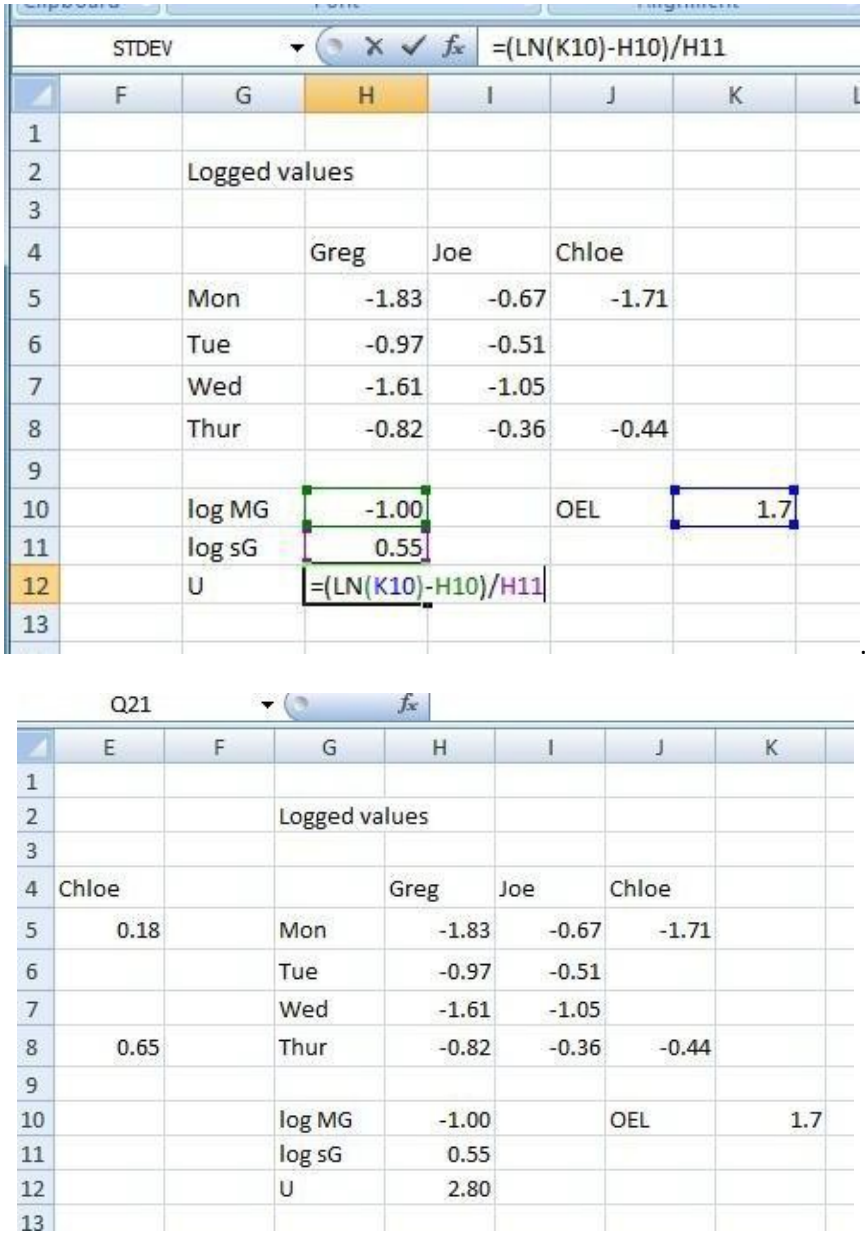


Fig A6. Calculation of the parameter U

A1.2.3 Analysis of variance (ANOVA)

We are now ready to do the necessary analysis of variance. At the top of the ribbon at the top of the worksheet, click the Data tab, then in the Analysis group at the right-hand end of the ribbon, click Data Analysis (in Excel 2002, this is in Tools). (If "Data Analysis" is not visible, it may be because the Analysis ToolPak is not yet installed – see Excel help.) This produces a window listing various statistical tests. Fig A7 shows this window. We select ANOVA: Single Factor, and click OK.

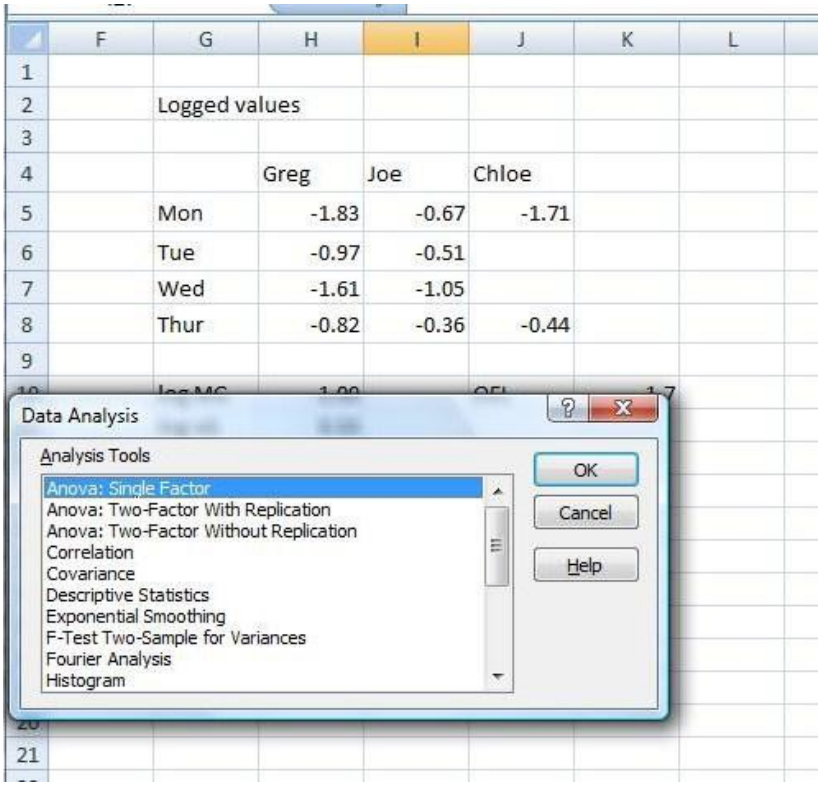


Fig A7. Selecting the ANOVA function

Selecting the ANOVA function produces the window shown in Fig A8. We click in the Input Range slot and type in (or select with the mouse) the cell locations of our table of logged values.

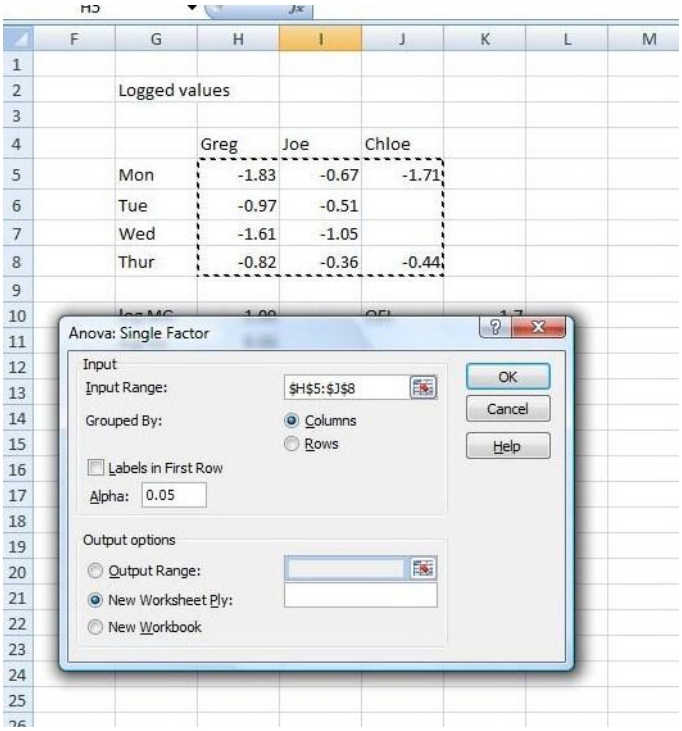


Fig A8. Selecting the input data

Then we check the button against Output Range, and in the slot we type the location of the top left hand of the area where we would like the results to be displayed. In this case, we choose cell M13 (Fig A9). (Instead of typing, we can click in the Output Range slot, and then click in cell M13.) Now we are ready to click OK, and the results of the Analysis of Variance are displayed (Fig A10).

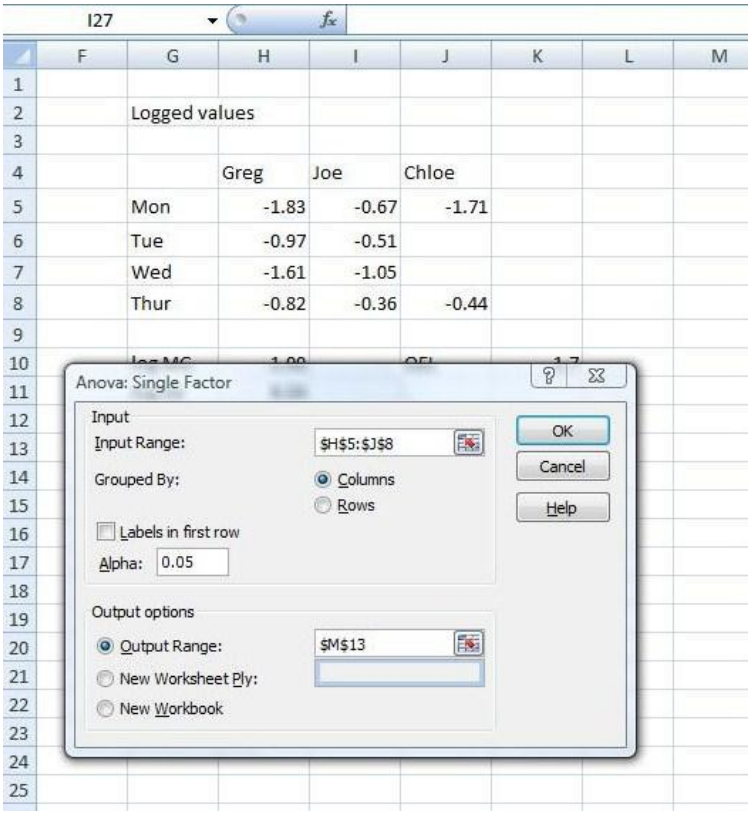


Fig A9. Selecting the Output Range – the place where the results will be displayed

For our purpose we only need some of the results in the analysis of variance (ANOVA) table. (A full explanation of it can be found in any statistics textbook, for example Wonnacott and Wonnacott, 1990.) We will use them to calculate the within-worker and between-worker variances. For explanation of the calculations, see Rappaport and Kupper (2008), p 47.

I37

	G	H	I	J	K
2	Logged values				
4		Greg	Joe	Chloe	
5	Mon	-1.83	-0.67	-1.71	
6	Tue	-0.97	-0.51		
7	Wed	-1.61	-1.05		
8	Thur	-0.82	-0.36	-0.44	
10	log MG	-1.00		OEL	1.7
11	log sG	0.55			
12	U	2.80			

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

ANOVA

Source of Variatior	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	0.879759	2	0.43988	1.706894	0.249008	4.737414
Within Groups	1.803954	7	0.257708			
Total	2.683713	9				

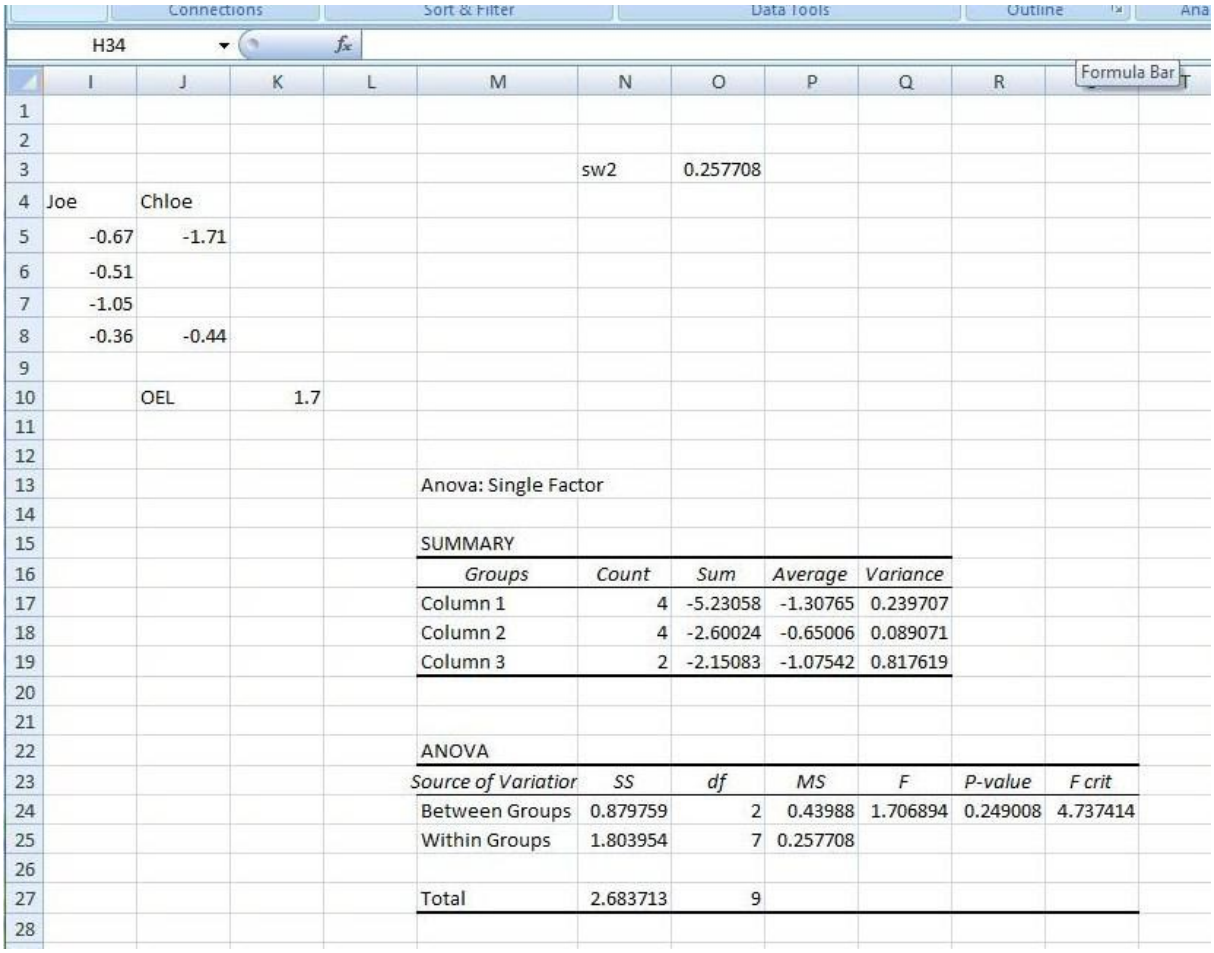
Fig A10. The results of the Analysis of Variance. (We have broadened column M so that the titles of the rows in the ANOVA are completely visible)

A1.2.4 Within-worker variance

The within-worker variance is estimated by the mean square (MS) figure in the "Within Groups" row of the ANOVA table, ie cell P25 of Fig A10, from which we can see that the variance is 0.257708 in this case. For convenience we will put this in cell O3. In O3, type

=P25

In N3, type sw2, to remind us that this is the within-worker variance. Fig A11 shows the resulting display.



	I	J	K	L	M	N	O	P	Q	R
1										
2										
3						sw2	0.257708			
4	Joe	Chloe								
5	-0.67	-1.71								
6	-0.51									
7	-1.05									
8	-0.36	-0.44								
9										
10		OEL	1.7							
11										
12										
13					Anova: Single Factor					
14										
15					SUMMARY					
16					*Groups*	*Count*	*Sum*	*Average*	*Variance*	
17					Column 1	4	-5.23058	-1.30765	0.239707	
18					Column 2	4	-2.60024	-0.65006	0.089071	
19					Column 3	2	-2.15083	-1.07542	0.817619	
20										
21										
22					ANOVA					
23					*Source of Variation*	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
24					Between Groups	0.879759	2	0.43988	1.706894	0.249008	4.737414
25					Within Groups	1.803954	7	0.257708			
26										
27					Total	2.683713	9				
28										

Fig A11. Displaying the within-worker variance in cell O3

We will later need the within-worker standard deviation, which is the square root of the variance. We can get Excel to calculate this and to put the answer in cell O4 by typing

=sqrt(O3)

in O4. Fig A12 shows the result, with a label added in N4.

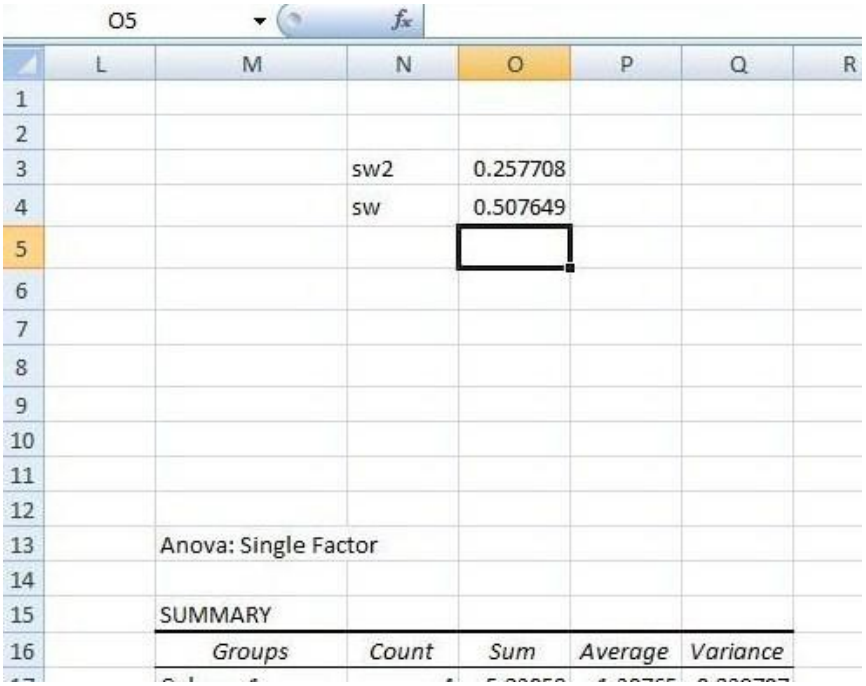


Fig A12. Calculation of the within-worker standard deviation

A1.2.5 Between-worker variance

To calculate the between-worker statistics we first need the between-worker mean square (MSB). This is already calculated by Excel, and appears in as the Between Groups MS in the ANOVA table. This is in cell P24 in Fig A11, which in this case shows the figure 0.43988. As in Section 3.4, we designate the within-worker and between-worker standard deviations as s_w and s_b respectively; the corresponding variances are the squares of these. If we had taken the same number of exposure measurements n_0 from each person in the SEG, then MSB would be given by

$$MSB = s_w^2 + n_0 s_b^2 \quad \text{(A1)}$$

(Rappaport and Kupper, 2008, Table 5.2.4), and then

$$s_b^2 = (MSB - s_w^2) / n_0 \quad \text{(A2)}$$

Our example is rather more complicated, and probably more realistic, because we could not get all the people we wished to measure present on every shift. In this case, n_0 is given by

$$n_0 = \frac{\left\{N - \frac{\left(\sum_{i=1}^{k} n_i^2\right)}{N}\right\}}{(k-1)} \quad \text{(A3)}$$

where N is the total number of measurements, k the number of people sampled, and n_i is the number of exposure measurements made of the i^{th} person (Rappaport and Kupper, 2008, p 47). The factor $\sum_{i=1}^{k} n_i^2$ is the sum of the squares of the number of samples taken for the individual workers.

In our example, we have 4 measurements for Joe, 4 for Greg, and 2 for Chloe, so $\sum_{i=1}^{k} n_i^2 = 4^2 + 4^2 + 2^2$.

R8 =(R3-(R4^2+R5^2+R6^2)/R3)/(R7-1)

	G	H	I	J	K	M	N	O	P	Q	R
2	Logged values										
3							sw2	0.257708		N	10
4		Greg	Joe	Chloe			sw	0.507649		n_1	4
5	Mon	-1.83	-0.67	-1.71						n_2	4
6	Tue	-0.97	-0.51							n_3	2
7	Wed	-1.61	-1.05							k	3
8	Thur	-0.82	-0.36	-0.44						n_0	3.2
10	log MG	-1.00		OEL	1.7						
11	log sG	0.55									
12	U	2.80									

Anova: Single Factor

SUMMARY

Groups	Count	Sum	Average	Variance
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

ANOVA

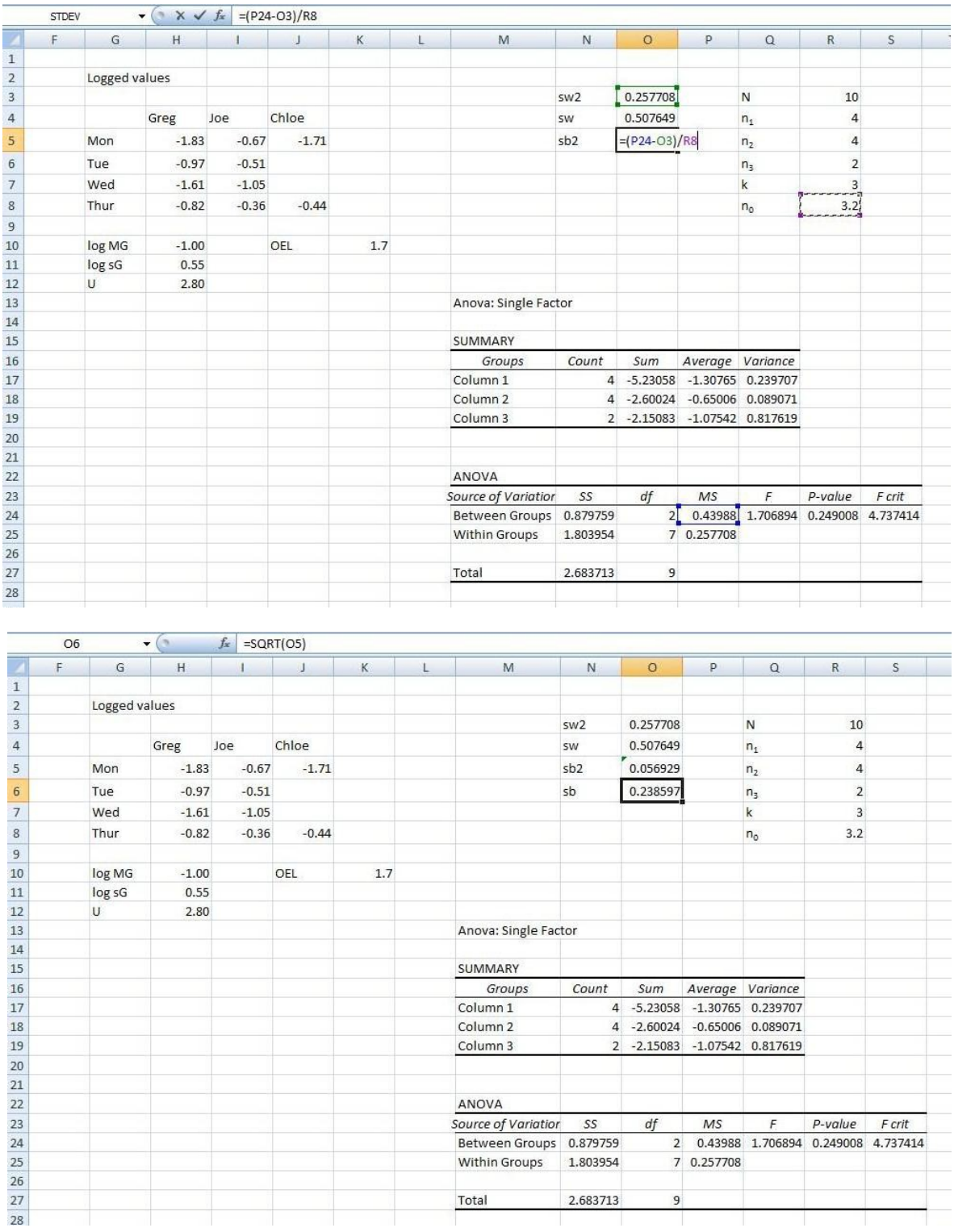
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	0.879759	2	0.43988	1.706894	0.249008	4.737414
Within Groups	1.803954	7	0.257708			
Total	2.683713	9				

Fig A13. Calculating the weighted equivalent number of measurements per person, n_0

In Fig A13, we have for clarity put into cells Q3 to Q7 the names of variables on the right hand side of equation A3, and in cells R3 to R7 we have put their values. Then in cell R8 we have calculated the value of n_0, by typing in the cell the formula which appears in the formula line at the top, which is a transcription of equation A3, calling up the values in cells R3 to R7.

We can now use equation A2 to calculate the between-person variance s_b^2, remembering that the between-worker mean square MSB is in the ANOVA table, and using the value of n_0 that we have just calculated. We will put the between-worker variance s_b^2 in cell O5, using Excel to do the calculation, and then put its square root, the between-worker standard deviation, in O6, with the appropriate labels in N5 and N6 (Figs A14a and A14b)

Because we are only estimating the variances from a limited number of measurements, it sometimes happens that our estimate of MSB will be less than our estimate of the within-worker variance (MSB < s_w^2), so that the calculation in Fig A14a results in a negative value for the estimate of the between-worker variance s_b^2. What this means is that the true value of the between-worker variance is probably small; we are only estimating the parameter and our estimate happens to have come out negative. It is conventional in such a case to set it to zero (Rappaport and Kupper, 2008, p46).



	G	H	I	J
2	Logged values			
4		Greg	Joe	Chloe
5	Mon	-1.83	-0.67	-1.71
6	Tue	-0.97	-0.51	
7	Wed	-1.61	-1.05	
8	Thur	-0.82	-0.36	-0.44
10	log MG	-1.00		OEL
11	log sG	0.55		
12	U	2.80		

	N	O	P	Q	R
3	sw2	0.257708		N	10
4	sw	0.507649		n_1	4
5	sb2	=(P24-O3)/R8		n_2	4
6				n_3	2
7				k	3
8				n_0	3.2

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	0.879759	2	0.43988	1.706894	0.249008	4.737414
Within Groups	1.803954	7	0.257708			
Total	2.683713	9				

	G	H	I	J
2	Logged values			
4		Greg	Joe	Chloe
5	Mon	-1.83	-0.67	-1.71
6	Tue	-0.97	-0.51	
7	Wed	-1.61	-1.05	
8	Thur	-0.82	-0.36	-0.44
10	log MG	-1.00		OEL
11	log sG	0.55		
12	U	2.80		

	N	O	P	Q	R
3	sw2	0.257708		N	10
4	sw	0.507649		n_1	4
5	sb2	0.056929		n_2	4
6	sb	0.238597		n_3	2
7				k	3
8				n_0	3.2

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	0.879759	2	0.43988	1.706894	0.249008	4.737414
Within Groups	1.803954	7	0.257708			
Total	2.683713	9				

Fig A14. Calculation of the between-worker variance and standard deviation in cells O5 and O6

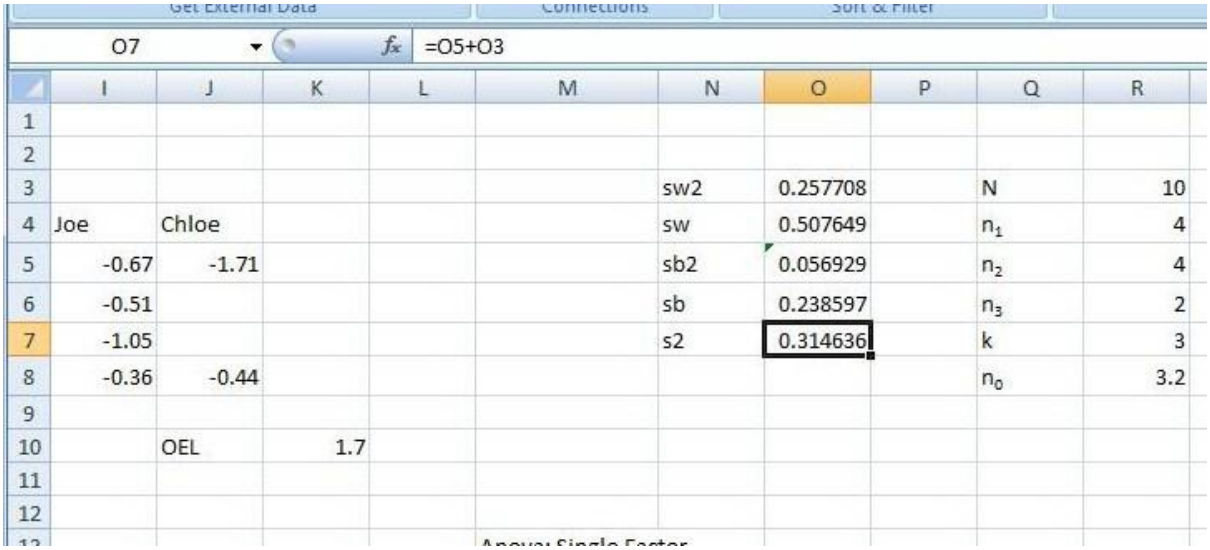
A1.2.6 Is the individual compliance test needed in this case?

As explained in section 3.6, individual compliance should be tested if the between-worker variance is more than 20% of the total variance ($s_b^2 > 0.2\ s^2$), because this indicates that differences in exposure

patterns of the individuals in the SEG may be important, so that some individuals in the group may have exposures exceeding the exposure limit even though the group as a whole is complying.

The total variance is the sum of the between-worker and within worker variances. In Fig A15 this has been calculated in cell O7. It can be seen that the between-worker variance in cell O5 (0.057 approximately) is less than 20% of the total variance in O7 (0.315), and therefore under our suggested rule there is no need to proceed to test individual compliance. (Although for clarity we have calculated the total variance, this was not really necessary. The way we calculated total variance makes it clear that the test $s_b^2 < 0.2\, s^2$ is equivalent to $s_b^2 < 0.25\, s_w^2$, which can be seen by comparing cells O5 and O3 in Fig A14b.)

Although in this example we do not need to test individual compliance, we will illustrate the calculation.



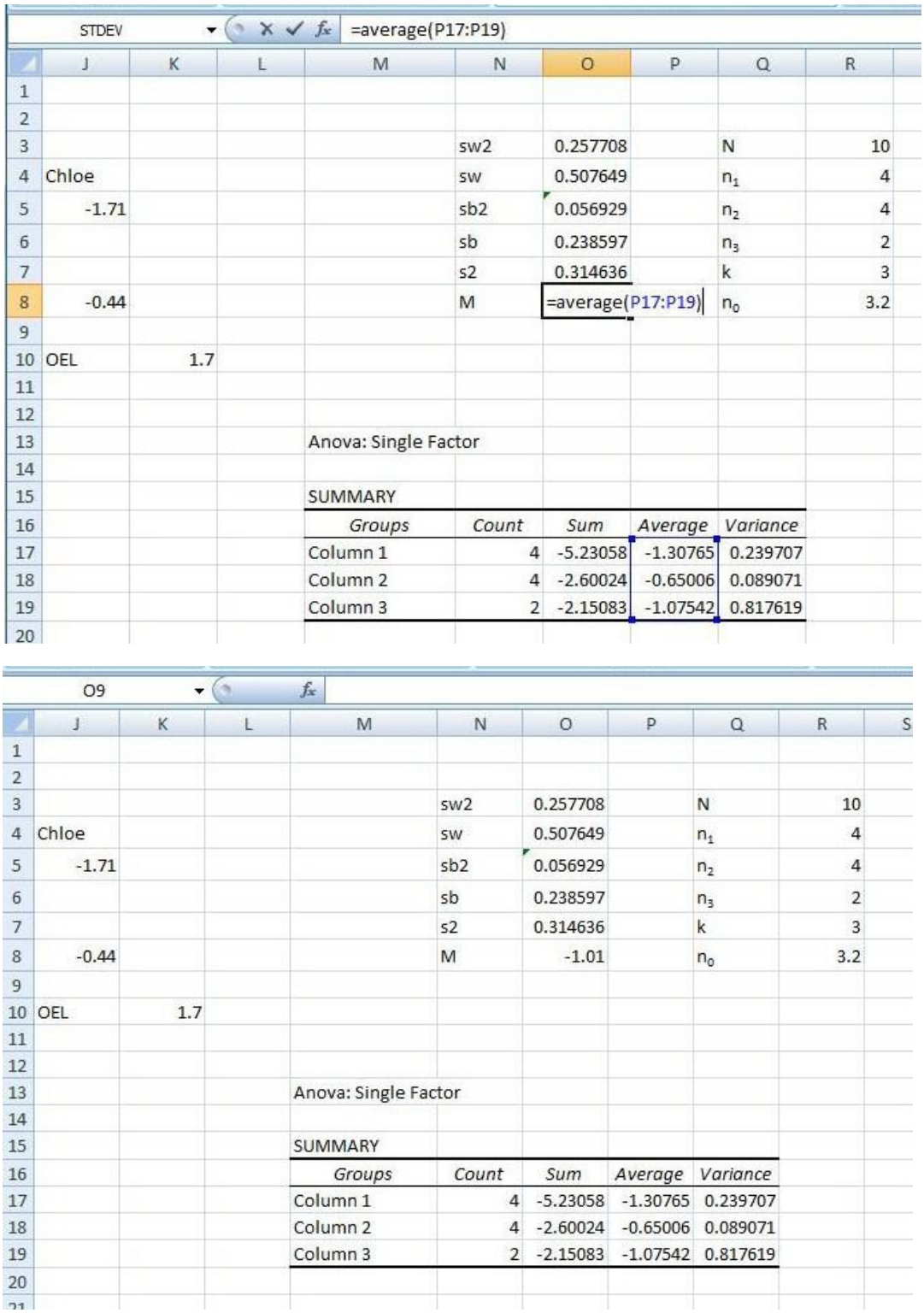
	I	J	K	L	M	N	O	P	Q	R
1										
2										
3						sw2	0.257708		N	10
4	Joe	Chloe				sw	0.507649		n_1	4
5	-0.67	-1.71				sb2	0.056929		n_2	4
6	-0.51					sb	0.238597		n_3	2
7	-1.05					s2	0.314636		k	3
8	-0.36	-0.44							n_0	3.2
9										
10		OEL	1.7							
11										
12										

Fig A15. Calculation of total variance

A1.2.7 Testing individual compliance

We will now test individual compliance, by calculating the probability of an individual member of the SEG having more than 5% of exposures >OEL. We follow the procedure in Hewett (2005), Appendix A. We need the mean of the distribution of logged values. We previously calculated this as log M_G and put it in cell H10. In doing so, we disregarded the fact that we had more measurements from Greg and Joe than from Chloe – we effectively assumed that all the workers had the same distribution, as implicitly assumed in the French procedure we followed (France, 2009). As we are now considering the possibility that the workers' exposure distributions may be different, we will estimate the mean of the whole group as the mean of the individual worker means, which are displayed in the ANOVA summary in cells P17 to 19 (Fig A14). However, in most cases the difference between the two ways of estimating the overall mean will be small – about 1.3 % in this example. In

Fig A16 we have calculated this new estimate of the mean of the logs in cell O8 and labelled it M in N8.



	J	K	L	M	N	O	P	Q	R
3					sw2	0.257708		N	10
4	Chloe				sw	0.507649		n_1	4
5	-1.71				sb2	0.056929		n_2	4
6					sb	0.238597		n_3	2
7					s2	0.314636		k	3
8	-0.44				M	=average(P17:P19)		n_0	3.2
10	OEL	1.7							

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

	J	K	L	M	N	O	P	Q	R
3					sw2	0.257708		N	10
4	Chloe				sw	0.507649		n_1	4
5	-1.71				sb2	0.056929		n_2	4
6					sb	0.238597		n_3	2
7					s2	0.314636		k	3
8	-0.44				M	-1.01		n_0	3.2
10	OEL	1.7							

Anova: Single Factor

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Column 1	4	-5.23058	-1.30765	0.239707
Column 2	4	-2.60024	-0.65006	0.089071
Column 3	2	-2.15083	-1.07542	0.817619

Fig A16. Entering the mean of the logged values, M

We now calculate a parameter H, in accordance with Section 3.6.

$$H = [\ \log(OEL)\ -\ (\ M\ +\ 1.645\ s_w\ )\ ]\ /\ s_b \qquad (A4)$$

It will be seen that instead of the overall standard deviation s, we are now using the within- and between-worker standard deviations which we calculated above. We put this in cell O9, with the label in N9.

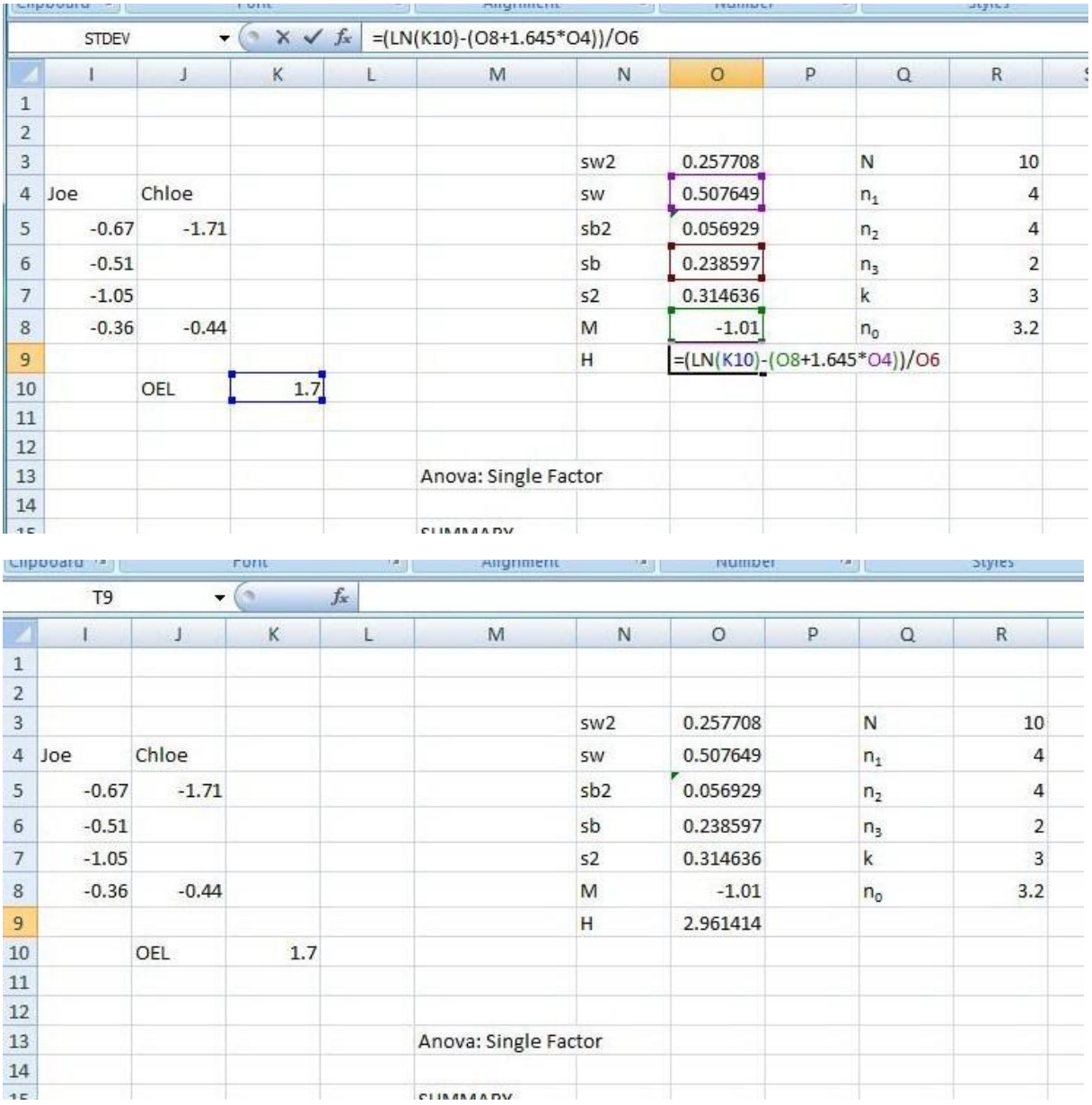
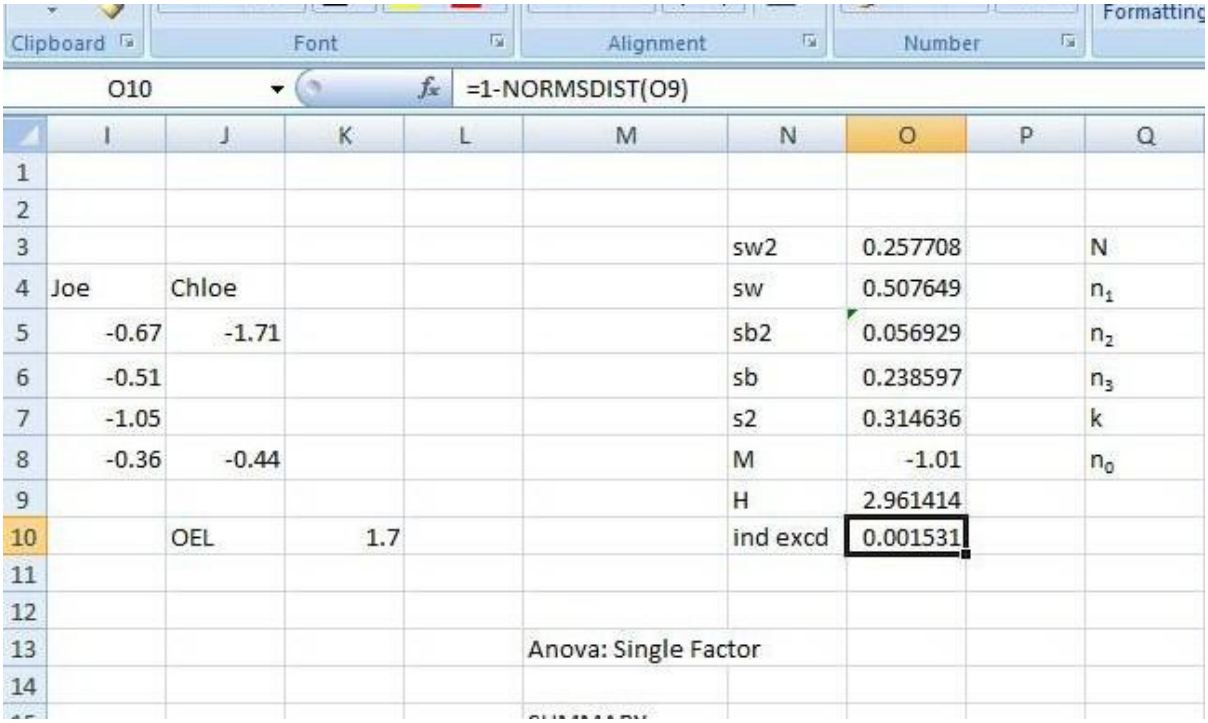


Fig A17. Calculation of parameter H

We use H to estimate the fraction of workers in the SEG having 95th percentiles greater than the OEL, called here *individual exceedance*. We do this using the Excel statistical function NORMSDIST. (This must be typed with care, as there is another Excel function NORMDIST which we do not want.) Fig

A18 shows this calculated in cell O10, with a label in M10 as usual. The formula line at the top of Fig A18 shows what was actually typed in O10.



	I	J	K	L	M	N	O	P	Q
1									
2									
3						sw2	0.257708		N
4	Joe	Chloe				sw	0.507649		n_1
5	-0.67	-1.71				sb2	0.056929		n_2
6	-0.51					sb	0.238597		n_3
7	-1.05					s2	0.314636		k
8	-0.36	-0.44				M	-1.01		n_0
9						H	2.961414		
10		OEL	1.7			ind excd	0.001531		
11									
12									
13					Anova: Single Factor				
14									

Fig A18. Calculation of the individual exceedance

It will be seen that the individual exceedance is calculated to be 0.0015, or 0.15%. This means that that it is estimated that 0.15% of workers in the SEG would be expected to have more than 5% of their exposures above the OEL. As explained in the main text (Section 3.6) we propose that the individual compliance test is passed if the individual exceedance is less than 0.2 (ie, that there was a less than 20% chance of any individual in the group having more than 5% of exposures above the OEL).

A1.2.8 Discussion of the individual compliance result

We had already concluded (section A1.2.6) that in this example there was little evidence that the individuals had different exposure patterns, and the individual compliance did not need to be tested, and the calculation confirms that in this case this test adds nothing to our decision based on the group compliance test. In the section on group compliance (section A1.2.2), we mentioned that the exposures would fail that test if the OEL was 1.1 mg/m^3 or less. Putting different values for the OEL in K10, we find that If the OEL is 1.1, the individual exceedance is 12.8%, and if the OEL is 1 mg/m^3, the individual exceedance is 23.0%. This shows that the individual compliance test would fail for about the same OEL as our group compliance test.

It may seem strange to say that "0.15% of workers in the SEG would be expected to have more than 5% of their exposures above the OEL" when there are only 3 workers in this SEG, but of course we this is just a more accessible way of making a probability statement. More formally, it means that on the basis of these results, we estimate that there is only a 0.15% chance of a random worker in the SEG having more than 5% of exposures greater than the OEL.

Once again, we draw attention to the explanation in the Introduction to this guidance that European law requires effective control, and that compliance with the OEL is not enough.

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Amendment history

20 Dec 2011	
Preface	Amendment of NVvA participants list at the end.
Section 2.2	Update of IHSTAT URL.
Sections 2.5 and 3.6	Typing errors.
November 2020	Update of references to EN 689 and inclusion of BWStat as a supporting Software tool.
November 2022	
Contents	Amendment of Chapter 1 and Chapter 2 titles to be consistent with the title given at the beginning of the chapter.
Preface	BOHS and NVvA addresses moved from cover and NVvA address updated.
Introduction	Amendment of “Britain” to “the UK”.
Summary, Sections 1.1, 1.2	Amendment of “EU” to “European”.
Section 1.1	Update of Stoffenmanager and GESTIS International Limit Values for Chemical Agents URLs.
Section 1.1	Amendment of “the European Union (EU)” to “Europe”.
Section 1.2	Update of IFA Analytical Methods for Chemical Agents at Workplaces URL.
Section 2.2	Update of IHSTAT, IHDataAnalyst, AltrexChimie and BWStat URLs.
Section 3.1	Update of reference to EN 689.
Section 3.8	Amendment of “the European Union” to “Europe”, update of reference to EN 689.
Section 4.2	Amendment of information about the Health and Safety Executive COSHH Essentials guidance on air sampling (HSE, 2006) to show that it refers to the previous version of G409.
Section 4.3	Update of information about IHDataAnalyst including IHDataAnalyst URL.
Section A1.2	Update of BWStat URL, addition of “A14” to figure label.
References	Update of various URLs including addition of one, and deletion of several that no longer work. Deletion of URL for HSE (2006) Exposure measurement: air sampling COSHH Essentials General Guidance G409 because it links to the updated 2022 version.