king paper on monitoring strategies in United Kingdom, Federal Republic of Germany and United States of America

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Working paper on monitoring strategies in the United Kingdom, Federal Republic of Germany and United States of America

Rapport
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SUMMARY

This study is a working paper on monitoring strategies used in the U.K.*, the FRG and the USA to assess exposure to airborne chemical substances. After a brief description of the basic philosophy on monitoring strategies, the requirements for monitoring from the different legal systems in the three countries are presented. The monitoring strategies are divided into small separate entities to facilitate comparison. Successively the initial assessment, surveys which are non-routine monitoring, the routine monitoring and their different elements are presented. Special emphasis is laid on how the different elements that can be discerned are covered in practice. A description of reports of monitoring data concludes the presentation of the monitoring strategies. In a final chapter a discussion is given on the material presented.

* See list of abbrevations and symbols

1. INTRODUCTION

This report is a working document that provides an outline of the situation in the UK, FRG and USA. It gives the possibility to make some comparisons. It is not to be considered as a scientific evaluation of the monitoring strategies in the three countries.
It is not an exhaustive study covering all details and giving definitive answers. The results of this study are intended to be used in the discussion in the Netherlands and to stimulate questions. This working document will hopefully lead to a monitoring strategy in the Netherlands. It seems wise to use the practical experience that has been gained in other countries.

The three countries were selected for different reasons. The USA was chosen because the thinking on monitoring strategies started in this country and because there has been quite some practical experience with the NIOSH scheme. Furthermore different aspects of the US monitoring strategies have been object of scientific debate and are reported in the literature. The FRG and the UK form part of this study because, to a certain extent, their legal systems are comparable with the Dutch legal system, because they have a number of years of experience in applying monitoring strategies, and because they are EC partners. The differences between the two lastmentioned monitoring strategies, which may best be characterized by 'Gründlichkeit' and 'as far as reasonably practicable', were the reason for including the two countries in this study. Other EC partners either do not have a general monitoring strategy, or have too little experience to warrant a substantial extension of the study by high-lighting new points of view.
Of course there are monitoring strategies issued by national and supranational bodies for specific substances (e.g. lead, asbestos). These have not been an object of study because by their nature they cannot be considered monitoring strategies on a general level. Other general monitoring strategies by international bodies have not been explicitly included because of lack of practical experience with these strategies.

It was quite difficult to find a form suitable for comparing the different monitoring strategies. Therefore the present report is a compromise.

One option was to describe the three monitoring strategies, and to analyse them for differences or similarities. This option was rejected because the contents of the resulting report would to a large extent have been based on the personal judgement of the authors.
For this reason the three monitoring strategies have been divided into small elements. Every element is reported country by country. An advantage of this approach is that it is easy for the reader to see how the different elements are treated in the three countries. One drawback of this approach is that the description of the procedures in the different countries sometimes has to be twisted to a certain extent in order to fit the general scheme, and that inevitably there will be a number of repetitions or cross references.

In order to represent the regulations and guidance as truthfully as possible the original texts (for the FRG in translated form) have been used as far as practicable. For legibility of this report not every sentence is accompanied by a literature reference, citing the exact place in the original text. This is an important remark because the authors do not wish to be accused of plagiarism. Of course the authors take full responsibility for any faults or omissions in the points of view expressed in this study.
Sometimes complications arose because translation of a certain technical expression from German into English was virtually impossible.

Chapters 4 to 7 deal with the monitoring strategies and their guidance notes. The discussion is reserved for Chapter 8, which comprises a summary of discussions from the literature, and discussions based on personal experience of the authors and a composition of opinions obtained during visits by the authors to certain expert informers in the three countries.

The discussion on a certain monitoring strategy is easier if this strategy is more detailed. Critical remarks must not be taken amiss as a denouncement of certain strategies but are intended to be used as a stimulation for further discussions. When discussing monitoring strategies one always has to bear in mind what the intention of a certain strategy was, and a discussion beyond the original intention of the strategy usually is meaningless. It is up to the reader to judge whether the authors have succeeded in avoiding this pitfall.

From this place the authors would like to thank the following persons from whom they received valuable help and comments and with whom they have had most stimulating discussions:

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A literature search has been done by the CID in different data bases to discover new viewpoints and literature on the object of the study.

Finally the authors would like to stress the fact that in all three countries monitoring strategies are very much alive and gradually changing. The picture which can be discerned from this study is merely a snapshot of the situation up to the first half of 1987.

2. BASICAL FILOSOFY ON MONITORING STRATEGIES

2.1 United Kingdom

Guidance Note EH 42 (Health and Safety Executive [1]) describes the monitoring strategies for toxic substances in the UK.
It covers workplace monitoring in general, and, for the benefit of people working in the field of occupational hygiene, describes some of the aspects that should be considered in the investigation of exposure to substances hazardous to health.
Sampling programmes may be conducted for two closely related purposes:
- estimating personal exposure;
- assisting in the assessment of the efficiency of control measures.

Figure 1 is a flow diagram for the monitoring strategies used in the UK.

The guidance note recommends a structured approach.
At the start of any investigation an initial assessment of all available pertinent factual information should lead to a decision whether a quantitative air sampling study is necessary and what form it should take. The initial assessment itself does not have to be reported in a certain format or even in written form.
If the outcome of an initial assessment is such that an air sampling study is needed, a preliminary survey should provide basic quantitative information of the efficiency of control measures and the likely extent of exposure. This preliminary survey can lead to immediate remedial action if some exposures are significantly in excess of the limit or to a low level of 'watchdog' routine monitoring if the exposures are well below the limit and as low as reasonably practicable.
In other cases the preliminary survey can be done at two different levels of detail. A second level strategy will be appropriate for most detailed surveys, at this level emphasis is placed on accurate measurement of time weighed average exposures (TWA). Occasionally, a high degree of sophistication (third level) is necessary in a sampling programme.

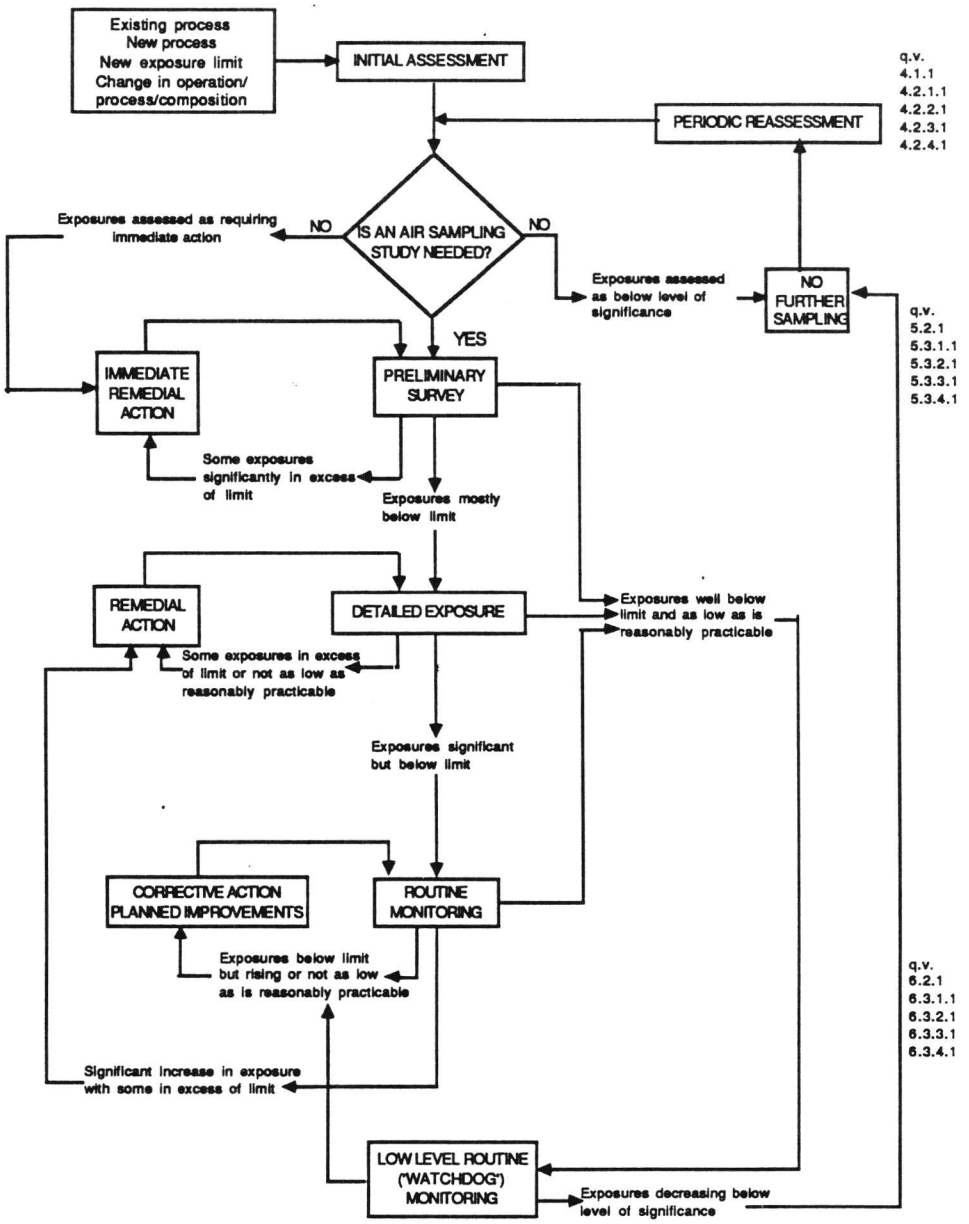

Figure 1 Flow diagram for monitoring strategies in the UK.

For example, if all reasonably practicable control measures have been taken, and personal exposures remain close to the relevant exposure limit, it may be necessary to increase the accuracy of the sampling programme to verify compliance. When after a detailed survey the conclusion is reached that some exposures are in excess of the limit or not as low as reasonably practicable, remedial action has to be taken. When, on the other hand, exposures are well below the limit and as low as reasonably practicable, a low level of 'watchdog' routine monitoring can suffice. In the case that exposures are below the limit but still significant, routine monitoring should be considered.
In routine monitoring the emphasis is on longer-term objectives such as checking that control measures remain effective and that compliance with the appropriate exposure limits is likely to be maintained in the future. Routine monitoring could lead to corrective action and planned improvement if exposures are below the limit but rising or not as low as is reasonably practicable, or could lead to remedial action if there is a significant increase in exposure with some in excess of the limit. On the other hand, if routine monitoring shows that exposures are well below the limit and as low as reasonably practicable a low level of 'watchdog' routine monitoring could be considered.
In any case, where the exposures are decreasing below a level of significance, no further sampling is necessary. Of course periodic reassessment remains necessary as work procedures, processes and limit values can change in time.

2.2 Federal Republic of Germany

In the TRGS 402 [3] from the AGS the monitoring strategies for toxic substances in Germany are described.
The purpose of the technical rules is to standardise the application of limit values for the concentration of dangerous substances in the air of the workplace. It takes into account the possibilities and limitations of the various analytical and statistical methods and of industrial practice, and constitutes an accepted guideline for measurement, planning and assessment of the values measured with regard to compliance with a limit value.
The technical guidance note [3] recommends a structured approach in two steps:
- a working area analysis (Arbeitsbereichanalyse);
- routine monitoring.

The working area analysis offers many different possibilities for adapting the nature of the monitoring to suit the various practical requirements and conditions. The analysis of the working area does not therefore contain any formal method for determining or effecting compliance but the possibility is created in every individual case to interpret it more as goal which is to be reached and to use it accordingly.
The first step, the working area analysis or WAA, can be divided into four different phases:
- phase 1: list substances involved at work;
- phase 2: obtain basic information;
- phase 3: obtain preliminary data;
- phase 4: establish the procedure for routine monitoring.

In principle there is the possibility to perform the WAA by:
- using statistical methods;
- looking at the worst case;
- calculating the concentrations;
- considering similar working areas;
- any combination of the preceding possibilities.

The WAA has to be recorded, but there is no fixed format.
The conclusion from the working area analysis has to be: compliance! In case of non-compliance, corrective action is to be taken until compliance can be determined and the WAA can be concluded with the etablishment of the procedure for routine monitoring.

The guidance note [3] is no more than a framework which leaves scope for the user how to conclude the WAA. This scope should be used to reach the goal at minimum cost [15]. This implies that an experienced user can work more quickly and efficiently than an inexperienced user.

If the conclusion of the working area analysis is that there is a state of 'permanently assured compliance' (dauerhaft sichere Einhaltung) no further action is required. In principle this conclusion can be reached after one measurement.

If this condition is not fulfilled, routine monitoring (Kontrollmessung) is to be done, to check if any of the conditions during the assessment have changed. The routine monitoring has to be done according

to a method described in the WAA. The frequency of monitoring depends on the concentrations measured.

The form used in this report to describe and compare the monitoring strategies in three countries obliges the authors to use a slightly different form than described in the scheme above.
In Chapter 4 the initial assessment in the FRG is discussed. This is done without monitoring and comprises phases 1 and 2, and part of phase 3 of the working area analysis. The survey in Chapter 5 includes phase 3 of the WAA. And in Chapter 6 on routine monitoring the establishment of the monitoring procedure concludes the WAA, of course Chapter 6 also contains the routine monitoring itself.

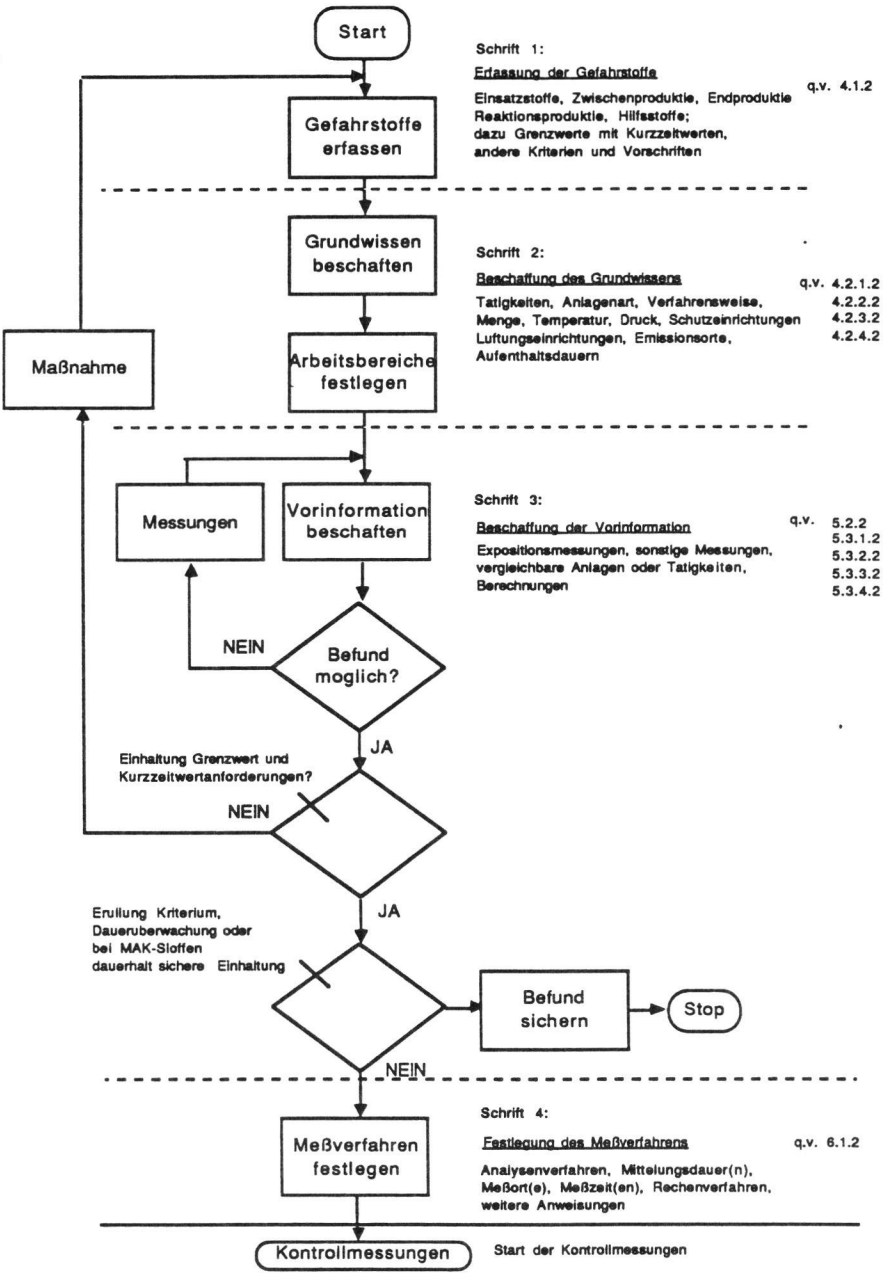

Figure 2 Monitoring strategies in the Federal Republic of Germany. Working area analysis.

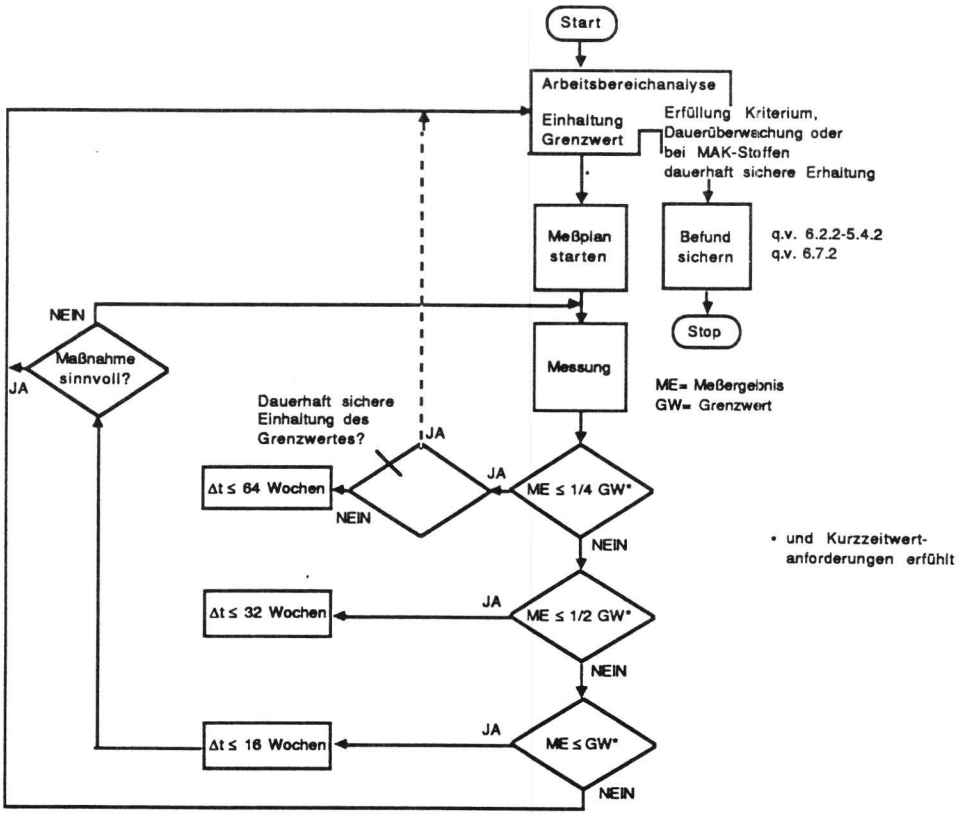

Figure 3 Monitoring strategies in the Federal Republic of Germany. Routine monitoring.

The different details will be discussed later.

2.3 United States of America

In 1977 the National Institute for Occupational Safety and Health (NIOSH) issued the 'Occupational Exposure Sampling Strategies Manual' [24], describing a logical framework of statistical methods and professional judgement to minimize sampling burden while providing adequate protection to exposed workers.

It was written for the purpose of explaining to employers how to meet the monitoring requirements specified in the new regulations of the Occupational Health and Safety Agency (OSHA).
The object of the NIOSH method is to determine compliance of a single day exposure measurement with a limit value. A decision is made for each measurement, after its upper confidence limit is calculated, as to whether it is an overexposure, a possible overexposure, or within compliance.
The upper confidence limit is compared to the limit value or an action level and the frequency or need for resampling is determinded according to a decision scheme.
Decision criteria are based on assumptions of normal and log-normal distribution models for sampling/analysis errors and for environmental fluctuations, respectively.
The manual also discusses topics of industrial hygiene, such as the determination of the need for exposure measurements, record keeping and the nature of effects and symptoms of toxic agents.
Sampling strategies for 8 hour time-weighed averages (TWA) and ceiling limits encompass selection of subjects, sampling times and statistical schemes.

The NIOSH decision scheme is shown in Figure 4. The scheme is only applicable to chronic hazards, and not to acute hazards (ceiling limits).

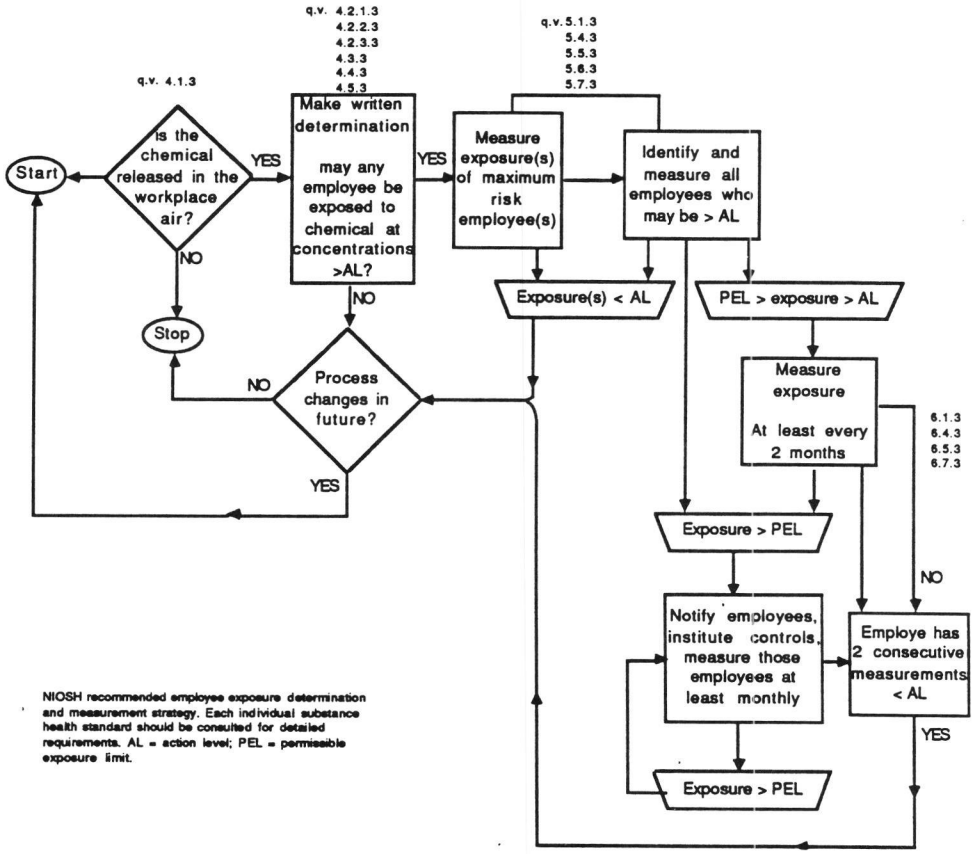

Figure 4 Flow chart of the NIOSH decision scheme [4] (the numbers in the margin refer to the sections of this report).

Starting at the left the following considerations are covered:

1. Is a chemical released in the workplace? Currently this step is initiated by consulting the 'Material Safety Data Sheet' that should legally accompany any 'raw' product containing hazardous substances.
   Only if the answer is 'no' can air sampling be ignored.

2. Determine the levels of exposure and make a written determination of the results. Literally the 'written exposure determination' is a means of making an exposure estimation without actual measurements.

All the qualitative and quantitative factors, affecting the exposure levels need to be considered. Full reliance is put on professional judgement. The 'written exposure determination applies to any employee that may be exposed to a regulated substance and should be made for each work situation or operation.
Minimum requirements for the contents of the report are given.

3. If it is found that an employee may be exposed to a chemical at or above the action level (AL = 1/2 of the limit value) the exposure of the 'maximum risk employee' shall be measured (one representative 8 h TWA). At this stage acceptable industrial hygiene techniques must be used to identify the maximum risk employee. A conclusive measurement of exposure less than the AL means that further monitoring is not necessary.

4. If the exposure measurement taken reveals exposure at or above the AL, all employees who may be exposed at or above the AL shall be identified and their exposures measured.

5.1 If exposures measure less than the AL, sampling may be discontinued.

5.2 If exposures exceed the limit value, immediate action is called for. Employees must be notified that they have been exposed to a toxic substance at a level above the limit value, and told the possible consequences. Steps must be taken to prevent a recurrence by changing the process, replacing equipment, substituting materials, or placing barriers and improving ventilation. Follow-up sampling must be done on a monthly basis until two consecutive measurements show exposure levels below the AL.

5.3 If the exposure level is less than the limit value, but not less than the AL, a second measurement is required within two months. If this shows that the level exceeds the limit value, the actions described in step 5.2 must be taken. Two consecutive measurements less than the AL are required before sampling can be stopped.

6. If process changes are made that could increase exposure, the complete scheme must be repeated* .

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* Note: In this report steps 1 and 2 will be called the 'initial assessment' (par. 4), steps 3 and 4 the non-routine monitoring' (par. 5), and step 5 the 'routine monitoring' (par. 6).

This basic scheme has become a legal requirement through its inclusion within the monitoring requirements in the new OSHA standards for toxic substances (Sect. 3.3), although depending on substance the sampling frequences may vary from the flowchart.
The scheme should be considered a minimum requirement that should receive routine application only in legal proceedings.
At the most a sequence of only two measurements to make a decision is used. All other measurements are in effect discarded, because they were non-decision producing. To account for day-to-day variability in exposure, an action level (set at 1/2 the limit value) is used to screen exposures measured.
The rationale of the action level (AL) is to assure that there is a low probability (5%) that even a small proportion (5%) of exposures on an unmeasured day will exceed the limit value [25] (see Sect. 8.1.3 for the limitations of using a single AL). This is not meant to imply that that as many as 5% of overexposure days is acceptable. It merely is a trade-off of statistical decision making, stating that the 5% overexposures, if they occurred, would be discovered at 95% of the time they were measured.

Since the NIOSH scheme is aimed at meeting OSHA requirements, only a few guidelines are given for strategies of periodic monitoring for long-term exposure (e.g. exposure distribution monitoring programs).
Only one section is devoted to the data analysis of long-term exposure data in order to decide whether to install engineering control.
In 1985 Leidel and Busch, the authors of the NIOSH manual, prepared a document in which monitoring strategies and data analysis requirements for long-term monitoring strategies are also discussed [26]. Moreover much of the comments on the original NIOSH manual are discussed and incorporated in this document.
In the following sections of the present report this updated document will also be treated.

3. MONITORING IN THE LEGAL SYSTEM

3.1 United Kingdom

Section 2 of the Health and Safety at Work Act (HSW Act) places upon employers a duty to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees. Employers and the self-employed are required by Section 3 to conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that persons not in their employment who may be affected by these work activities are not thereby exposed to risks to their health and safety.
While only the Courts can give a binding decision on the interpretation of these legal requirements, some practical guidance can be given. There are two key phrases in the requirements of the HSW Act; first 'to ensure, ...the health, safety and welfare at work .....' and second, 'so far as is reasonably practicable'.

The first phrase sets the objective to be achieved. The method of achieving it is largely left to the person on whom the duty is placed although he must pay heed to any more specific requirements which amplify the general duties. In terms of preventing ill-health from exposure to substances hazardous to health, these obligations are usually met by eliminating or minimising exposure to such substances.

The duty to ensure health and safety at work in the HSW Act is qualified by the phrase 'so far as is reasonably practicable'. Although this expression is not defined in the Act, it has acquired a clear meaning through long established interpretations by the Courts. Someone who is required to do something 'so far as is reasonably practicable' must assess, on the one hand, the magnitude of the risk of a particular work activity or environment, and, on the other hand, the physical difficulty, time, trouble and expense which would be involved in taking steps to eliminate or minimise those risks. If, for example, the risks to health and safety of a particular work process are very low, and the cost or technical difficulties of taking certain steps to avoid those risks are very high, it might not be reasonably practicable to take those steps. The greater the degree of risk, the less weight can be given to the cost of measures needed to avoid that risk. Only if there is a gross disproportion between them, the reduc-

tion in risk being insignificant in relation to the sacrifices needed to achieve the reduction, is the obligation met.

The comparison does not include the financial standing of the employer. A precaution which is 'reasonably practicable' for a prosperous employer is equally 'reasonably practicable' for the less affluent. Furthermore, if someone is prosecuted for failing to comply with a duty 'so far as is reasonably practicable', it is the responsibility of the accused to show the court that it was not reasonably practicable for him to do more than he had in fact done to comply with the duty.

As the HSW Act is more a document which gives a legal framework there is no direct mentioning in it of concrete monitoring strategies nor of a direct obligation for employers to regularly monitor their workplaces (according to the scheme described in Figure 1 in Sect. 2.1).

At the time this report was researched and written (March-May 1987) the Health and Safety Executive was preparing a redraft of Guidance Note EH-42 and perhaps even more important, the HSE was considering new regulations on toxic substances: the COSHH regulations (control of substances hazardous to health). At this time it is still impossible to give a picture of the impact of the coming COSHH regulations on a future version of EH-42 and the future monitoring strategies in the UK.

3.2 Federal Republic of Germany

Section 17 of the Gefstoff V 1986 (Gefahrstoffverordunung [23]) places upon the employer who handles dangerous substances the duty to take all the necessary precautions for the protection of human life, health and environment which are required by law. In any case he has to take into account the general safety, health and hygiene rules and general technical knowledge.
In Section 18 the monitoring requirements are presented:

- If the appearance of one or more dangerous substances in the air of the workplace cannot be excluded, it has to be decided if concentration is below limit or above the action level. The combined action of different dangerous substances has to be assessed.

- The results of the measurements shall be recorded in writing and kept for thirty years. In case of cease of business these results shall be handed over to the social security institutions.
- The authorities can on special occasions ask for the monitoring of both a TWA-limit or TRK-value and the biological workplace limit (Biologische Arbeitsplätztoleranzwert).

The Geffstoff V 1986 is a general document. More specific requirements regarding monitoring are to be found in TRGS 402. This is a quite recent document (November 1986). In fact it succeeds the older documents TRgA 401 and TRgA 402. The first document concerned the monitoring of carcinogenic substances and TRgA 402 covered other dangerous substances in the air of the workplace. As a temporary provision, the industries which have certain duties according to TRgA 401 have until 1 October 1988 to comply with the new TRGS 402.
The limit values of carcinogenic substances (TRK-Werte) have been published in TRGS 102* and the TWA values (MAK-Werte) in TRGS 900* . In a yearly update the Deutsche Forschungsgemeinschaft (DFG) gives access to the most recent limit values [4].

The Federal Republic also operates a system of action levels. When certain concentrations in the air of the workplace or concentrations in body fluids are exceeded the necessary measures for the protection of health have to be taken.
For more information the reader is referred to TRGS 100*.

3.3 United States of America

The Occupational Health and Safety Act (OSH Act, 1970) specifies the employer's obligation to furnish to each employee a place of employment free from the recognised hazards causing or likely to cause death or serious physical harm, and to comply with standards promulgated by OSHA.
The final responsibility for compliance with this provision of the Act rests with the employer. OSHA standards for chemical exposures fall into two categories, viz. those originally adopted as existing stan-

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* These can be obtained from: Carl Heymanns Verlag KG,
Luxemburger strasse 449
5000 Köln 41
BRD

dards under the OSH Act (29 CFR Sect. 1910-1000) and those developed as new standards (29 CRF Sect. 1910-1001 to 1047).
Those adopted as existing standards include exposure limits most of which had originally been issued as Threshold Limit Values (TLV's) by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968. The new OSHA standards (currently covering roughly 40 chemical substances) are much more comprehensive than those adopted as existing standards. Besides a permissible exposure limit (PEL) (8 h TWA and for some substances also a 15 min. ceiling limit or short term limit) they also include for each chemical a second criterion, the action level, usually set at 1/2 of the PEL.
Detailed requirements are given regarding such areas as: methods of measurement, sampling strategy (based on the NIOSH scheme), medical surveillance, methods of compliance, handling and use of liquid substances, employee training, record keeping, sanitation and good house keeping.
Note that the NIOSH scheme has become a legal requirement in the new OSHA standards.
For establishments where any of the regulated substances are released into the air of the workplace, the standards also require the employer to make a 'written exposure determination' (initial assessment). This written assessment must be made even if the results are negative. Only if the assessment is positive (exposures at or above the AL) is the employer required to measure exposures according to the NIOSH scheme.

The PEL was intended to represent the constant level to which a worker could be exposed over a working life without harmful effects (OSH act, 1970).
However, in the interest of regulatory feasibility, PELs are interpreted by OSHA as absolute levels applicable to any 8 hour work period rather than a lifetime of exposure. The same holds for ceiling limits. So if any particular measurement exceeds the limit value there has been a violation of the law.
Since workers' exposures are not constant from day to day, but show large variability in time, the chance of finding a non-compliance situation increases with the number of measurements taken. Inevitably a large number of samples will include some from the high end of the distribution. In view of OSHA's heavy reliance upon voluntary compliance on part of the employers, the latter will tend to adhere to the minimum monitoring requirements set forth in the standards in order to avoid the risk of finding a non-compliance situation. Hence the

current regulatory framework does not provide much incentive to use sampling strategies for long-term exposure assessment.
However, in spite of strict OSHA regulations, the majority of industries performing such monitoring programs have developed strategies which allow some overexposure to occur, taking account of long-term exposure variability and the health risks involved.

4. INITIAL ASSESSMENT

4.1 Substances

4.1.1 United Kingdom

(a) Information on substances

The following information is to be included in an initial assessment:
- the substances that occur at the workplace (raw materials, intermediates, product contaminants, ancilliary chemicals);
- the airborne form of the substances (dust, fume, aerosol or vapour, if a dust whether it is fibrous and inspirable or respirable);
- how hazardous the substances are: whether the effect of the combination of substances is hazardous even when the individual substances are essentially non-hazardous;
- whether there is a real possibility of exposure to these substances by inhalation, ingestion or skin absorption.

In the initial assessment information on the substances can be obtained from labels on containers or packages, from data sheets etc. made available by manufacturers, importers and suppliers under section 6 of the HSW Act, from HSE Guidance Notes and from other sources including trade associations, technical literature and previous operating experience.
There are two main types of exposure limits in the UK [2]. A long-term exposure limit, a time-weighted average (TWA) over eight hours, and a short-term exposure limit, a ten-minute TWA-value.
Exceptions are asbestos with a 4-hour TWA limit, and VCM with an additional mean annual concentration. For a specific list of substances [2] the long-term limit is a control limit. The other limits are recommended limits. From a legal angle the distinction between control limits and recommended limits is more important than that between 8-hour and 10-minute TWAs.

In an assessment of the results it is necessary to distinguish between those relating to substances for which;
(a) a Control Limit has been adopted by HSC;
(b) a Recommended Limit is listed;
(c) no UK exposure limit is available.

Control Limits have been judged after detailed consideration of the available scientific and medical evidence to be 'reasonably practicable' for the whole spectrum of work activities in Great Britain. These exposure limits are known specifically as Control Limits and should not normally be exceeded.
Compliance with Control Limits should normally be achieved by the application of appropriate plant and process control techniques. However, there may be special circumstances in which such measures are not reasonably practicable, e.g. certain maintenance operations, and in such cases the use of suitable personal protective equipment is acceptable in order to achieve compliance.

Recommended Limits are considered to represent good practice and realistic criteria for the control of exposure, plant design, engineering controls and, if necessary, the selection and use of personal protective equipment. HSE inspectors will use these exposure limits as part of their criteria for assessing compliance with the HSW Act and other relevant statutory provisions.

Recommended Limits have not been subject to the same rigorous scrutiny as Control Limits. They should be considered useful guidelines for deciding whether exposure is too high.

Results for substances for which no exposure limits are listed need to be interpreted on a case basis to ascertain whether exposure has been controlled as far as is reasonably practicable. An employer should make an assessment of the risk to health and the cost of reducing exposure and use these data to set, after consulation with his employees, a tentative exposure limit for his own use.

(b) Sampling equipment and analytical methods

Sampling equipment should be compatible with the available analytical methods, and these should have been validated over a suitable range of concentrations above and below the exposure limits. Personal sampling is the preferred method and can be employed in nearly all circumstances. However, fixed positions, static or area monitoring can be used where a useful predictive correlation with personal sampling has been demonstrated.

It is important to choose the correct sample collection device for the substance(s) of interest. Details of recommended sampling methods are published in HSEs Methods for the Determination of Hazardous Substances (MDHS) series. Each title in this series covers either a specific chemical substance or a group of substances that can be detected using simular procedures. Advice on the correct selection and use of sampling equipment is given in addition to details of the laboratory analytical procedures.
In this series 53 publications have been made available or are in preparation (March 1987). The complete list can be found in [2].
All equipment and analytical methods need regular checking and calibration. A method that constantly gives results at or close to zero may be comforting but should be critically examined. The aim should be to obtain appropriate information of an acceptable quality at a reasonable cost. Sampling strategies can be classified into three broad levels of sophistication in relation to the purpose of the survey.
A first level strategy is an attempt to obtain relatively crude quantitative information on exposure in order to decide whether an exposure problem exists at all and, if so, to assess its possible seriousness. Such a strategy may be appropriate for a brief preliminary survey and will often employ relatively unsophisticated sampling equipment and analytical methods. It will tend to concentrate on assessing the 'worst case' situation and will use this as an index to the overall risk. The higher levels of sophistication are presented in 5.1.1.

(c) Personnel

Emphasis is put on the fact that an initial assessment should be made only by a trained and experienced person, especially if reliance is to be placed on a conclusion that no further action is necessary.

4.1.2 Federal Republic of Germany

(a) Information on substances

In the initial assessment, the hazards and properties of the chemical substances has to be assessed. This implies examination of substances, raw materials and impurities, reaction products, intermediates, end products and ancillary chemicals, so far as they can contribute to the exposure. Limit values and the corresponding short-term values for these substances have to be included in the initial assessment.

The maximum permissible concentration (MAK) of a chemical compound present in the air in a working area which, in the light of current knowledge, generally does not impair the health of the employee nor cause undue annoyance, is related to a daily exposure period of eight hours and an average working week of 40 hours. As a rule the MAK-value is integrated as a time weighted average concentration over periods up to one workday or one shift. Scientifically based criteria for health protection, rather than their technical or economical feasibility, are employed.
Quite recently attention was drawn to the relationship between MAK-values and pregnancy. A classification of substances in three different groups has started [4].

MAK-values have always been conceived and applied as 8-hour time-weighted averages. In practice, however, the actual concentrations of chemical compounds in the workplace air fluctuate frequently and widely. Excursions above the TWA must be restricted for many substances in order to avoid impairment of health. As the degree of risk to health from such peak concentrations depends on the particular behaviour and effects of the substance in question, a system has been developed in which as many as possible substances in the MAK-value list [4] have been classified into distinct categories, whose definitions take into account both toxicological considerations and analytical practicability.
The 8-hour time weighted average must in any case be observed. Under these conditions the following categories apply for limitation of excursions above the 8-hour TWA:

Table 1 Peak limitation categories in the Federal Republic of Germany.

Category		Short-term level		Frequency
		Peak	Duration	per shift
I	Local irritants	2-MAK	5 min, momentary value*)	8
II	Substances with systemic effects. Onset of effect ≤2 h			
	II, 1: half-life**) <2 h	2-MAK	30 min, average value	4
	II, 2: half-life 2 h - shift length	5-MAK	30 min, average value	2
III	Substances with systemic effects. Onset of effect >2 h Half-life > shift length (strongly cumulative)	10-MAK	30 min, average value	1
IV	Substances eliciting very weak effects. MAK>500 ppm	2-MAK	60 min, momentary value*)	3
V	Substances with an intense smell	2-MAK	10 min, momentary value*)	4

*) The momentary value is the concentration that should never be exceeded. It represents a limit to be observed in work area technical planning; the analytical testing can then be carried out by use of sampling procedures designed for recording average values.
**) Half-life is the time in which an existing concentration falls to half its original value.

For each substance the appropriate category is given in a special column, 'Peak Limitation', in the MAK-values list. A scientific justification of the above classification with analytical control procedures has been published in 'Toxikologisch-arbeitsmedizinische Begründung von MAK-Werten' and the data for the individual substances are to be included in the 'Begründungen' of the MAK-values. Both publications are obtainable from the publisher: VCH Verlaggesellschaft mbH, D-6940 Weinheim.

In the Federal Republic a distinction is made between limit values of carcinogenic and mutagenic compounds and other chemical substances. For the first category, technical guiding concentrations (TRK-Werte)

are used. Even adherence to TRK cannot fully exclude potential danger to health.
The technical guiding concentration (TRK) of a hazardous working material defines that concentration of gas, vapour, or airborne particulates which serves as a directive for necessary protective measures and surveillance by measuring techniques. TRK values are assigned only for hazardous working materials for which MAK values confirmed by toxicological or industrial medical experiences cannot be established at the present time. Adherence to TRK values is meant to reduce the risk of a health hazard but cannot completely eliminate it.
The technical guiding concentration is oriented towards industrial circumstances and the possibility of practicable prophylaxis and considers the current industrial-medical knowledge of the effects of handling the hazardous material.
Since adherence to TRK values cannot fully rule out the risk of health impairment, attempts must be made to keep the concentration as much as possible below the TRK values by continually improving the industrial circumstances and technical protective measures.
TRK values require constant adjustment to the state of technical developments and the analytical possibilities as well as review according to the latest state of knowledge of industrial medicine.

For substances with a danger of cutaneous absorption a special action level is used [5]. As a rule this action level comes into operation when the handling of a certain substance leads to direct skin contact. For certain processes or work procedures, special action levels can be given.

(b) Sampling equipment and analytical methods

The sampling equipment and analytical methods have to produce results that can be considered representative for the exposure of the workers. Sampling should be done at breathing height and in the direct vicinity of the employees. If possible, personal sampling equipment should be used for the assessment of a TWA exposure. Area monitoring can be used when assessment of exposure at the workplace is possible on basis of sufficient knowledge on work patterns and concentrations. The 'worst case' should be chosen when there is any doubt on the place of monitoring.

The measurement procedure must be appropriate to the elements to be measured, their MAK values and the factory atmosphere. The measurements produced must give a clear indication of the level (concentration of the elements to be measured); the procedure must supply measurements directly or indirectly (e.g. by conversion) in the same dimension as the limit value.

The detection limit, sensitivity and accuracy of the measurement procedure must be appropriate to the limit value. The procedure must be capable of measuring concentrations of the elements involved of at least between one tenth of and three times the limit value. With automatic measuring instruments the final value of the smallest measurement range should not be more than five times the limit value.

Comparative tests (e.g. with standardised procedures) or combined tests (e.g. with test gases) should be used to ensure that the analytical procedure is correct.

Where the measurement procedure is not specific, the measurement result must be considered to be the value for the substance in question.

The level of uncertainty calculated as an integral error from all systematic and incidental errors occurring when measurements are taken should not exceed 30%.

The measurement procedure should have been proved to be practicable.

Analytical methods are examined by, for example, the Working Party on Analytical Chemistry formed by the Committee on harmful substances at work of the Deutsche Forschungsgemeinschaft (German Society for the Advancement of Scientific Research), the Institute for Industrial Safety of the Employers' Accident Insurance Associations (BIA) and the Bundesanstalt für Arbeitsschutz (National Institute for Industrial Safety).

The Commission's research group 'Analytical Chemistry' has compiled and published established methods for the analysis of air as well as biological material* .
A description of the methods for the analysis of approximately 360 substances is available from the BAU. Their sources are the DFG, BIA, NIOSH and HSE, MDHS [6]. If there is no suitable measuring method that meets the criteria described above, the WAA is to be repeated once every 64 weeks. During this WAA, if possible, exposure measurements should be done.

(c) Personnel

TRgA 400 [7] lists the monitoring requirements institutes have to fulfill. Directors of such institutes should be suitably qualified and experienced. TRgA 400 also provides information on which institutions in the Federal Republic are allowed to do which measurements. For practical purposes dangerous substances are grouped in five categories (substances in dusts, asbestos and fibrous dusts, inorganic gases and vapours, organic gases and vapours, substances which require high analytical skills).

* 'Analytische Methoden zur Prüfung gesundheitsschädlicher Arbeitsstoffe', obtainable from the publisher:
VCH Verlagsgesellschaft mbH, D-6940 Weinheim.
Volume 1: 'Luftanalysen' (analyses of the air)
Volume 2: 'Analysen in biologischem Material' (analysis of biological materials)
supplementary reports at yearly intervals are anticipated. The Commission welcomes suggestions for inclusion of new chemical compounds, as well as methods of determination. Contact the work group 'Analytische Chemie' at the Deutsche Forschungsgemeinschaft, 40 Kennedyallee, D-5300 Bonn 2. Analytical methods for carcinogenic workplace substances are published in cooperation with the working group 'Analytik des Fachausschusses Chemie der BG Chemie' ('Von den Berufsgenossenschaften anerkannte Analysenverfahren zur Feststellung der Konzentration krebserzeugender Arbeitsstoffe in der Luft in Arbeitsbereichen', Carl Heymanns Verl. KG, D-5000 Köln).

4.1.3 United States of America

(a) information on substances

The first step in the 'written exposure determination' is to determine and tabulate, by process area or operation, all materials that may be used or produced in work operations or manufacturing process and that may be released in the air of the workplace or contaminate the skin. This information can be obtained from Material Safety Data Sheets (MSDS) which by law have to be provided for any raw material and product by the manufacturer or supplier. These sheets provide information on the hazardous constituents of a product, the PELs of each constituents, hazard information on the product, health hazard information, relevant routes of entry and physical data (airborne form, vapour pressure, etc.).

Over 400 toxic substances have been tabulated in the Code of Federal Regulations (29 CRF Sect. 1910-1000). Permissible exposure levels for these substances have been adopted from TLVs issued by the American Conference of Governmental Industrial Hygienists. Exposure limits are expressed as long term exposure limits (8 h TWA) and short term exposure limits (STEL).

There are three different ways in which the time period for a ceiling standard may be defined (29 CFR Sect. 1910-1000).

1. 29 CFR Sect. 1910-1000 (a) (1) for Table Z-1: No time period. 'An employee's exposure...shall at no time exceed the ceiling value...'
2. 29 CFR Sect. 1910-1000 (b) (2) for Table Z-2: Short time period (5 to 30 minutes) defined as 'maximum duration' for 'maximum peak'. The ceiling standard may be exceeded for short periods up to a concentration defined as 'acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift'.
3. Under the current joint NIOSH OSHA Standards Completion Program, all ceiling standard substances in Table Z-1 of 29 CFR Sect. 1910-1000 will have the standard defined for 15-minute period as: '... concentrations not in excess of ... averaged over any 15-minute period during an 8-hour work shift'.

In OSHA's new regulations (29 CFR Sect. 1910-1000 to 1045) the period for the short term limit value is 15 minutes.

(b) Sampling equipment and analytical method

OSHA standards describe suggested measurement methods for each substance. The methods are usually derived from sampling and analytical procedures validated by NIOSH [27].
Air samples should be taken in the breathing zone of the employee (air that would most nearly represent that inhaled by the employee). Area sampling may significantly underestimate exposure variability (GSD > 1.5).
The method shall have an accuracy, to a confidence level of 95%, of not less than ± 25%. This OSHA requirement takes into account (1) repeatability of the sampling device and the analytical procedure, (2) systematic errors in the sampling and analytical method. This general requirement with respect to accuracy may vary from substance to substance depending on the state of the art of the sampling and analytical method. Validated NIOSH methods specify for each method its coefficient of variation (CV_t) or relative standard deviation as an estimate for random errors in sampling and analysis.
If the method is unbiased, CV_t can be used to judge if the method has the required accuracy [accuracy (95% confidence level) = ± 1.96 * CV_t].
Note that CV_t values provided by NIOSH, only apply to laboratories with adequate maintenance and calibration facilities and a quality control program [28].

Neither the NIOSH scheme nor the OSHA standards require actual measurements to be made during the initial assessment, although it may be simpler to actually perform air sampling than rely only on professional judgement.

(c) Personnel

In the initial assessment to a large extend professional judgement is called for, however no specific requirements as to the person doing the assessment is mentioned.
The NIOSH manual only suggests using a competent industrial hygiene consultant when an employer does not have the background or training to perform measurements.

4.2 Identification of factors affecting exposure

4.2.1 Processes and sources

4.2.1.1 United Kingdom

The guidance note [1] states that in the initial assessment information is needed or which processes or operations are likely to involve exposure. Many primary variables may affect airborne concentrations:

- the number of sources from which the contaminant is released;
- the rates of release from each source;
- the type and position of each source;
- the dispersion or mixing of the contaminant in the air of a workroom, as influenced by local ventilation and random movements or turbulence of the air;
- the ambient conditions, particularly for outdoor operations, where such factors as wind speed, direction and air temperature are important factors.

Variations between processes are summarised as variations due to the nature of the processes as influenced by operating procedures, product composition, ambient conditions, etc.
The initial assessment may be supported by simple qualitative tests which provide information on the extent of an emission problem.

4.2.1.2 Federal Republic of Germany

The purpose of obtaining basic information is to pinpoint possible hazards and to define working areas. Basic information includes technical and in-house knowledge of the working area and the working routine.
The working area is the specific physical or organisational area of a factory which is to be evaluated. It may include one or more workplaces and is characterised by the fact that, when engaged in his activity of activities, the individual employee remains at the various workplaces within this area for varying lengths of time which cannot be defined more precisely, making a further subdivision of the working area into smaller units impossible.
The checklist [9] recommends making a sketch or photograph as supplementary information.

The information required includes in particular knowledge of activities, the nature of the plant, the methods used, safety and ventilation equipment, emission points and the duration of the employees' periods of attendance.

The working area may be described by details of the actual area involved, activities or methods and nature of the plant or the working materials.

Particular emphasis must be put on emission peaks (where, when, how frequent).

The initial assessment must be reported in writing, but no specific forma is prescribed. In order to be able to give some information on the extent of what is usually taken into account in assessing exposures the data reporting sheet used by the BIA to present the results of environmental monitoring will be used as an example (Appendix C). Though the measurements can be considered fitting in the chapters 5 and 6 it is also presented here to show the information which is to be recorded. The measurements done by the BIA can be considered to be exemplary to others in industry.

In [7] a checklist is presented with nine different kinds of processes (production, regainment, clearing, storing, filling, transportation, manufacturing, working up, otherwise) and six different kinds of control measures (LEV, general ventilation, recirculation of workplace air, lower than atmospheric pressure, closed system, otherwise)

The checklist [7] comprises seven types of processes (free, in a closed space, continuous, discontinuous, closed system, open system, otherwise).

The checklist in [9] is more extensive, because it allows for a description of the process.
Machines and installations all into several categories:
automatic - semi-automatic - manual;
open - closed;
continuous - discontinuous;
process conditions: temperature;
pressure.
Sources of exposure as well as the control measures can be qualified.

The control measures in Appendix C concerning exhaust ventilation will be dealt with in 4.2.2.2. Other control measures presented in Appendix C the dust control measures (none; wet work; clean room conditions).

4.2.1.3 United States of America

Variables to be taken into account according to the NIOSH manual are:
- Process types (e.g. hot operations, liquid operations, solid operations, pressurized spraying, shaping operations) in relation to the contaminants released.
- Any anticipated changes in production process or control measures that could result in an increase in airborne concentrations.

Reference [26] also mentions:
- Rate of operation (e.g. mass or volumetric rate, revolutions per minute, linear rate, items in a given period of time).
- Energy conditions of operation (e.g. temperature and pressure).
- Degree of automation.
- Emissions from adjacent operations.

This survey is to be continued by a visit for the purpose of observing working conditions and operations (4.2.3). It is here that a determination is made whether an employee may be exposed to a hazardous substance.
The following observations are made:
- Sensory observations. Some hazardous operations can be identified by the senses, such as sight (dust, smoke, mist), smell (odours), taste and irritating effects on the respiratory tract.
- Employee location in relation to a source of contaminants.
- Improper design, installation, or maintenance of control equipment.

Area monitoring is recommended where source emissions are measured rather than individual exposures.

4.2.2 Working environment

4.2.2.1 United Kingdom

EH-42 gives some guidance on the subject of assessing the influence of the working environment on the exposure. It describes some variables that affect airborne concentrations:

- the dispersion or mixing of the contaminant in the air of a workroom, as influenced by local ventilation and random movements or air turbulence;
- the ambient conditions, particularly for outdoor operations, where such factors as wind speed, wind direction and air temperature are important.

General ventilation characteristics may vary from day to day or display a seasonal pattern.

4.2.2.2 Federal Republic of Germany

TRGS-402 gives some guidance on assessing the influence of the working environment on exposure as cited in 4.2.1.2. In Appendix C there ar different categories for the size of the workplace (in the open air, closed or partly closed < 50 m^3; 50-500 m^3, 500-5000 m^3 and > 5000 m^3) and the height of the workplace (< 3 m; 3-6 m; > 6 m).
There are ten categories of general ventilation, and three categories defining the nature of the ventilation (point, plane, general).
The ambient meteorological conditions are also taken into account. Three weather categories (sunny/cloudy; rain/snow; hazy), three wind speeds (low, moderate; high/storm) and three temperature categories are distinguished (less than 10 degrees centigrade difference between inside and outside; 10-20°C; > 20°C). There is also a possibility to describe different recirculation processes of workplace air (four categories).
General hygiene is not explicitly stated in Appendix C nor in the checklists in [7] and [9].
In the checklist in [9] the same aspects as in Appendix C can be assessed somewhat more extensively.

4.2.2.3 United States of America

The NIOSH manual mentions:
- High temperature locations which would give rise to higher evaporation rates.
- Natural ventilation with respect to location of doors and windows.
- General room ventilation and air flow patterns.

Leidel and Busch [26] add to these:
- Environmental factors:
  - age, size and physical lay-out of the plant;
  - meteorological conditions.
- Factors causing time cycles or trends in exposure:
  - contaminant build-up from morning to afternoon;
  - exponential clearance due to air flushing and dilution during non-working hours;
  - cyclic process operations;
  - work shifts;
  - time of year (seasonal variations).

4.2.3 Work procedures

4.2.3.1 United Kingdom

The HSE [1] states that the overall pattern of personal exposure may be very complex indeed when the actions and behaviour of employees are considered. At the simplest level, an employee's exposure will depend on his distance from various sources of exposure, and on the time spent in the area where airborne contaminants are present. This may vary from day to day and from one worker to another, even though the jobs may appear to be similar. Further difficulties are introduced when the employee has direct influence over the process or the numbers or nature of sources of contaminants release. This can be particularly important where manual handling operations such as scooping or shovelling dusty materials or unloading or sampling liquids are concerned. In such cases the details of each operation and each individual's work practices can have an important influence on the overall personal exposure pattern.

4.2.3.2 Federal Republic of Germany

The information required includes in particular knowledge of activities, the methods used, emission points and the duration of the employees' periods of attendance.

Particular emphasis must be put on emission peaks (where, when, how frequent).

In [9] there is a checklist for the initial assessment of the workplace (Arbeitsbereichanalyse) in which special attention is paid to work procedures.
For a number of activities the frequency and duration are to be assessed (sampling, weighing, filling, emptying, cleaning, drying, warming and filtering). Other activities can also be assessed.
There is a category for special activities, such as the switching on and off of machines, repairs, maintenance work.

4.2.3.3 United States of America

The NIOSH manual pays attention to:
- procedures or methods the worker uses to perform his job (including improper use of control equipment).
- Careless handling and unintended happenings (spills, instrument failure, operator errors, process interruptions, lack of maintenance).

In addition Leidel and Busch [26] introduce behavioral factors affecting work habits, which in turn affect exposure levels (see Sect. 4.2.4.3).

4.2.4 Organisational aspects

4.2.4.1 United Kingdom

A preliminary survey may highlight defects or deficiencies in operator awareness and training etc. [1].
Other aspects like the responsibility for e.g. safety and hygiene at the workplace for meeting the needs of correct work procedures, and the use of RPE, are not explicitly stated.

4.2.4.2 Federal Republic of Germany

When collecting preliminary data the question of whether respirators are provided should not be taken into account. When evaluating compliance with MAK values, and determining the measurement procedure for the control system, areas where and times when respirators are worn must not be taken into consideration. Reference should be made to the corresponding rules for the use of respirators.
Other organisational aspects are not explicitly taken into account in the checklists of [7] and [9].

4.2.4.3 United States of America

These aspects are not mentioned in the NIOSH manual as variables to be considered in the initial assessment. Leidel and Busch [26] introduce behavioral factors affecting work habits which in turn may affect exposure levels:

- Job practice, movements and habits of a worker.
- Training of a worker.
- Attitude of a worker.
- Attitudes of management and supervisors.
- The presence of equipment for measuring exposure, industrial hygiene personnel or supervisory personnel.

4.3 Population at risk

4.3.1 United Kingdom

Everyone exposed to chemical substances in hazardous amounts should be identified through the initial assessment.

4.3.2 Federal Republic of Germany

The measurement procedure must supply representative results on the exposure to which employees are subject.

4.3.3 United States of America

In the initial assessment should identify employees and/or work operations that may be associated with exposures at or above the action level (AL).

This identification is made on best professional judgement considering all variables affecting exposure levels. Little guidance is given on how to make such a decision.
If an employer finds that exposure at or above the AL may occur for a specific operation and chemical substance, he is obliged to make an exposure measurement of the employee believed to have the greatest exposure (maximum risk employee). Criteria for identification of maximum risk employees are discussed in Section 5.4.3.

4.4 Other (exposure) data

4.4.1 United Kingdom

During the initial assessment information may be obtained from previous operating experience. The design and operation of the process or work activity should be studied and the exposure assessed.

4.4.2 Federal Republic of Germany

The purpose of obtaining preliminary data is to determine compliance with MAK values. Preliminary data, based on measurements, consist of knowledge of the spatial and temporal distribution of the substance in the working area. The required information on the concentration of the substance in the working area is provided by the available exposure measurements, other measurements available, comparable plants or activities and reliable calculations.

If the information is insufficient, it should be supplemented by measurements, generally specific measurements in the working area. They may record the exposure directly, or the concentration at the emission points from which the exposure may be calculated. Depending on the analytical possibilities and the work procedures recorded, the locations, times and durations of the measurements must be selected so that they can be used together with the information already available to calculate the shift average. In addition the level, duration, frequency and interval of the exposure peaks which occur systematically in the working routine must be recorded with reference to short-term value requirements.

The many different possibilities of taking measurements may all be used here in order to make allowance for the different conditions in

the different types of working areas and to prevent erroneous evaluations from being made because the approach is pre-established and rigid.

The checklist in [9] states that the hygienist has to determine if other monitoring data from the same factory of from the literature are comparable because operations and work procedures can be considered similar.

For simple calculations the mean use per hour of the basic substances, and the concentration of dangerous substances can be used. It is also be possible to use emission measurements and ventilation data as input data for a calculation:

c = mass per hour/total ventilation volume per hour.

In [16] and in [9] examples are given of calculations. It is assumed that there is an even mixing of the contaminant in the air of the workplace, and that the air change rate is equal for the whole working area. Since a steady state situation is usually reached within an hour, this state can be used for calculating the concentration.
A further discussion on the calculation of concentrations is given in 8.4.2.

4.4.3 United States of America

No guidance is given for using existing measurement data from comparable situations.
Some guidance is provided for the use of equations to estimate concentrations of solvents in the breathing zone. However, it is sometimes simpler to actually perform some measurements than to make calculations that may be questioned by an OSHA inspector.
OSHA regulations require that employee's complaints or symptoms that may be attributable to significant exposure must always be considered in the initial assessment. Any occupational health nurse or physician seeing the employees should be consulted in this respect.

4.5 Initial Conclusions

4.5.1 United Kingdom

An initial assessment can lead to the conclusion that no further sampling is necessary because exposures are assessed to be below a level of significance.
It may also lead to the conclusion that exposures require immediate remedial action before any air sampling studies are appropriate.
However, it may be concluded that the initial assessment cannot be completed without first-hand evidence of exposure levels. In such a case quantitative sampling for the contaminant(s) in question will have to be arranged (q.v. 5.1.1).

4.5.2 Federal Republic of Germany

After the substances involved at the workplace have been listed, and basic information on the nature of the plant, work procedures, working areas and preliminary data have been obtained there comes the question whether a decision is possible at this stage.
If the answer is no, a survey has to be done for the purpose of supplementing the preliminary information by measurements. In that case the procedure continues with chapter 5. If a decision is possible on the material collected so far, one possibility is that there is no compliance with the 8-hour TWA limit or the short-term requirements. In that case measures need to be taken to reduce the exposure, after which the procedure of the WAA can start again. If there is compliance, it is necessary to establish its permanence or the fulfillment of a substance criterion. In the latter case the procedure can be stopped, and there is no need of routine monitoring. This last conclusion needs to be checked regularly because of possible changes in the process or the MAK values.
In all other cases a procedure for routine monitoring has to be established(q.v. 6.1.2).

4.5.3 United States of America

If exposures are found to be below the AL, there is no need for exposure measurements to be made. If exposures may be above the AL, the exposure of the maximum risk employee for each hazardous work operation should be measured (see Section 5).

In both cases a report should be written containing the following data:

- Date of report.
- Name and social security number of each employee considered in a work operation.
- Work operation performed at time of measurement.
- Location of work operations.
- Chemical substances to which the employee may be exposed in each work operation.
- Any information, observations and estimates that may indicate exposure of this employee to a chemical substance.
- The PELs or TLVs for each chemical.
- Complaints and symptoms that may be attributable to chemical exposure.
- Types and effectiveness of any control measures taken.
- Operating conditions and ranges for production, process, and control measures.
- Summary including any further action required.

5. SURVEYS (NOT ROUTINE MONITORING)

5.1 Introduction

5.1.1 United Kingdom

In the UK surveys are conducted on different levels of sophistication (see Section 2.1 for a flow diagram of monitoring strategies).
A preliminary survey should provide basic quantitative information on the efficiency of process and engineering control measures and on the likely extent of exposure of workers to hazardous substances. If the extent and pattern of exposure cannot be reliably assessed by a brief preliminary survey a more detailed survey, will be necessary. This is particularly appropriate when:

- the results of the preliminary surveys show that exposure is very variable;
- large numbers of people may be at risk of excessive exposure;
- personal sampling results are close to or in excess of the appropriate exposure limits and the cost of additional control measures cannot be justified without further evidence as to the extent of the risk.

Preliminary and detailed surveys are exploratory, self contained and are concluded once prevailing conditions have been determined. The aim should be to ensure that all workers are protected on a day-to-day basis and that any necessary remedial measures are put in hand if the possibility of excessive exposure is identified. They should be conducted, if indicated by the initial assessment:

- on start-up of a new process;
- on setting of a new exposure limit or revised action level;
- when there has been a substantial change in the process, operations or control measures;
- when unusual, intermittent or infrequent operations or processes are to be conducted (batch production, major maintenance or during decommissioning of plant).

Since exposure patterns are often subject to considerable and frequently unsuspected variations, and since numerical data may be subject to large errors, assessing exposure to hazardous substances requires more than a single measurement. The errors can be reduced by refining the techniques used and by including supportive evidence such

as the observations of a competent investigator. The strategy selected will depend on the purpose of the survey being conducted. If the pattern is very variable, or if large numbers of workers are involved, it is unlikely that a first-level stratey (4.1.1) will prove very reliable.
A second-level strategy will be appropriate for most detailed surveys. At this level, emphasis is placed on the accurate measurement of TWA exposures and relating this to the appropriate 10-minute and 8-hour TWA limits (see 4.1.1). Occasionally a high degree of sophistication is necessary in a sampling programme. It is beyond the scope of the guidance note EH-42 to give full details of the procedures necessary for such a third-level strategy.

The surveys do not have to be reported in a certain format or even in writing. In order to be able to give some information on the extent of what is usually taken into account when exposures are assessed, the data reporting sheet used by HSE personnel to present the results of environmental monitoring will be used as an example (Appendix A). Though these measurements, which are mainly done by the Field Consultant Groups, cannot easily be fitted into the normal pattern of preliminary survey, detailed survey or routine monitoring, the monitoring can be supposed to be at least comparable to a detailed survey of secondary level. The measurements done by the HSE can be considered to be exemplary to others in industry.

5.1.2 Federal Republic of Germany

If the is information available is insufficient for determining compliance with the limit and reaching conclusion in the initial assessment, supplementary information has to be obtained by a survey.
In the Federal Republic, the survey usually forms part of an initial assessment, because a WAA (Arbeitsbereichanalyse) can cover a survey and initial assessment at the same time. In order to discern the different stages of the monitoring strategies in three countries, this leads for the FRG to a rather artificial distinction between the initial assessment and surveys. Unfortunately this means there will be quite some cross references in this chapter.

5.1.3 United States of America

Once a written exposure determination is made indicating exposures at or above the AL, the employer is obliged to make an exposure measurement of the maximum risk employee(s). If the exposure of the maximum risk employee is at or above the AL, it is necessary to identify and measure all employees whose exposures may be ≥ AL. The same considerations that were used in the previous chapter must now be employed to select and categorise workers according to expected risk potential.

5.2 Substances

5.2.1 United Kingdom

(a) Information on substances

In 4.1.1 a description is given of the assessment of the chemical substances involved.
In the dataform (Appendix A) used by HSE there is space for four different substances to be analysed from one sample. Normally this space is sufficient.

(b) Sampling equipment and analytical methods

Reference is made to Section 4.1.1.

(c) Personnel

The same conditions as stated in 4.1.1 can be applied to this Section.

5.2.2 Federal Republic of Germany

The information on substances and its different aspects is the same for this place as that for the initial assessment. Reference is made to Section 4.1.2.

5.2.3 United States of America

The same applies as mentioned in Section 4.1.3.

5.3 Identification of factors affecting exposure

5.3.1 Processes and sources

5.3.1.1 United Kingdom

Section 4.2.1.1 lists some primary process variables can affect airborne concentrations. It also applies to surveys.
Surveys require a detailed knowledge not only of the processes involved and the nature and the substances used, but also of the individual tasks of employees. Static or background samples may help in assessing exposure patterns, and provide additional information on the performance of engineering controls. If the extent and pattern of exposure cannot be reliably assessed by a brief preliminary survey, a more exhaustive investigation will be necessary.
The number of samples to be taken will depend on the circumstances, but the investigator must be confident that, within reason, he has adequately covered all work and exposure cycles.
It is often useful to select the individual workers and the static positions for monitoring partly on a systematic basis in relation to the expected exposure pattern but also to include certain random elements to serve as a check on the qualitative preliminary assessment.

The guidance note emphasises the variations in concentrations possibly due to the nature of the processes. The amount of space reserved for describing processes and sources in the dataform (Appendix A) is limited.
The only place where a description of the process (and specific job) can be entered is under the heading 'sample description'.

When the 'exposure type' is considered to be normal, i.e. if in the hygienist's opinion, or on the basis of no other information to the contrary, the exposure estimate obtained from the sample is likely to be a valid estimate for normal working conditions at that site, the exposure type is coded as N. If, in the hygienist's opinion, the exposure estimate is likely to be higher, for example if throughput is much higher than normal or if ventilation has broken down, the exposure type is coded as H. By consequence, if in the hygienist's opinion the exposure estimate is likely to be lower, for example when the general ventilation is better because of high winds etc., the exposure type is coded as L.

Two types of control measures are coded in the data sheet with environmental monitoring results: local exhaust ventilation (LEV) and respiratory protective equipment (RPE).
'Yes' is entered on the data sheet for environmental monitoring results if LEV was provided at the process concerned. 'No' is entered if LEV was not provided, or if the LEV provided was obviously ineffective. A fine judgement as to how effective the LEV was is not required for this purpose.
For personal samples, 'yes' is entered on the data sheet if RPE was worn by the employee sampled. 'No' is entered if RPE was not worn or if the RPE worn was obviously unsuitable. A judgement as to whether the actual protection factor was adequate for the exposure expected is not required for this purpose.

A detailed description of the process or operations used, of tools and equipment, machines and installations, raw materials, intermediates, products, contaminants, ancillary chemicals, process conditions, routing and other control measures is normally not given in the dataform previously mentioned (Appendix A).

Of course there is always the possibility of mentioning other relevant data and observations in the visit report. EH-42 states that numerical results should be supported by and interpreted in the light of other information, such as measurements of ventilation performance or the observations by a competent person of leak sources, work procedures etc. Results should, therefore, be tabulated and relevant ambient and operating conditions noted. The tables may also include a column recording what action if any is to be taken by whom and when. As the above mentioned information is not likely to be included in Appendix A or B, it will not be included in the data bases (7.1). The interpretation of the results in the light of other information will then be difficult.

5.3.1.2 Federal Republic of Germany

The information on processes and sources is the same in this phase as that in the initial assessment. Reference is made to Section 4.2.1.2. On the monitoring [3] gives information. Depending on the analytical possibilities and work procedures, the locations, times and durations of the measurements must be selected so that they can be used together with the information already available for calculating the shift average. In addition the level, duration, frequency and interval of the exposure peaks which occur systematically in the working routine must be recorded with reference to the short-term value requirements. A precise evaluation of the short-term criteria presented in Table 1, and translation of the criteria into a monitoring strategy, is tedious. Not only have substances of categories I, IV and V to be sampled just as long as the duration of the period of higher exposure, because the concentration (of twice the limit) is defined as an instantaneous value but also the frequency of the excursions has to be taken into account.
The substances of categories II.1, II.2 and III have a time base of 30 minutes, which means that sampling times have to be chosen of 30 minutes or less.
In the FRG guidance is given on the frequency of monitoring for samples that do not cover a whole shift.
The averaging time is the time basis for individual readings. It is often a characteristic of the analytical procedure and is determined by the sampling time and/or time action of that procedure.
A particularly appropriate method of determining the average value is to obtain the average for the whole exposure time during a shift. If the averaging time in the analytical procedure is shorter, the minimum number of measurements required over 8 hours must be taken from Table 2. Only when exposure is considerably shorter can the number be reduced.

The TWA shift average is the arithmetic average of the individual readings with a short averaging time. When the averaging times vary a time-weighted arithmetic average must be calculated.

Table 2 Minimum number of samples.

Averaging time (sampling time)	Number of samples
10 seconds	≥30
1 minute	≥20
5 minutes	≥12
15 minutes	≥ 4
30 minutes	≥ 3
1 hour	≥ 2
≥2 hours	≥ 1

The frequency of monitoring depends on the TWA of the measurement (see 5.7.2). If the measured value is less than a quarter of the limit, monitoring has to be done at least once every 64 weeks. If the TWA is more than a quarter and less than half the limit the monitoring has to be repeated within 32 weeks; and if the TWA is more half the limit but in compliance with the limit the frequency is at least once every 16 weeks. For the interpretation see 5.7.2.

5.3.1.3 United States of America

The same applies as mentioned in Section 4.2.1.3.

5.3.2 Working environment

5.3.2.1 United Kingdom

Section 4.2.2.1 lists some primary variables that affect airborne concentrations in the working environment. Ambient conditions should be taken into account if they are likely to have a significant effect on exposures. This is particularly relevant to outdoor operations where wind speed and direction can have a major effect.

In the data sheet used by HSE for reporting the environmental monitoring results (Appendix A) the only reference to factors relating to the working environment is under 'exposure type' and LEV which has been reported in 5.3.1.1.

Other factors concerning the size of the workplace, or influencing general ventilation or general hygiene, are not normally reported in the data sheet mentioned previously.

5.3.2.2 Federal Republic of Germany

The information on the working environment is largely the same as that in the initial assessment. Reference is made to Section 4.2.2.2. For some aspects the checklist in [9] goes into more detail, these will be presented here. The place of monitoring has to be represented by a photograph or topographical sketch.

Working environment:	open; partly open; closed
size:	50 m^3 <; 50-500 m^3; > 5000 m^3.
Ventilation:	general windows/doors: open; closed;
	open/closed skylights;
Mechanical ventilation;	outside air; clean air; recirculation
local exhaust ventilation	no/yes
hood:	pipe; slot; with blowing jet
hood position:	at side; above table; ventilation/booth;
other:	
Control measures:	no/yes; wet process
	Local controls; central controlmeasures.
Filtering devices:	mechanical, electric, wet
Ventilation air:	removal; recirculation.
Distance source and LEV:	0.5 m <; 0.5-1 m; > 1 m.
Airspeed at hood of LEV:	< 0.5 $m.s^{-1}$; 0.5-5 $m.s^{-1}$; > 5 $m.s^{-1}$.
Dimensions of hood:	diameter ... cm or ... cm x ... cm.
Ambiant meteorological	
conditions:	sunny - cloudy - overcast - rain/snow - hazy.
Wind speed:	low - moderate - high - storm.
Outside temperature:	°C.
barometer reading:	Pa.
relative humidity:	%.

For the duration and frequency of monitoring see 5.3.1.2.

5.3.2.3 United states of America

The same applies as mentioned in Section 4.2.2.3.

5.3.3 Work procedures

5.3.3.1 United Kingdom

Section 4.2.3.1 contains some remarks on work procedures. Although they also apply to this section they will not be repeated here.
The best approach to a sampling strategy is to divide the exposed population into groups that are as homogeneous as possible in relation to the type of work, duration of exposure etc. The groups with the highest suspected exposure are then selected, and the pattern of work in relation to suspected sources of contaminant release is studied. Periods of elevated or 'peak' exposure are identified, and sampling is conducted during these phases of the work cycle. Personal sampling techniques should be used, but static or background sampling may be useful in verifying the existence and types of sources of contaminant release, and in assessing the effectiveness of engineering control measures. The number of samples to be taken will depend on the local circumstances, but the investigator must be confident that he has within reason covered adequately all individual work patterns and the overall work and exposure cycles. Periods of maximum exposure should be identified and compliance with both 10-minute and 8-hour TWA limits should be re-assessed by repeating any measurement on different days or shifts sufficient to cover the range of anticipated exposure conditions.
If there is considerable variation in the day to day working pattern it may be necessary to sample on sufficient days to cover the anticipated variations.
It is important to take account of operations carried out at the beginning or end of the work period, so that operations which may significantly influence the overall exposure level, such as weighing out for and charging batch mixing machines and machine cleaning, can be included. Valuable additional information may be obtained by splitting the shift into separate shorter sampling periods.
Every effort should be made to identify any individual with an abnormal exposure pattern due to different or poor work procedures. The HSW Act refers to all employees and, consequently, it is the individual

results that are important for compliance purposes and not just group average exposures.
In 5.3.1.1 reference has been made to the space alloted for writing a 'sample description' and 'exposure type' in which work procedure related matters are also to be reported.

5.3.3.2 Federal Republic of Germany

The information on work procedures is largely the same as that in the initial assessment. See Section 4.2.3.2. For duration and frequency of monitoring, see 5.3.1.2.
Appendix C shows that every working area (Arbeitsbereich) in which normally a specific number of activities is done, has its own identification code.

5.3.3.3 United States of America

The same applies as mentioned in Section 4.2.3.3.

5.3.4 Organisational aspects

5.3.4.1 United Kingdom

In the UK the guidance note [1] gives a slight reference to organisational aspects in the way that a preliminary survey may highlight defects or deficiencies in operator awareness and training etc.
Other aspects like the responsibility for e.g. safety and hygiene at the workplace, for meeting the needs of correct work procedures are not explicitly stated in the guidance note.
The use of RPE is reported on the data form (Appendix A). This is presented in Section 5.3.1.1.

5.3.4.2 Federal Republic of Germany

The information on organisational aspects is largely the same as that in the initial assessment. See Section 4.2.4.2.
When evaluating compliance with limit values, areas where and times when respirators are worn must not be taken into consideration. For the use of respirators, reference is made to the corresponding rules.

5.3.4.3 United States of America

The same applies as mentioned in Section 4.2.4.3.

5.4 Population at risk

5.4.1 United Kingdom

Not only those who may be routinely exposed (e.g. process operators) need to be considered, but also those liable to be intermittently exposed (e.g. maintenance workers, cleaners, crane drivers, etc.). This requires a detailed knowledge not only of the processes involved and the nature and composition of the substances used but also of the individual tasks of employees.

The best approach to a sampling strategy is to divide the exposed population into groups that are as homogeneous as possible in relation to the type of work, duration of exposure etc. (see e.g. 5.3.3.1).
A second-level strategy will be appropriate for most detailed surveys. At this level, emphasis is placed on the accurate measurement of TWA exposures and relating this to the appropriate 10-minute and 8-hour TWA limits. This means that, whenever possible, the entire period of an individual exposure should be covered, either by one or by several consecutive samples. Where several samples must be taken and sampling is not continuous, care must be taken to ensure that the periods of high exposure are thoroughly covered and fully considered in time-weighting calculation. This can be accomplished by a regime of 'stratified' sampling which concentrates more sampling effort into the period of probable maximum exposure. The overall aim should be to quantify personal exposures as accurately as is necessary to provide evidence of control within exposure limits and of the efficiency of work procedures and engineering control methods. Periods of maximum exposure should be identified and compliance with both 10-minute and 8-hour TWA limits should be re-assessed by repeating any measurement on different days or shifts sufficient to cover the range of anticipated exposure conditions.
On premises where a number of people are engaged in similar jobs, sampling can be carried out most effectively on a group basis. The people exposed should be divided into jobs doing identical or similar work in the same area. If there is considerable variation between the work of each shift (e.g. between day and night shifts) workers on each shift

should be regarded as a separate group. Any individuals with unique exposure patterns should be identified so that their exposure can be measured separately. Where a group measurement is planned, the air sampling should be carried out on a random sample of individuals from the whole group. Sufficient samples should be taken to cover the range of activities and exposures within the group and to provide a sound basis on which to assess these exposures and any predictable changes in future exposure.

5.4.2 Federal Republic of Germany

The measurements in the guidance note [3] are intended to give an assessment of exposure. Exposure means the presence of a substance in the air within employees' breathing areas. Exposure is quantified by indicating the concentration and its time reference. The time reference in TRGS 402 is the shift length.
In Germany the working area (Arbeitsbereich) is a central point in the analysis. The working area may include one or more work stations. The population at risk as distinguished in the UK or USA is totally different in the FRG, and depends on how many different working areas are defined in a certain workplace during the initial assessment. For a discussion see 8.4.2.
For the duration and frequency of monitoring, see Section 5.3.1.2.

5.4.3 United States of America

In the absence of measurements at this stage, the selection of the maximum risk employee(s) must be made by comparing for each work operation the estimated exposure levels of the workers exposed.
Criteria recommended are:

- The employee closest to the source.
- Valid time-concentration estimates for workers with various work stations or work tasks.
- Air movement patterns. Air flow could result in higher concentrations further away from the source.
- Differences in work habits of individual workers.
- All information obtained during the initial assessment (Section 4).

The selection should be made by a competent, well-informed person.
However this approach is subject to frailties of professional judgement which could lead to erroneous conclusions.

If the 'maximum risk worker' cannot be selected with reasonable certainty, then the second approach is random sampling of a group of workers believed to have similar (high) exposure (e.g. the same operation). This approach is less efficient than the non-random sample obtained by professional judgement. The objective of the second procedure is to select a subgroup of adequate size, so that there is a high probability that the random sample will contain at least one worker with high exposure, if one exists. Tables are provided giving the required sample size (n) of a random sample drawn from a group (N) with homogeneous exposures, which ensures 90% or 95% confidence that at least one individual from the highest 10% or 20% of exposures is contained in the sample.
This technique makes no assumption on distribution and the required sample sizes are large, particularly in small groups ($N<20$).
The actual workers to be measured are selected randomly using a table of random numbers. OSHA regulations state that if an exposure of an employee, regardless of how he is identified, is $\geq$ AL, then it is necessary to identify for all workers with exposures $\geq$ AL.
This provision cannot be met by sampling a subgroup of workers and assigning the average exposure obtained to all workers in a group because of the considerable variation in inter-employee exposure. Hence once a worker is found with overexposure with respect to the AL, the whole group should be measured.

Another method is the zoning method [29, 30]. It uses zoning of workplaces to group employees on the basis of similarities in job and environment.
The procedure of selecting zones involves an examination of all processes, material inventories and ventilation systems. With this information and the job classification by department, employees are preliminarily assigned to zones. After the cohort size in each zone is determined, an appropriate number of employees from each zone is randomly selected for determining the mean exposure of all employees in a given zone and the expected number of employees with exposures in excess of the AL. The sample size is derived assuming log-normal distribution of concentrations and a geometric standard deviation (GSD) of 2.3.

The zoning method and the NIOSH method are not mutually exclusive. Both are designed to minimise the burden of sampling, and both involve preselection of employees prior to sampling.

The zoning strategy does not involve characterisation of each employee per se, but characterisation of work with respect to exposure. The NIOSH strategy also identifies (as required by OSHA regulations) these employees.

Special groups

If jobs are associated with intermittent exposure, best professional judgement is called on for deciding if and when exposure measurements are required.
Special consideration should be given to;

- The toxic potential of the chemical (particularly acute toxic effects). Generally those substances with ceiling limits should be looked at.
- The duration and frequency of exposure.

Outside contractors must be provided with all necessary information concerning the potential hazards of the substances to which they may be exposed and appropriate protective measures required to minimize their exposure.

Whenever possible, the contractor or agency management should be provided with a list of the hazardous chemicals and the safety data sheets for the materials their employees will be using in the course of their work in our area.

Monitoring

The minimum requirement for assessing the exposure of the maximum risk employee or the employees who may be exposed to a level ≥ AL is a single measurement representative of the maximum 8-hour TWA exposure.
The measurement may take place by any combination of long-term or short term samples over the period of the PEL. The following measurement types for a single-day measurement of the 8-h TWA are described in the NIOSH manual:

- Full period single sample (8-h sample).
- Full period consecutive samples (continuous series of several samples of shorter duration covering the full 8 hours).
- Partial period consecutive samples (one or several samples covering only a portion of 8 hours).

- Grab samples (several samples of short duration (minutes) taken at random intervals over the 8 hours).

The 'full period consecutive sampling' procedure is the 'best' strategy in that it yields an estimate with the closest confidence limits. This is because in the NIOSH approach of decision making, the uncertainty in the single estimate of exposure is only a function of measurement errors (see §4.1.3).
The substantial day-to-day variability is not taken into account.
Generally two consecutive samples provide sufficient precision and may reveal substantial differences in exposure levels during the full period.
'Full period single sampling' is the 'second best' strategy. 'Partial period consecutive sampling' is less desirable. Reliable knowledge and professional judgement must be used to extrapolate the results to an 8 hour estimate. For non-compliance demonstration, the statistical test of power is low. The sampled period should cover at least 70 to 80% of the full period. If this is not possible, it is better to have recourse to a grab sampling strategy.
OSHA officers try to take at least samples over 7 hours during the first day of visit. If there is a hazard, full shift sampling (usually 3 consecutive samples) is always performed on the second day.
For non-compliance situations it should always be demonstrated that the day of sampling is a representative day. On scheduled inspections at least 2 to 3 employees per operation are sampled.

The 'grab sampling' strategy is the least preferable, because the uncertainty of the 8-hour estimate is dominated by the considerable intra-day variability of exposure levels which are substantially larger than the errors in the measurement method itself.
The optimum number of grab samples is between 8 and 11 taken at random intervals during the entire 8-hour period. A table for selecting random sampling periods during 8 hours is provided.
This applies only if the employee's exposure levels are adequately uniform during the work shift.
If the worker is at several work locations or operations during a shift, then at least 8 to 11 grab samples should be obtained during each period of anticipated uniform exposure that substantially contributes to the TWA. The duration of each grab sample need only be enough to collect sufficient mass of contaminant to exceed the lower detection limit of the analytical method.

Measurements taken for the purpose of determining exposure for substances with a ceiling limit should be taken as a 15-minute sample (the time period of ceiling limit under the new OSHA standards) or a series of consecutive samples totalling 15 minutes.
Distinction is made between environments in which the period of highest short term exposure can be predicted and those where this is not possible.
For 'predictable peak exposures' a minimum of three measurements should be taken on one shift during periods of maximum expected concentrations. OSHA officers usually take 6 samples.
All pertinent information related to the process or operation should be considered so that only air samples likely to represent peak exposures are taken.
For 'unpredictable peak exposures', sampling intervals must be selected at random throughout the work shift to allow statistical inferences to be made.
If the process appears constant during the work shift, the number of periods that should be sampled is estimated on basis of the same distribution free technique as for selecting a sample from a homogeneous risk group.
The premise used is that at least one period is from the top 10 or 20% of the distribution. The particular time periods to be sampled are selected in the same way as for the grab sampling procedure.

In the NIOSH manual no guidance is given for the assessment of exposure to mixtures.

5.5 Check on results

5.5.1 United Kingdom

Where group sampling is carried out the results should be carefully analysed to make certain that they are valid for all the individuals of the group.
A wide distribution of results shows considerable variation within the group and could indicate that particular individuals have not been grouped correctly. In such circumstances further subdivision of the group could focus on those at risk of excessive exposure and make most efficient use of sampling resources.
Within a homogeneous group exposure patterns will still be subject to both random and systematic variations, particularly for indoor condi-

tions. A useful rule of thumb is that no individual's exposure should be less than half or greater than twice the group mean.
Every effort should be made to identify any individual with an abnormal exposure pattern due to different or poor work procedures. The HSW Act refers to all employees and, consequently, it is the individual results that are important for compliance purposes and not just group average exposures.
A further check on the results can be made by not only selecting the individual workers and static positions for monitoring on a systematic basis in relation to the expected exposure pattern, but by also including certain random elements.

5.5.2 Federal Republic of Germany

No special reference is made of a check on the results apart from the normal procedures for examining the analytical methods.

5.5.3 United States of America

In practice data are rejected only when gross measurement errors are suspected (full time consecutive sampling may give a clue) and the cause can be identified (e.g. tampering with the sampling device). Visual observations of the employees activities during sampling is important.

When subgroups from a homogeneous risk group are sampled the exposure variability should not be too high, otherwise exposure estimates of individual employees will have a substantial amount of uncertainty (zoning methods). If the variability of the distribution exceeds a GSD of 3.0, the selection of the risk group should be re-examined [26]. Further sampling may be necessary to define a more limited population in order to achieve tight enough confidence intervals for making decisions.

5.6 Calculation of TWA

5.6.1 United Kingdom

Results should normally be reported as an 8-hour TWA. If one whole shift sample is taken, then results should be calculated as follows:

- If the working shift is exactly 8 hours, then the result of a whole shift sample is the 8-hour TWA.

$$TWA = c_1 \cdot t_1/8 = c_1 \qquad t_1 = 8.$$

- If the working shift is less than 8 hours, the TWA can be calculated assuming zero exposure during the remaining time. Any assumption of zero exposure during a non-sampling period should be evaluated critically. It may alternatively be assumed that exposure during the non-sampling periods is the same as that measured (i.e. continuous exposure) or is at some intermediate level. Any such assumption should be justified by some evidence.

$$TWA = (c_1 \cdot t_1 + o)/8 = c_1 \cdot t_1/8 \qquad t_1<8.$$

- if the working shift is more than 8 hours, the TWA should be determined for a representative 8-hour period of the working shift..

$$TWA = c_1 \cdot t_1/8 \qquad t_1>8.$$

Calculation of 8-hour TWA from split samples should be made by summing the products of individual sampling results and corresponding duration of sampling in hours and dividing the resulting sum by 8.

$$TWA = (c_1 \cdot t_1 + c_2 \cdot t_2 + ...)/8 \quad t_1 + t_2 + ... = 8.$$

Calculation of TWA for intermittent exposures can only be done when an operator's daily work patterns are known. The exposure level for each job should be measured or estimated from other information. From the measured, known and assumed concentrations and the duration of the normal daily work pattern, a TWA can be calculated analogous to that from split samples.

Calculation of 10-minute TWA concentration can be done from a 10-minute sample, which should be taken at periods of 'peak' or elevated exposure as identified by previous study of the phases of the work cycle. Furthermore, a 10-minute TWA exposure should not be assessed on the basis of addition of intermittent short periods of less than 10 minutes of high exposure during a working day. The 10-minute TWA exposure should usually be assessed by sampling for a 10-minute period. If methods are available for sampling over periods of less than 10 min-

utes, the results may be averaged down so as to obtain a 10-minute TWA.

Mixed exposures should be assessed in a slightly different way [2]. It is essential that all the assessments are based on the concentrations of each of the constituents 'in air' to which workers are exposed. If there are no expert assessments for a particular mixed exposure, the various types should be considered in the following order:

- Synergistic substances. Specialist advice should be obtained on the assessment.
- Additive substances: where there is reason to believe that the effects of the constituents are 'additive', and where exposure limits are based on the same health effects, the mixed exposure should be assessed by means of the formula:

$$C_1/L_1 + C_2/L_2 + C_3/L_3 \ldots < 1$$

  where C_1, C_2 etc. are the concentrations of constituents in air and L_1, L_2 etc. are the corresponding exposure limits.
- Independent substances: where no synergistic or additive effects are known or considered likely, the constituents can be regarded as acting 'independently'. Every substance is regarded on its own.

Exposure to mixtures does not necessarily have to mean that there is a simultaneous exposure to different substances during a certain time. Even when an employee works with different substances for a different period of time during one shift this may need to be considered as exposure to a mixture.

5.6.2 Federal Republic of Germany

Different analytical procedures produce readings with different averaging times and yield different amounts of information. In order to be able to evaluate all measurements in the same way, standardised quantities must be obtained from the different readings. The reference period is introduced for this purpose. It is the period to which all the results used in the assessment must relate, either because they have the reference period as their averaging time, or because values can be produced from them, either by averaging or some other procedure, which relate to this reference period.

For the purpose of this TRGS [3] the reference period is standardised as one shift. All readings must therefore be processed so that they produce a result based on a period of one shift. The result is based on the arithmetic mean of the measured concentrations. When the averaging time of the different measurements is not uniform, the TWA has to be calculated:

$$TWA = (c_1 \cdot t_1 + c_2 \cdot t_2 + \ldots)/(t_1 + t_2 + \ldots)$$

If the duration of exposure by nature of the work procedures is shorter than a shift, the measured exposure is to be related to the length of the shift. Of course compliance with the short term requirements is necessary.
For substances without a short-term value, concentrations of exposure shorter than one hour should not exceed 8 times the shift limit.

If the exposure can be considered to be similar during the non-monitoring hours, an 8-hour TWA can be calculated from a very limited sampling time. This time can be found in Table 2. If, on the other hand the exposure during non-monitoring hours is zero, the 8-hour TWA is lowered proportionally. For the monitored periods a check on the short-term requirements remains necessary.

A special guidance note [10] covers the assessment of exposure to mixtures. The calculation involved is not unconditional:
- it is only permitted for substances with a MAK-value;
- it is only permitted for components in the breathing air for which a similar biological effect is probable or cannot be excluded. This additive effect is to be considered when constituents of a mixture have the same target organ in the body;
- it is only permitted if the concentration of the substance is more than 10% of the MAK-value for that substance. (There are, however, exceptions to this rule. They are listed in an annex to the MAK-value list [11]).

For substances whose effects are independent, the calculation is not in order, and compliance with the different individual MAK-values is necessary. If there is a scientifically based TWA-value for a certain mixture, the calculation formula should not be used, either.

The index for exposure mixtures is to be calculated from the 8-hour TWA-values of the individual constituents (Ci) and corresponding MAK-values:

$$I = (C_1/MAK_1) + (C_2/MAK_2) + \cdots$$

For TWA values with a shorter reference time than 8 hours (see Table 1) the substances of groups II.1, II.2 and III, the corresponding TWA for a 30 minute period has to be calculated to assess whether there is compliance with the short-term requirements.
This also has to be done for the substances of group I on a 5-minute basis, group V on a 10-minute basis, and group IV on a 60-minute basis.
As the substances in the last three groups (I, IV and V) are momentary values which may not be exceeded at any time (this requirement is to be considered an objective), any information of the original results which has not been averaged out, should also be considered when checking on compliance.

5.6.3 United States of America

Results should be reported as 8-hour TWA.
According to OSHA regulations (29 CRF Sect. 1910-1000 d) TWA is calculated by integrating the concentration values of 'full period single' or 'consecutive samples' over the total time base of 8 hours.

$$TWA = (c_1.t_1 + c_2.t_2 + \ldots + c_n.t_n)/8 \qquad t_1+t_2+\ldots+t_n = 8$$

The same applies for ceiling values. However, the time base is the period of the ceiling limit.
For 'partial period consecutive sampling' the TWA is calculated for the period samples.

$$TWA = (c_1.t_1 + c_2.t_2 + \ldots + c_n.t_n)/(t_1 + t_2 + \ldots + t_n) \qquad t_1+t_2+\ldots+t_n < 8$$

For an estimate of the 8-h TWA, the employer may assign the TWA of the partial period to the whole period. If the habits of the employee and the work operations are identical during the samples and unsampled period, it is assumed that the unsampled period had the same average ex-

posure as the sampled period. However, the statistical tests in 5.7.3 are not fully valid in this situation.
The OSHA compliance officer may demonstrate non-compliance by comparing the partial period TWA to a partial period PEL ((8h/total time of samples)•PEL (8h)).

For grab samples all samples can be directly averaged if the exposure is relatively constant during the work shift. Sampling time can be omitted if the duration of each sample is short compared to the period of the limit value (e.g. each sample is less than 5% of that period). If the employee was at several work locations during the work shift, and several grab samples were taken during each operation with different expected exposures, the results should be averaged for each operation. The TWA is then calculated by integrating the different averages over the time base taking account of the exposure times.
Data analysis and decision procedures for this type of sampling are not given in the NIOSH manual. For different time bases, see [31].

In the case of exposure to a mixture of air contaminants with additive effects OSHA specifies the following procedure for computing equivalent exposure I:

$$I = C1/L1 + C2/L2 + C3/L3 + \ldots \leq 1$$

5.7 Interpretation

5.7.1 United Kingdom

Once the sampling and analysis have been completed the results should be meticulously collected to make interpretation easier so that the maximum possible amount of information is extracted. One figure for the exposure of one worker at one process on a specific day is rarely a reliable indicator in itself of the exposure of other workers on that or other days. Numerical results should be supported by and interpreted in the light of other information, such as measurements of ventilation performance or the observations by a competent person of leak sources, work procedures etc. Results should, therefore, be tabulated and relevant ambient and operating conditions noted. The tables may also include a column to record what action if any is to be taken by whom and when.

If in a preliminary survey some exposures are significantly in excess of the limit immediate remedial action should be taken. If on the other hand exposures are well below the limit and as low as reasonably practicable a low level of 'watchdog' routine monitoring can be observed. If the exposures are mostly below the limit a detailed survey may be necessary.

The following practical guidelines are given [1]:

Results	Action
< 0.1 limit*	Normally no further action, if exposure is as low as is reasonably practicable.
0.1 to 1.5 limit	Investigate process/control measures; make detailed survey to check source of high results.
Some results > 1.5 limit	Investigate; take remedial action (e.g. improve control measures, provide respiratory protection); repeat survey to assess effects of improvements. Respiratory protection may provide an effective, if short term, remedial measure for those workers with high exposure whilst investigations continue and engineering controls are improved.

* A level higher than 0.1 limit may be indicated if the limit is based entirely on 'nuisance' or odour and there are no known effects at the maximum exposure concentration measured.

If in a detailed survey some exposures are in excess of the limit or not as low as reasonably practicable, remedial action should be taken. If, on the other hand, exposures are well below the limit and as low as reasonably practicable, a low level of 'watchdog' routine monitoring can be observed. If exposures are significant but below the limit the routine monitoring begins (see Section 6).

The following practical guidelines are given [1]:

Results	Action
< 0.25 limit	Normally no further action, if exposure is as low as is reasonably practicable.
< 1.25 limit	Investigate control measures; take appropriate remedial action; repeat survey, using refined techniques if possible to reduce errors.
Mean < 0.5 limit, all results < limit	consider routine monitoring, and suitable frequency.
Mean > 0.5, some results > limit	Investigate control measures; improve control measures where possible; repeat survey to assess effects of improvements; consider routine monitoring.

However, the practical guidelines, which are no more than rules of thumb, need to be applied with caution. They may not be of universal application and may need to be modified to take account of other factors such as:

(a) the precision and accuracy of the sampling and analytical techniques used and the type of sampling strategy. If relatively unsophisticated techniques have been used, it would be unwise to place too much confidence in the results, especially when they are close to the exposure limit. However, if the results are very high or very low, a reasonable assessment of the extent of the problem can usually be made. As the techniques and strategies become more refined, more confidence can be placed in the results.

(b) the qualitative evidence in the form of other information and measurements and observations by a competent person.

No specific statistical analysis of data from a survey is recommended in the UK. When a high degree of sophistication has been used in the monitoring programmes, statistical analysis of the results becomes possible. These analyses may include statistical studies for estimating the arithmetic mean and sample variance, and fitting the data to a theoretical distribution function. These could be used as some of the criteria for considering the reliability of the overall assessment and the confidence that can be attached to any claim that the exposure limits are being met.

5.7.2 Federal Republic of Germany

For the interpretation an unambiguous scheme is presented. There is non-compliance unless the initial assessment and survey show that the TWA does not exceed the limit and the short-term requirements in respect of the level, duration, frequency and interval between peaks are met.

On the conclusion of compliance (but not permanently assured) during the WAA the routine monitoring scheme is to be designed and recorded (see. 6.1.2).

Table 3 Short-term requirements for periods longer than a half hour and shorter than the shift length in order to assess compliance with the limit values.

Category II.1		Category II.2		Category III	
Duration (h)	Level	Duration (h)	Level	Duration (h)	Level
≤ 0.5	2 limit value	≤ 0.5	5 limit value	≤ 0.5	10 limit value
1	1.3 limit value	1	3 limit value	1	5 limit value
≥ 2	1 limit value	1.5	2 limit value	2.5	2 limit value
		≥ 4	1 limit value	≥ 6	1 limit value
Permitted frequency of exposure peaks					
4 times per shift		Twice per shift		Once per shift	

The intervals between peaks with higher exposure shall be at least three times the short term reference time given in Table 1.

The short-term values for Categories I, IV and V are defined as momentary values. The instantaneous value for the concentration should not be exceeded at any time, and is therefore to be aimed at when designing the workplace. The TWA for periods of high exposure can be used to check compliance.

The short-term values for Categories II and III are defined as TWA. If the duration of the exposure peak is equal to or shorter than 30 minutes, the short-term value in Table 1 or 3 for half an hour is to be used. If the duration of the exposure peak is longer than 30 minutes, the lower level for the short term requirement from Table 3 is to be used. Linear interpolation for time intervals not given in the table is permitted.

If there a permanently assured compliance, there is no need to do routine monitoring.
Permanently assured compliance ('dauerhaft sichere Einhaltung') can be concluded:

- if a certain work process of substance criteria is fulfilled, or
- if there is permanent supervision and alarm if necessary and there are measures taken to ensure that no shift value can exceed the limit, or
- if the TWA shift values on a long term basis do not exceed a fourth of the limit. For limit values with a reference time of a year, half the shift value has to be used.

Even when there is no need for routine monitoring, because of permanently assured compliance, regular checking of the conditions having led to the decision may be necessary. This also implies a change in the level of a limit value.

If there is non-compliance of TWA or short-term requirements corrective measures should be taken to reduce exposure levels. Measurements and remedial action have to succeed each other until compliance can be concluded.

In [7] two methods are presented which can be used to decide on compliance on a statistical basis. Both statistical methods make certain assumptions on distribution and peaks of the shift averages. In both circumstances the days of monitoring have to be chosen at random. (For a discussion see 8.7.2).

A. As a first step the individual shift average (TWAi) is compared with the limit. If TWAi > MAK, non-compliance is the result. If TWAi ≤ MAK then the second step is taken.
The geometric mean is calculated:

$$GM = \sqrt[n]{TWA_1 \cdot TWA_2 \cdot \ldots \cdot TWA_n}$$

GM has to be divided by the MAK value of the substance in question

n	1	2	3	4	5	6
L	0.10	0.14	0.16	0.18	0.19	0.20
(GM/MAK)						

If the calculated value (GM/MAK) is under the limit L, the result is compliance and routine monitoring can start (6.1.2). If the calculated value is above L, more measurements have to be done. If too many measurements have to be performed, reduction of exposure should be considered.
If compliance is concluded from three or fewer measurements the working area analysis can be concluded with permanently assured compliance, when there is certainty from, e.g., the initial assessment, that the fluctuations of the shift values are small.

B. In order to be able to decide on compliance, at least three random measurements are needed.
The first step is the same as in A. If TWA_i > MAK, non-compliance is the result, if $TWA_i \leq$ MAK the second step is taken:
The TWA_i values are transformed into the logarithm of the quotient of the TWA_i and MAK. For these transformed values a mean and standard deviation by the n-1 method is calculated with standard statistical techniques. The quotient of mean and standard deviation is then compared with a limit L.

$$TWA_i^* = \ln (TWA_i/MAK)$$

$$\overline{twa} = \frac{1}{n} \sum_{i=1}^{n} TWA_i^*$$

$$s = \sqrt{\frac{\sum_{i=1}^{n} (TWA_i^* - \overline{twa})^2}{n-1}}$$

n	3	4	5	6	7	8	9	10
L	7.66	5.15	4.20	3.71	3.40	3.19	3.03	2.91

($\overline{twa}/s$)

If the calculated value is above the limit L, the conclusion is compliance, and routine monitoring can start. If the result of the calculation is less than L, more measurements or corrective measures have to be considered.
If compliance is concluded from three or fewer measurements, the working area analysis can be concluded with 'permanently assured compliance', when there is certainty from, e.g., the initial assessment that the fluctuations of the shift values are small.

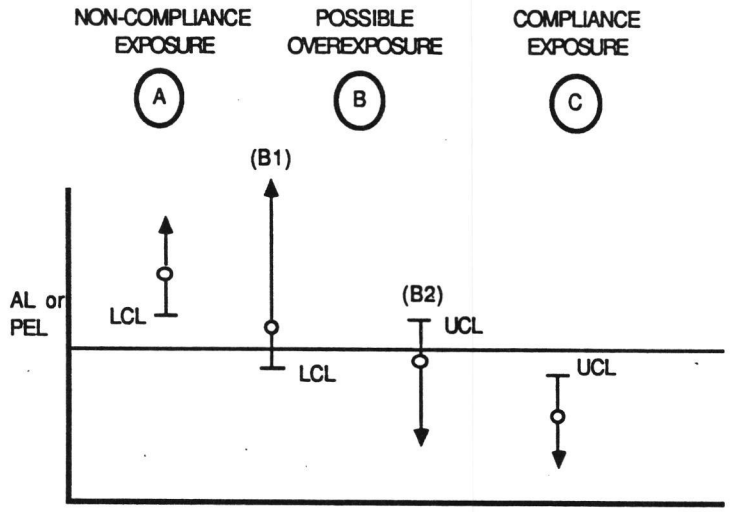
References [10] and [7] describe the calculation of TWA values for mixtures (see 5.6.2). The conclusion from this calculation is that there is compliance if the resulting index I is not more than 1. If I is greater than 1, there is non-compliance. According to [9] the conclusion of non-compliance has to be drawn if I exceeds 0.5. Because this last publication is a few years old, the figure 0.5 may not be correct at the moment.

5.7.3 United States of America

The methods presented for 8-h TWAs are based on the computation of confidence limits around a single exposure estimate.
The primary purpose is to estimate the uncertainty due to random errors of the sampling and analytical procedure (denoted by CV_t; see Section 2.3). Random errors are assumed to be normally distributed with a mean of zero and a relative standard deviation (CV_t). All procedures in the NIOSH manual use one-sided confidence limits chosen at the 95% confidence level.
CV_t is treated as a known quantity and the normal z-value, not the Student-t, is used.

The one-sided confidence limit (upper or lower limit, UCL or LCL) is used to classify exposures into one of three possible categories (Figure 5).

Although the manual describes the classification procedure in relation to compliance with an occupational standard, the same procedure should be used for compliance with other criteria such as the action level.



CLASSIFICATION SYSTEM FOR EMPLOYEE EXPOSURE TO CONTAMINANTS

	Classification	Definition	Statistical criterion
A.	Non-compliance exposure	There is 95% confidence (based on measurements) that a worker's exposure is above the standard.	LCL (at 95%) > STD
B.	Possible overexposure	Any individual who cannot be classified in A or C.	
C.	Compliance exposure	There is a 95% confidence (based on measurements) that a worker's exposure is below the standard.	UCL (at 95%) ≤ STD

Figure 5 Classification according to one sided confidence limits [24]

The employer uses the upper confidence limit (UCL) to demonstrate compliance. If the UCL is smaller than the AL, measurements can be terminated.

If the AL is within the UCL, there is possible overexposure. However, no final statistical statement can in this case be made, and more samples should be taken. If the exposure estimate is at, or above the AL

or PEL, follow-up measurements at a frequency given by the decision scheme (Figure 3) are required (Section 6.4.3).

The compliance officer uses the lower confidence limit (LCL) to demonstrate non-compliance in the same way as described above.

For full period consecutive samples, procedure for calculating the confidence limits are given for the case of uniform exposure during the work shift, and for the case of highly non-uniform exposure situations. For partial period consecutive samples, the employer or the compliance officer compute UCL or LCL respectively, for the 8-h TWA, using the criteria mentioned in Section 5.6.3.
Grab samples are treated assuming a log-normal distribution of the sampling results. Measurement errors are assumed to be negligible. The mean (m_l) and the standard deviation (s_l) of the log-transformed data, together with the number of samples, are plotted on a classification chart in order to classify the exposure. If the value of s_l is greater than 0.5 (GSD > 1.6), one or more measurements are relatively distant from the main body of the sample distribution. Additional measurements should be obtained for this employee.
The average exposure ($\bar{x}$) or arithmetic mean is estimated using the relation:

$$\bar{x} = \exp.\ (m_l + 1/2\ s_l^2)$$

When the number of grab samples is larger than 30, statistical analysis is performed assuming a normal distribution of the sampling results.
The NIOSH method for sampling a subgroup of a homogeneous risk population in order to identify the maximum risk employee(s) is so designed that there is a high probability of finding at least one employee with a high exposure. The exposure data are checked for compliance in the same way as full period or consecutive period samples are treated for a single employee.

For zoning strategies the data are analysed first by computing the GM, GSD and AM for each zone (assuming log-normal distribution).
If the averages are above the limit value at least one employee is exposed above that value.

An estimate can be made of the expected number of overexposed employees. If the averages are lower than the limit value, the probability of finding employees with overexposure is determined.

Measurements taken for compliance with ceiling limits are analysed using the following procedures (for sampling strategies, see Section 5.4.3).

- Predictable peak exposures

  The highest of all measurements ($n \geq 3$) is taken as a good estimate of the upper exposure for one work shift. The 95% upper confidence limit of this value is used to classify the exposure in the same way as full period or consecutive period sampling for an 8-h TWA. If the sample value exceeds the ceiling limit, the environment is declared unsafe. No follow-up strategies are given.

- Unpredictable peak exposures

  Sampled periods are treated as above. For unsampled periods the probability (p) of compliance with the limit value for any one unsampled period is tested. No confidence limits are calculated. A log-normal distribution is assumed. Measurement errors are considered to be negligible. The classification is performed as follows:

$p > 0.9$	classify as compliance;
$p < 0.1$	classify as non-compliance;
$0.1 \leq p \leq 0.9$	classify as possible overexposure, take more samples to make a decision.

6. ROUTINE MONITORING

6.1 Introduction

6.1.1 United Kingdom

Once the preliminary or detailed surveys have been completed and appropriate remedial action has been decided upon and is being implemented, further routine monitoring may be necessary. Here the emphasis is on longer term objectives, such as checking that control measures remain effective and that compliance with the appropriate exposure limits is likely to be maintained in the future. Useful information can also be obtained on trends or changes in patterns of exposure, so that action can be taken before excessive exposure occurs.

For the results of a routine sampling programme to be of real use it must be possible to compare consecutive sets of results. This implies that the methodology used for collecting the samples needs to be rigorously planned to ensure that the overall error can be estimated and that genuine changes in the exposure pattern can be recognised. Routine monitoring programmes that are not well designed can produce an apparently reassuring bulk of paperwork, but the real information content may be low and interpretation with any degree of confidence extremely difficult.

6.1.2 Federal Republic of Germany

After the conclusion is reached in the working area analysis (Arbeitsbereichanalyse) that there is compliance (and that there is no permanently assured compliance) step 4 in the working area analysis has to be taken. This means that the monitoring methods for the routine monitoring have to be recorded:

- sampling and analysis method;
- averaging time;
- sampling place or places;
- sampling duration;
- a method for the calculation of the results from the measured values;
- other guidance for the monitoring.

Step 4 completes the working area analysis and routine monitoring starts,
In order to be able to check the results of the analysis of the working area, and to identify changes in exposure using the control measurement system, the basic information and preliminary data should form the basis for establishing the measurement procedure for each measurement during routine monitoring. Such a measurement is always a programme of measurements over the length of a shift, the results of which must be compared with the MAK value.

The measurement procedure lays down the analytical method(s), the averaging time(s) the location(s) and time(s) of the measurements, the method for calculating the result from the reading(s), and further instructions on taking measurements.
For example, the shift average may be measured directly and compared with the MAK value. Another possibility is to take a number of separate measurements with a shorter averaging time during the shift and to use the readings to calculate the results, either by averaging or by other weighting methods suited to the exposure.

If the exposure is characterised by exposure peaks, these must also be recorded, in line with the short-term value requirements.

Before routine monitoring is performed, it is assumed that there is compliance. At the end of the working area analysis, a specific monitoring method is recorded. According to this scheme the routine monitoring has to take place at certain time intervals that depend on the airborne concentrations. The advice is given to start the first routine monitoring on completion of the working area analysis.
The use of a written monitoring scheme seems right, but in practice it is not, because changes in the process conditions or any other changes that may substantially influence the exposure automatically lead to a new working area analysis. Also a changing limit value leads to a new working area analysis. Because the whole process of assessment is completed and the analysis itself is recorded, this new WAA is not very time-consuming.
A second important aspect of a written monitoring scheme is that the uniformity of the sample collection guarantees that results of different routine monitoring excercises are easier to compare than when the sampling procedure has not been carefully recorded.

6.1.3 United States of America

With respect to the NIOSH scheme we consider routine monitoring all follow-up measurements for cases where in the non-routine monitoring stage employees or a group of employees have been measured and identified with an exposure ≥ AL.
If in the non-routine monitoring stage employees have been identified with exposures above the AL and below the PEL, the basic frequency of routine monitoring should be one measurement at least every two months. If in the non-routine monitoring stage or the routine monitoring stage, employees are identified with exposures above the PEL, the monitoring frequency should be raised to at least one measurement every month and immediate action is called for. Only when two consecutive measurements of one employee taken at least one week apart, show exposures < AL, can monitoring be terminated.
It should be noted that decisions whether to continue, increase or terminate measurements on an employee are based on only one or two (consecutive) samples. All previous exposure data are omitted from the decision making.

This section also discusses non-regulatory strategies with the purpose of estimating exposure distributions of target populations over a time period of more than one day [26].
The objective of such strategies is to detect unacceptable exposure situations and to identify substantial changes in exposure distributions.

6.2 Substances

6.2.1 United Kingdom

(a) Information on substances.
(b) Sampling equipment and analytical methods.
(c) personnel.

The same applies as stated in 5.2.1. From the fact that this section refers to routine monitoring, it also follows that the preceding matters have been identified during the initial assessment, and that some experience has been gained during the survey(s).

Static sampling can be carried out in the work areas to supplement personal sampling. This will provide information on the relationship between personal samples and the concentration of airborne contaminants at fixed points and will enable the role of static sampling in future air monitoring programmes to be determined. However, if static sampling is to be used instead of personal sampling, employers should be able to demonstrate that personal exposures are not higher than the concentrations at the static sampling locations in the work area in question or that the ratio of static to personal sampling results is fairly constant so that a reliable estimate of personal exposure can be made.

6.2.2 Federal Republic of Germany

(a) Information on substances.
(b) Sampling equipment and analytical methods.
(c) Personnel.

The same applies as stated in 5.2.2. From the fact that this section refers to routine monitoring, it also follows that the preceding matters have been identified during the initial assessment, and that experience has been gained during the survey(s).
In [7] reference is made to specialists (e.g. a safety specialist or measuring engineer) who collect the samples.

6.2.3 United States of America

The same applies as stated in 4.2.3.

6.3 Identification of factors affecting exposure

6.3.1 United Kingdom

In 5.3.1.1; 5.3.2.1; 5.3.3.1; 5.3.4.1 information is presented on these matters during the surveys.
As routine monitoring is designed to provide a rather different type of information from that obtained by preliminary or detailed surveys, if follows that the sampling strategies used may not be the same. A sensible selection should be made in relation to the particular circumstances of the workplace and the reliability of the information required.

The frequency of each cycle of monitoring will vary from, perhaps, once per month when 'high' exposure may occur to less than once per year when exposures are considered to be well controlled. The monitoring frequency may also need to be adjusted in the light of the health hazards, with a higher frequency indicated when dealing with particularly toxic or hazardous substances such as carcinogens.
The routine air monitoring programme should be reviewed in the light of experience, if any new processes are introduced, or if other changes occur that might affect the pattern and degree of exposure.

6.3.2 Federal Republic of Germany

In 5.3.1.2; 5.3.2.2; 5.3.3.2 and 5.3.4.2 the information on the identification of possible exposure with reference to processes and sources, working environment, work procedures and organisational aspects is presented.
A difference between routine monitoring and WAA is that when during routine monitoring respiratory protective equipment is used the monitoring is to be stopped, and the concentration is not taken into account for the calculation of a TWA.
In practice this means that (exceptional) tasks with high exposure (e.g. opening and filling of batches) still lead to a conclusion of compliance if personal respiratory protection is used. During monitoring no judgement is to be made whether the RPE was suitable and adequate.

6.3.3 United States of America

The same applies as mentioned in 4.2.2.3; 4.2.3.3 and 4.2.4.3.
The NIOSH decision scheme can only be disregarded when it is certain that no new processes or process changes which raise exposure levels will be introduced in future.

6.4 Population at risk

6.4.1 United Kingdom

During the preliminary or detailed survey the likely pattern of exposure has been assessed. During the routine monitoring the emphasis shifts to longer term objectives such as checking that the control

measures remain effective and that compliance with the appropriate exposure limits is likely to be maintained in the future.
The frequency of monitoring will vary (see 6.3.1).

The preliminary survey will enable the details of the routine monitoring programme to be established, such as deciding the number and location of sampling points (personal and static), the balance required between personal and static sampling where both methods are used, and the frequency at which subsequent routine monitoring should be carried out. Personal sampling on a routine basis should be carried out as for the preliminary survey. However, where the preliminary survey or other results show that there is a consistently satisfactory pattern of exposure to airborne contaminants, it may be appropriate to reduce the frequency at which sampling is carried out and/or the length of sampling time during routine sampling, so long as it covers a representative period.

Sufficient samples should be taken during routine monitoring to enable any major changes in exposure levels to be identified. Any individual results above the exposure limits should be carefully investigated and steps taken to reduce exposure to as low as is reasonably practicable and within the exposure limits. For groups, the results should be compared with the results of the preliminary survey and any other results from the same group. Abnormal results should be investigated further and appropriate corrective action taken.

Where exposure is intermittent, it is recommended that the sampling periods should be designed to coincide with specific operations so that satisfactory time-weighted averages for both the long term and short term exposures of work people can be calculated.

The routine air monitoring programme should be reviewed in the light of experience, if any new processes are introduced, or if other changes occur that might affect the pattern and degree of exposure.

6.4.2 Federal Republic of Germany

Because the monitoring scheme of the routine monitoring has to be recorded beforehand, no addition to 5.4.2 is necessary.

6.4.3 United States of America

In the NIOSH strategy the target population is defined in the non-routine monitoring phase (paragraph 5.4.3).
The results of the non-routine monitoring phase determine the frequency of the follow-up monitoring.
The monitoring frequency is the minimum legal requirement. More frequent measurements should be made based on professional judgement of the exposure situation.

For other than regulatory monitoring programmes the selection of an adequate frequency for monitoring should be based on [26]:

- Nature and degree of the health hazard.
- Ratio of the previous exposure levels to the limit value and possible trends in this ratio.
- Degree of variability in exposure seen in previous studies and trends over time.
- The variables affecting exposure levels (Section 4.2).
- Reliability of decision-making techniques used. (For an exposure estimation on basis of a log-normal probability plot, a minimum of 6-10 exposure data are generally required to make a rough estimate of the upper tail of the distribution. To obtain a statistical estimate with low uncertainty of the central 80% of the exposure distribution, 30-60 samples are necessary, but unusual behaviour in the 10% upper tail still cannot be determined confidently [32]).

NIOSH monitoring strategies for determination of compliance with ceiling limits on a single day are dealt with in Section 5.4.3. No information is given to assist the industrial hygienist in evaluating acute hazards over longer periods.

6.5 Check on results

6.5.1 United Kingdom

This section is analogous to Section 5.5.1.

6.5.2 Federal Republic of Germany

See Section 5.5.2.

6.5.3 United States of America

The adequacy of the log-normal distribution model can best be checked by plotting on logarithmic probability graph paper and visual judgement. A random sample of 6 to 10 measurements is needed as a minimum for a rough estimate of the exposure distribution [26]. Statistical tests for goodness of fit have the characteristic that the test will reject any practical data set if there is a sufficiently large number of samples, or will accept almost any set if there is a small number of samples.
For other checks on the results see also Section 5.5.3.

6.6 Calculation of TWA

6.6.1 United Kingdom

This section is analogous to 5.6.1.

6.6.2 Federal Republic of Germany

The calculation of TWA values for routine monitoring is nearly the same as for surveys (see 5.6.2). The only exception is the fact that concentrations during the use of RPE are not recorded, and not used for the calculation of the TWA.

6.6.3 United States of America

The same applies as mentioned in 5.6.3.

6.7 Interpretation

6.7.1 United Kingdom

Once the sampling and analysis have been completed, the results should be meticulously collected to make interpretation easier, so that the maximum possible amount of information is extracted. One figure for the exposure of one worker at one process on a specific day is rarely a reliable indicator in itself of the exposure of other workers on that or other days. Numerical results should be supported by and interpreted in the light of other information, such as measurements of ventilation, performance, or the observations by a competent person of

leak sources, work procedures etc. Results should, therefore, be tabulated and relevant ambient and operating conditions noted. The tables may also include a column to record what action if any is to be taken by whom and when.

If routine monitoring shows exposures to be below the limit but rising or not as low as is reasonably practicable, corrective action or planned improvements should be considered. If there is a significant increase in exposure with some exposures in excess of the limit, remedial action is appropriate. If, on the other hand, exposures are well below the limit and as low as is reasonably practicable, a low level of 'watchdog' routine monitoring could be appropriate.

The following practical guidelines are given for the interpretation of routine monitoring [1]:

Results	Action
All results	Check individual values, mean, 'range' etc. for reliability of compliance with exposure limit; consider need for corrective action.
Results significantly different from previous survey	Consider need for corrective action, detailed survey or revision of protocols (e.g. selection of groups, coverage of variations within groups, assessment of exposure cycles)

No specific statistical analysis of data from routine monitoring is recommended in the UK.

6.7.2 Federal Republic of Germany

The routine monitoring leads to the conclusion of non-compliance if a TWA is above the limit, or if a short term requirement is not satisfied.
The requirements are described in Tables 1 and 3, and have been dealt with in 5.7.2.

When there is a permanent surveillance of a limit with stationary equipment, there is compliance if from 20 successive TWA shift values at most 2 TWAs are above the limit. There is permanently assured compliance when measures which are to be taken at an alarm can guarantee that no TWA can exceed the limit.

If routine monitoring leads to the conclusion of non-compliance, a new WAA is necessary, during which remedial action should lead to such a reduction of exposure that compliance can be concluded. In principle it is permitted to conclude permanently assured compliance after one measurement under a quarter of the limit value. However, it is recommended [7] merely to conclude 'compliance' in such a case of one measurement. It is better to check if the conclusion 'permanently assured compliance' can be validated on more than one measurement.
Results between 1/4 MAK and MAK should lead to further measurements. If the TWAs of two measurements are not below 1/2 MAK, corrective action to reduce exposure should be considered.

The result of every routine measurement determines the maximum time interval until the next measurement. The monitoring frequency has to be at least once:
- every 64 weeks if the TWA is below a quarter of the limit;
- every 32 weeks if the TWA is more than a quarter but not more than half the limit;
- every 16 weeks if the TWA is more than half the limit but not above the limit.

Routine measurements have to be done under normal operational conditions. In certain circumstances this may mean that the time schedule has to be changed, in agreement with all who are responsible for health and safety at the workplace.

If the TWA is in the neighbourhood of the limit, corrective measures leading to reduction of exposure should be considered.

Compliance or non-compliance for mixtures can be decided on by the calculation of a mixture index I (see 5.6.2 and 5.7.2). During routine monitoring it is possible to use a certain compound as a 'tracer' for the whole mixture, in order to reduce the monitoring effort. Of course one must know enough of the local situation (WAA) to be able to ascer-

tain a certain constituent which can be considered representative for the mixture as a whole.
When such a 'tracer' is chosen all the people responsible for safety and health at a workplace should agree. Criteria for such a choice can be the toxicity of the substances found during the WAA, their share in the total concentration and analytical practicability.

6.7.3 United States of America

Statistical analysis and decision making in the NIOSH scheme are analogous to Section 5.7.3. The decision to increase, continue or terminate monitoring is based on compliance or non-compliance with two criteria, the AL and the PEL, of, at most, only two single measurements.

Techniques recommended in the technical appendices of the NIOSH manual for evaluating exposure distribution estimates (multi-day results) are:
- Control chart plotting.
- Probability plotting.
- Distribution fitting (a statistical technique to estimate one or more fractiles).

Control chart plotting is best done by plotting the exposure averages of an employee on semilog graph paper. Plotted data can be analysed for possible cycles or trends.

Probability plotting is actually only recommended for making preliminary judgements about the suitability of the log-normal model (Section 6.5.3).
Distribution fitting is recommended when decisions should be made about introduction of engineering controls. One of the actions to be taken, if exposures are found above the PEL, is to institute engineering controls.
The important question in this respect is whether the one-day exposure measurement truly reflects long term exposure. The following procedure is given.

A set of daily exposures (number and frequency not mentioned) representing a 'stable' exposure situation (to be checked by control chart

plotting) is used to calculate the probability of overexposure on the long term.
Assuming a log-normal distribution of exposure data, the proportion of days an employee will be overexposed is estimated. If this proportion is greater than 0.05 (5%) a strong indication exists that engineering controls should be implemented. The geometric mean (GM) is the test criterion.
In their later paper, Leidel and Busch [26] discuss more comprehensive techniques to evaluate long-term exposure.
Probability plotting can be extended by drawing a line representing the exposure limit in the graph.
The risk of overexposure can be estimated by the probability indicated at the intersection of the plotted exposure data and the line of the exposure limit. An additional feature can be the plotting of one- or two-sided tolerance limits around the distribution. A tolerance limit can be thought of as a confidence limit for designated fractiles of a distribution population (usually the 95th percentile). For instance, using the one-sided (95% confidence level) upper tolerance limit for the 95th percentile, one is able to estimate graphically the concentration below which one is 95% confident that 95% of the daily exposures will be.

Statistical (mathematical) techniques complementing the graphical techniques can also be used. The distribution parameters (GM and GSD) are estimated from random samples assuming a log-normal distribution. Consequently the best estimate for the proportion of the exposure distribution exceeding an exposure limit can be calculated. In addition tolerance limits at a desired level of confidence can be computed for the fractiles to indicate the uncertainty.
In the regulatory framework of the USA no legal decision making is possible for these strategies.
Decisions regarding the acceptability of a situation should be based on experience and competent professional judgement. Decisions should take account of [26]:
- The slope of the exposure distribution (or GSD).
- Health effects of the contaminant.
- Experience with similar situations.
- Knowledge of variables affecting the exposure levels.

For decision making the following qualitative terms are suggested [26]:

An 'acceptable' exposure distribution is one for which one is confident that almost all the exposures are less than the exposure limit.
A 'marginal' exposure distribution has a moderate proportion of exposures exceeding the exposure limit.
An 'unacceptable' exposure distribution has at least a substantial proportion of exposures exceeding the desired exposure limit.

In an 'acceptable' situation, low-level routine monitoring should be used as follow-up.
A 'marginal' situation calls for measurements aimed at adequate preventive measures.
While in an 'unacceptable' situation the actions would follow the same course as in the NIOSH scheme for exposures above the exposure limit.

No guidance is given for evaluating long term exposure to substances with ceiling limits.

7. REPORTS OF MONITORING DATA

7.1 United Kingdom

Results from air monitoring exercises should be recorded and retained as they provide information on the effectiveness of control procedures and may be useful for epidemiological studies.
Numerical results should be supported by and interpreted in the light of other information, such as measurements of ventilation performance or the observations by a competent person of leak sources, work procedures etc. Results should therefore be tabulated and relevant ambient and operating conditions noted. The tables may also include a column to record what action if any is to be taken by whom and when.

Appendix A demonstrates that in the UK measured values and calculated TWA values are treated as separate entities. The TWA values are calculated according to the procedure described in 5.6.1.
In 5.3.1.1, 5.3.2.1, 5.3.3.1 and 5.3.4.1 the different variables that are to be reported on a data form (Appendix A) are mentioned. Of course the information on processes and sources, working environment, work procedures and organisational aspects can also be summarised in a visit report. There is a restrictive tendency in summarising these data in a visit report, because mostly both the inspector and the FCG are aware of the specific situation in a certain workplace.
The monitoring procedure, date, sampling time and duration are all reported on in Appendix A.

In order to gain better access to the results of surveys, routine monitoring and visit reports HSE has established a National Exposure Data Base (NEDB). It contains information on exposure to toxic substances gathered from a whole range of workplaces in the UK. Input is all airborne sampling data plus additional detail concerning control measures gathered during visits to workplaces by HSE Specialist Hygiene Inspectors. The long-term aim is to input similar data from industry so that NEDB becomes a national focal point for information on exposure. The database will be used to improve the level and quality of exposure information available to standard-setting and advisory bodies. In addition to this prime use, NEDB is likely to become a major tool in input of exposure data to epidemiological studies. Such studies currently suffer from a lack of good-quality exposure data linked to particular processes or jobs. Because of the usefulness of such information both

nationally and internationally, it is expected that summary outputs in an anonymised form (with regard to specific workplaces) will in due course be directly accessible by subscribers.
The collection of information for NEDB was rationalised as a first step. A standard double-sided proforma (Appendix A) is now used to present airborne sampling data from all visits by Hygiene Inspectors. The proforma contains the basic information about the workplace visited and the substances to which exposure was sampled. Apart from individual sample details, such as process, job, sample period and sample results, the proforma contains the industry descriptor, cross-reference to other databases, and essentially qualifying information which ties up with the essentially numerical data (sample results).
The information collected on proformas as described above forms part of a visit report which is sent to the customer Inspectorate for further action as appropriate. Copies of the whole visit report arrive at the HQ Occupational Hygiene Group for further processing. Summaries of the visit report (Appendix B) are input to another data base called the Occupational Hygiene Visit Report Database (OHVR), and the contents of the proformas are input to the NEDB.

7.2 Federal Republic of Germany

In the guidance note [3] an obligation is laid down to record the WAA, and the process followed to accomplish a WAA and the routine monitoring data. The following has to be recorded:
- monitoring institution;
- a description of the WAA;
- measuring method;
- monitoring strategy;
- conditions at the workplace during the measurements;
- results;
- conclusion and actions.

(a) Working area analysis

The first record has to be one of the working area analysis, because this is the first element in the German approach. The official inspecting institute (Gewerbe Aufsicht) has to be able to form an independent opinion of the nature of the workplace, the risks of exposure and the accuracy of the conclusion from these records of the WAA. The employer can justify his actions with the WAA. Especially when the

conclusion is that there is permanently assured compliance, or when a risk is totally absent, a careful evaluation of all the steps in the process of arriving at this conclusion may be necessary in a later situation. When no routine monitoring is done, or when one bases the conclusions on an analogy argument, a careful description may be very useful. A more extensive elaboration of the different elements which should be included in the report of the working area analysis is presented in 4.2.1.2; 4.2.2.2; 4.2.3.2 and in 5.3.2.2.

(b) Routine monitoring

In [9] the most elaborate checklist is presented on the data for the routine monitoring. In Appendix C a proforma is given which is used extensively in practice.
The measurement record needs to present the name of the firm, the working area and the substance in question. The data, the sampling times (beginning/end) and duration. If it was a PAS or a stationary sample. The type and number of the pump, gasmeter, PAS-device, nature of the sampling device (absorption tube, filter, washing bottle) and filling material, the flow rate, and air velocity at the inlet. The different elements covering the working area and conditions are dealt with in detail in 5.3.2.2.

Computer databases are, of course, used in the German Federal Republic too. The companies have their own database management systems for recording and retrieving monitoring data. The database of BIA is particularly noteworthy, because it contains a huge amount of monitoring data. There are no plans to establish a kind of central database of all measurements done by industry, government or social security institutions.

7.3 United States of America

Under the OSHA regulations (29 CRF Sect. 1910.20) the employer is required to make a written determination (initial assessment), report (Section 4.5) and to keep an accurate record of all measurements taken to determine employees' exposure to a particular regulated substance. This latter record shall include as a minimum:
- The data of the measurement.
- Operations involving exposure to the substance being monitored.
- Operating conditions and control methods.

- Sampling and analytical methods used and evidence of their accuracy, including the method results, and date of calibration of sampling equipment.
- Number, duration, and results of samples taken.
- Name, social security number, and exposure of the employee monitored.

An example of the type of information that should be recorded for each measurement is shown in Appendix D of this report.
The record must be kept for at least 30 years.

Measurement data from OSHA inspections are computerised according to industrial activities (standard industrial code) and chemical substances. It is anticipated to add also occupational titles.

8. MONITORING IN PRACTICE, PRACTICAL CONSTRAINTS AND POSSIBLE IMPROVEMENTS

8.1 General remarks

8.1.1 United Kingdom

Though the monitoring strategy presented in EH-42 is very flexible, there may still be a difference between the advice given in the guidance note and the implication in a practical situation. The guidance note received favourable comments when it was first published in 1984, and seems to be compatible with practices in industry. The reason for reconsidering the text of EH-42 is not to make any big changes in the basic philosophy, but to bring it into line with the new COSHH regulations and make some minor alterations in the wording.

The aim of the guidance note is to ensure a proper assessment of the conditions. In order to achieve this, helpful practical suggestions are presented. However, these rules of thumb need to be applied with caution. They may not be of universal application or need to be modified to take account of other factors. In this area no clear cut rules can be given, and one has to rely on the best professional judgement to choose the right actions.

Another general remark on the UK monitoring strategies is that they are addressed to airborne contaminants, and other routes of exposure are not explicitly covered. The same applies to the monitoring strategies in the FRG and USA.

The number of measurements done by the HSE according to the monitoring strategies of EH-42 in the whole of the UK is about 800 a year.
The number of measurements done by industry is not known, and most probably will be a multiple of the number done by the HSE. However great this effort is, it still will not be enough to cover all the monitoring recommended in the guidance note.

8.1.2 Federal Republic of Germany

Monitoring strategies as described above are all very recent. The legal obligation to monitor the workplace has only just come into force. This means that a whole operation of monitoring throughout industry is

starting, and that sufficient experience of monitoring in the new setting, particularly for smaller firms, is lacking at the moment. In a few years this experience will have been built up.

Another recent change in the German system of monitoring strategies is that the yearly average concentrations for TRK values have been abandoned in favour of a shift TWA with a reference time of 8 hours. In the CEFIC document on monitoring strategies [12], the concept of these very long term averages has been translated into a system which allows larger excursions of daily exposures above the limit than the present German system. Some people in the FRG would prefer the Cefic system.

One problem with the German monitoring strategy is the question what exactly is a 'working area' (Arbeitsbereich)? When the whole mix of working environment and work procedures is included, every different mix leads to another 'working area' and WAA. It not only means that there are as many working areas as employees but also that may be even every day a new working area has to be defined.
This approach is of course impractical, and is not used in practice. Mostly some kind of production unit is chosen as a field for the WAA. A second reason for this approach is that in industry production workers nowadays have to be flexible and job rotation between people working in one production unit is common. This means that most production workers, (skilled operators, semi- and unskilled workers) and odd groups as maintenance workers and foremen are covered in one and the same WAA.
People not covered are employees whose workplace systematically is not in that specific working area. One could think of subcontractors, construction workers, more specialised maintenance and cleaning personnel, and electricians or mechanics.
In German industry there is a strong tending to exclude from the WAA all persons spending less than, e.g., 10% of their time in the working area.
Practicality is a strong argument in favour of such an approach. Some caution has to be advised if the bulk of the exposure takes placedur-ing the odd operations mentioned. If the people performing those hazardous operations are properly protected, including them in the WAA would be over cautious.

How the German approach works out in practice for the prevention of harmful effects on health depends on the nature of the work process,

the substances and the knowledge and experience one had in estimating the exposure and taking precautions during the hazardous operations. When a WAA is done by inexperienced personnel, the results may reassuring without being trustworthy.
For mobile workplaces, e.g. in the construction industry, an application of the guidance note [3] is as a rule impossible [16]. A high priority should be given to the development of requirements for certain substances or work procedures which ensure compliance with the limit for these situations.

Another practical complication that is not easily covered, unless different working areas are discerned, is the possible difference between day and night shifts at the same production unit.

It should further be remarked that the FRG puts less emphasis on personal sampling than do the UK and USA. This difference is more a matter of judgement than of principle.
The UK argument is that individual exposure cannot be easily related to a stationary concentration at a certain place because people tend to move about during a working day and, perhaps more important, during their activities sometimes have to come very close to a source. For this reason personal exposures tend to be higher than stationary measurements during the same operations and in the same working area.
The FRG argument is that, when sources are controlled, a few stationary measurements near the original source can confirm that exposure of any significance can be excluded. In those cases personal exposures tend to be lower than the stationary measurements.
Both arguments may be true and both approaches may be useful in practice. Personal sampling gives an idea of the extent of the problem. A careful search for the sources (which could be either processes or work procedures) is necessary to control the problem. Once exposure has been reduced and brought under control, personal monitoring can be used for a regular check-up. If the number of sources is so small that they can be covered by a programme of stationary monitoring, this approach may suffice.

An analogous argument can be brought forward for the 'worst case' strategy. There are certain grounds for favouring of a concentration of effort on worst cases, and other grounds for favouring an approach that provides an estimate of the representative exposure. The use of either is a matter of judgement.

8.1.3 United States of America

The NIOSH manual describes a regulatory screening strategy for estimating and classifying exposures of individual employees on a single day. It addresses only airborne substances and other routes of exposure are not explicitely covered.
The NIOSH scheme, applied literally, does not determine or account for variability in exposure actually encountered.
The representativeness of a sample for the long-term exposure should be demonstrated. However, no guidelines are given on how to verify this.

Day-to-day variability of exposure is more or less accounted for by using an action level as a cutt-off for screening single day exposures.
The rationale of using an action level is to screen exposures so that there is a probability of 5% that 5% of the actual daily exposures will exceed the limit value (PEL) to which the action level (AL) is linked* .

Leidel et al. [25] demonstrated that the AL to achieve this premise is a function of the day to day variability (or the GSD) of the exposure levels. However, the regulatory AL was for practical reasons fixed at 50% of the limit value. This AL is keyed to a GSD of 1.22.
In fact it is assumed that all workplaces can be characterised by a single 'typical' exposure variability. As a matter of fact, higher GSDs require lower ALs. A GSD of 2.0 requires an AL of 11.5% of the exposure limit.
Tuggle [33] analysed the NIOSH scheme and concluded that as exposure variability increases, the decision scheme assumes an increasing probability of incorrect decisions to terminate monitoring for environments with high exposure risks where monitoring should definitely be continued or even increased.
On the other hand, if ALs are made dependent on GSD, the decision scheme may tend to be too conservative (incorrect decisions to continue or increase monitoring) [34, 35]. Moreover in practice one will

* Note that a required assumption for the application of an action level is that the PEL is sufficiently protective.

not have enough samples to determine a GSD. A compromise could be to lower the AL to 25% of the PEL, as in the CEFIC sampling strategy [12].

The ultimate weak point of the NIOSH strategy may be that it bases important decisions on relatively small amounts of data without considering the previous data. The great day to day variability suggests that compliance outcomes based on one or two exposure estimates may have little to do with the degree of chronic hazard.

Since OSHA interprets the limit values as absolute values, never to be exceeded on any day, another sticky problem is created.
In view of exposure variability, it can never be shown that the exposures are always under the limit value.
Rappaport [36] and Rock [35] have demonstrated that sample size is the major determinant of compliance outcome in the NIOSH scheme.
In other words, the more one samples, the higher the probability of some TWA values being out of compliance. So the industrial hygienist is placed in the situation of having to choose between a monitoring strategy that adequately defines long-term hazards (which requires relatively many measurements) and one which maximises the probability of compliance (which occurs when a minimum of samples is collected).
By enforcing the limit value in terms of parameters of the cumulative exposure distribution (GM and/or GSD) or a point estimate (e.g. 95th percentile) more incentive for monitoring is present, since confidence limits surrounding the parameters will become narrower with increasing sample size (see also Section 8.7.3).This becomes especially important for declaring compliance when the mean exposure approaches the exposure limit [36].

Although the NIOSH manual provides guidance for determining compliance with ceiling limits, it never explicitly states that the decision scheme is also applicable to acute hazards. Anyhow the sample size and the frequency of sampling seem to low to prevent acute hazards. The NIOSH manual departs to some extent from the concept of absolute ceiling limits by suggesting that some acceptable fractile of the distribution of unmeasured exposures may exceed the limit. However, it does not state that it would be acceptable for some fractile of the distribution of all exposures to exceed the limit.
Again, the use of a limiting distribution with its 95th percentile set at the ceiling limit might solve this problem [27, 38]. That is, expo-

sures should not be allowed to exceed the limit value more than 5% of the time. The slope of the limiting distribution (or the GSD) should be chosen with a view to the severity of the toxic effect. Rappaport [37] demonstrates that this approach in most cases requires fewer samples relative to the distribution-free technique for selecting the number of random samples recommended by NIOSH for situations where maximum peak exposures cannot be predicted.

Obviously, these approaches require major changes in the enforcement of occupational standards. Allowing some overexposure with respect to short-term exposure limits (STELs) implicitly assumes that the STELs have appropriate safety factors, as is generally the case [37]. If the 8-h TWA is allowed to exceed the limit value, the acute effects of the chemical must be also considered.

Some 'in-house' sampling strategies allow a small fractile of the long-term exposure distribution to be in excess of the limit value [39, 40, 41]. In practice there is a great need in the USA for recommended strategies and decision schemes for the interpretation of populations of daily exposures.

8.2 Substances

8.2.1 United Kingdom

(a) Information on substances

The list of occupational exposure limits [2] contains about 500 substances. There have been 45 revisions of/or additions to the 1987 edition, and the Advisory Committee on Toxic Substances has advised HSE to adapt 32 changes or new additions in the 1988 edition of the guidance note EH-40.
If indicated by initial assessment, surveys should be conducted on the setting of a new exposure limit or revised action level [1]. In most workplaces there is exposure to different substances during a workshift. This means that a frequent revision of initial assessments and surveys is necessary in the workplaces in the UK.

The short-term (10-minute) TWA limits are not strictly enforced in industry. For the HSE, these 10-minute TWA values are convenient because they are more readily enforceable.

Some industries have 'in-house' limits if there is no limit in EH-42. ICI, for instance, handles about 7000 substances a year on a basis of more than a ton. For 250 of these, there are special 'in-house' limits.
The basic philosophy on exposure of mixtures has shifted during the past years. At first it was assumed that combined exposure should be considered additive, unless it could be shown to be independent. At the moment it will be supposed independent unless it is shown to be additive. Synergistic combinations are thought to be few in number.

(c) Personnel

It is clear to all people who have been consulted for this study that the guidance note EH-42 is not directed at laymen and is not intended to be a monitoring manual.

8.2.2 Federal Republic of Germany

(a) Information on substances

The list of occupational exposure limits [4, 11] contains about 400 substances. There have been 25 revisions of/or additions to the 1986 edition, and the German MAK commission is evaluating 120 substances in order to decide on a revision or addition.

In the FRG it is advised to reconsider the WAA after a change in the limit. As there is exposure to different substances in most workplaces during the workshift, a frequent revision of initial assessments and surveys is necessary in the workplace.

A survey of the chemical industries in Germany has shown that there are about 4500-4600 substances which are handled in quantities exceeding 10 tons a year. For most of these substances there are no limits, though some larger industries sometimes have a system of 'in-house limits'.

According to some people who are monitoring in practice, the short-term requirements (see 4.1.2 and 5.7.2) with requirements for the level, frequency, and the time interval between peaks for five different groups of substances can be met. One way of meeting the short-term re-

quirements in practice is prescribing the use of RPE during peak exposure (e.g. cleaning, opening of a vessel, sampling from a batch process). If RPE is used, the concentrations are not included in the measurement and, as a consequence, short-term limits are complied with.
Others state that this system of short-term requirements is too complicated and not enforcible, and would like to make the system less complex. They argue that the system of short-term requirements has been devised more from a toxicological point of view than with practical enforcibility in mind. Of course, they want to retain some short-term requirements, and do not want to drop the approach altogether.
Still others argue that the system of short-term requirements has its value, but has to be seen in perspective. First of all, compliance with the TWA has to be ensured. When this is accomplished, compliance with the short term requirements has to follow as a second step. Though this view is very practical, it is not correct from a legal point of view.

According to the Gefstoff V., the manufacturer, importer or supplier has to furnish the necessary data on health effects and safe handling of substances at the request of a user.

(b) Sampling equipment and analytical methods

The level of uncertainty calculated as an integral error from all systematic and incidental errors should not exceed 30%. This is quite a strict requirement, especially when personal sampling is considered of substances with a low limit value and a complicated analytical method (e.g. respirable quartz dust). There are two solutions to this problem.
The first is that instead of personal samples, stationary sampling equipment is used. This means that a larger volume of air is sampled with larger pumps, and consequently a smaller error. The personal exposure is, of course, more difficult to ascertain in that case.
The second solution is to do a new WAA every 64 weeks, and to use the best techniques available to make an estimate of the exposure.

A more realistic approach in the opinion of the authors would be to demand a high degree of accuracy depending on sampling equipment and analytical methods. This accuracy can differ from one substance to another. But it can take into consideration the evolution of analytical

methods. This approach is adopted in OSHA's 'new' occupational hygiene standards (Section 4.1.3).

8.2.3 United States of America

(a) Information on substances

The code of Federal Regulations 29 CRF Sect. 1910-1000 ('adopted TLV standards') establishes permissible exposure limits for about 400 chemical substances. Additionally some 40 substances are regulated in individual 'new' standards (29 CRF Sect. 1910-1001 to 1046). Short-term limit values are usually associated with solvents.
For all other non-regulated substances, the material safety data sheets (see Section 4.1.3) list only scant toxicological information and usually one must review data on toxicology, and medical or epidemiological evidence to determine the need for exposure measurements. Prediction of chemical toxicity on basis of structure/activity relationships may also be used. Some industries have 'in-house' procedures to assess risk potential through priorisation of chemical substances [39, 42].
The need for exposure measurements is focused on the highest degree of risk.

(b) Sampling equipment and analytical method

The NIOSH strategy classifies exposures by considering one-sided confidence limits based on random errors of measurement (CV_t).
For the user of the manual, the most difficult part is to determine accurate CV_ts for his sampling and analytical method.
The NIOSH manual of analytical methods [27] mentions CV_t values which are actually lower bounds attainable only with extensive quality control programmes. Moreover, it is assumed that sampling and analytical methods are unbiased, which will certainly not be true in practice.
Since the random errors of the sampling procedure are set at an constant value of 5% in the assessment of the CV_t [28], it is no more true that CV_t is independent of concentration, an assumption made in calculating the confidence limits around an measurement value.

Area monitoring is only allowed when it can be demonstrated that the results are comparable to personal sampling.

For exposure distribution monitoring surveys (long term hazard control) there is a tendency to monitor the minimum required number of exposures via personal sampling and to conduct more extensive investigations via area monitoring.
This allows insight to be gained into the degree of exposure and the sources responsible without documenting excursions above the permissible exposure limit [36].

(c) Personnel

The manual is written for industrial hygienists. The initial assessment largely calls on professional judgement.
On the other hand, the statistical protocols are designed in such a way that a minimum of professional judgement is required, leaving the user little freedom of interpretation. The statistical procedures are written for non-statisticians. Some of the procedures are even simplified into black-box approaches (e.g. monograms). Nevertheless users in the field have considerable difficulty in applying the statistical protocols. In the view of many practising hygienists in the United States of America, experience and competent judgement is the best way to proceed.
Another complaint is that the manual is too much written as a textbook, and that it fails to cover the actual situations encountered in practice.

8.3 Identification of possible exposure

8.3.1 United Kingdom

Apart from the recommendation of reconsidering the exposure at the setting of new limits (8.2.1) there is the same recommendation on the start-up of a new process or when there has been a substantial change in the process, operations or control measures.
The questions is what is a new process? What criteria can be used to answer this question?
Best professional judgement is the most likely answer to get in the UK. Naturally this depends to a large extent on the constancy of a certain process or working environment. For some continuous production processes for the manufacture of a bulk product under strictly defined conditions, this may be the case for quite a number of years. Process life may be 7 years. When processes change much faster (when e.g a

factory does not employ a bulk process) process lifetime may be somewhat shorter, ranging from a few years to a few months. Especially when batch processes are involved, process life may be short.
This means, in principle, that initial assessments and, if appropriate, surveys, need to be conducted quite often.

The working environment may also have a major influence on the exposures. This can be the case when concentrations depend on wind speed, or when concentrations are influenced by LEV as, for instance, in welding operations, where a difference of a few decimetres in the position of a hood, can change exposure levels by a factor of ten.
There are also many work operations, which by nature of the work, are often done at different workplaces, e.g. painting, maintenance, cleaning, contracting or construction work. For these operations no really satisfactory strategy has yet been devised.

A way of limiting the number of samples is to use a static sample, which can be considered to give a good approximation of personal exposures, or which could be used as a tracer. This leads to a kind of quality control on the level of working conditions, and should give a clear picture of whether a plant is performing badly or is complying with the law. In accordance with industry procedures on quality control a set of action levels could be used. These may also assist in monitoring operational control when they are used as levels at which corrective action is necessary in order to ensure that exposure will remain within the relevant exposure limits. This may also be prudent if there is uncertainty as to the accuracy or reliability of measured exposures and will be necessary if the exposure pattern is highly variable.

Not only the working environment, but also the work procedures have a marked influence on the personal exposure of employees. The problem is to find out which work procedures must be considered to pose the greatest risk, or must be considered the 'worst case'. Especially for the evaluation of 10-minute TWA values a thorough knowledge of the work processes and work procedures involved is essential. General criteria for discovering 'worst case' situations cannot be given and recourse must be taken to best professional judgement. For quite a number of situations a quick visual inspection and a talk with the employees leads to a choice of people (and places) to be monitored.

This visual inspection also shows if the situation is obviously not acceptable because of e.g. bad maintenance.

The concept of action or intervention level is also important for the organisational aspects. It can be used to set a level below the exposure limit so that once a significant upward trend in the average exposure level is detected there is time to remedy any plant defects before any individual exposures exceed the limit. The plant response time (i.e. the time taken to implement corrective measures) may range from a few minutes to several months. The longer the response time and the greater the variability of the data, the lower will be the intervention level. This response time can be illustrated by a careful book-keeping of the planned remedial actions, and of who does what and when.

8.3.2 Federal Republic of Germany

In 8.3.1, the section concerning the UK, there has been some elaboration on the necessity of conducting a new initial assessment on the start-up of a new process, or when there has been a substantial change in the existing process. In the FRG this is restricted to situations that have a considerable effect on exposure. An analogous question arises as in the UK: what is a considerable effect on exposure? What criteria are to be used to answer this question?
The changes in process life time will most probably be similar in the FRG and in the UK, for the two countries are also EC partners.

For the working environment, the reader is also referred to 8.3.1, because the situation in the FRG is similar to that in the UK.
In [18] a comparison is made of short-term and 4-hour measurements. The outcome of both methods is similar, though the requirements (number of samples) of Table 2 are not met.

8.3.3 United States of America

The NIOSH manual provides little guidance for making the initial assessment (written exposure determination). It is treated as a means of assessing exposure levels without actually measuring. Although it is stated that a competent, well-informed person should make this assessment, the frailties of professional judgement could lead to the wrong decision, viz. that no monitoring is required. An improvement

would be the introduction of at least some personal sampling and/or source monitoring in this phase.
Since the determination is made for each situation (process or operation) where a (regulated) substance is used, the primary focus may be on job related exposures. Task-related exposures (e.g. maintenance personnel) with multiple exposures and non-fixed work stations may escape attention. Moreover, additive effects of multiple exposure are not explicitly considered.
Some 'in-house' strategies estimate hazard from each job-chemical combination [39].

A new written determination must be made whenever there is a change in production, process or control measures that could result in an increase in exposures to a regulated substance. However, anticipated changes can be covered in the original written determination, excluding the need for a reassessment [24].

It is particularly important for all factors affecting exposures to be considered with a forward look in mind, so that allowance can be made for the lag of time inherent in altering work procedures or conditions, if adverse health effects are anticipated.

8.4 Population at risk

8.4.1 United Kingdom

In 4.4, 5.4 and 5.5 as much as is necessary has been said in the selection of the population and the check afterwards to see if the right choice has been made.
One rule of thumb embodies the criterion that no individual exposure should be below half or above twice the mean group exposure. This implies that the value of the GSD of that group is 1.97 or lower.
Since many jobs in a factory involve higher GSDs, it follows that several groups have to be distinguished instead of just one. This complicates matters when measurements over a few shifts are done on one employee doing the same job on different days and his exposure has a GSD of more than 1.97, so that he is to be classified into different exposure groups.

The different work patterns are dealt with in 8.3.1. Partly this leads to different population groups. Workers from e.g. subcontractors, or

temporary workers do not constitute special risk categories. They are supposed to be covered by the standing regulations.

An appendix to EH-42 [1] presents some information on the routine monitoring of selected groups.
Typical group sizes may range from 10 to 50 workers. Once the groups have been selected, biases can be reduced by 'statistical sampling' i.e. selecting at random a number of members of a group as a representative sample for the purpose of each trial in the air-monitoring programme. It should be stressed that professional judgement is required when deciding on sample size, particularly when small groups are concerned. However, as a general rule, sampling should be carried out for at least one employee in 10 in a properly selected homogeneous group unless a smaller proportion can be justified from statistical or other considerations. The frequency at which trials should be made and the number of group members selected for monitoring, will depend on how accurate the estimates of the distribution parameters such as the mean and variance need to be, on how close to the exposure limit the plant is being operated, and on the rate of change of the contaminant concentration in air and the significance of the prevailing exposure levels.

At large chemical firm in the UK uses stratified random monitoring in, which workers are selected in alphabetical order. Mostly group sizes during a survey are so small that the whole group is monitored during a typical day of field work. This previous restriction in group size can be admissible, because there is previous knowledge of the processes, work procedures and exposure patterns. Quite often one is only interested in a certain department of a workplace.

The HSW Act applies to all employees, implying that a group considered to be exposed has to be monitored in its entirety. For the people who are not monitored one has to be certain to be able to exclude overexposure. These requirements demand a thorough knowledge of exposure patterns. Such knowledge can only be derived from a great number of measurements.
The practical situation in the UK seems to differ from the fundamental requirements.

8.4.2 Federal Republic of Germany

The population at risk is covered by the working area analysis. The emphasis is on the working area and not on an individual working in such an area, who may belong to a higher risk group. There is much less emphasis on personal sampling than in the UK.
As a rule of thumb a minimum of three measurements is taken for a working area analysis in a large industry in Germany. These measurements cover some 10-20% of the people working in that area.
No specific requirements are given in the guidance note [3].
Though working area analysis seems a practical and good way of making a first assessment, and after the evaluation and if necessary control of sources a few carefully chosen samples may suffice to verify compliance on a regular basis once the situation has become known, a scrupulous assessment of a working area with more attention for personal exposure and especially the higher risk groups seems appropriate to the authors as an indispensable stage somewhere between the first assessment and the routine monitoring.

A careful check on the short term requirements, if they are to be evaluated scrupulously, will demand many personal and material resources. A way of overcoming these difficulties is to prescribe a lavish use of RPE during possible peak exposures. Because of operational difficulties it will be most probable that this does not lead to a solution that is more than (a theoretical) compliance with regulations.

The cost of a working area analysis and (initial) survey of a working unit of about 60 persons and 10 different chemicals may be estimated at about DM 30,000. A possible range is DM 10,000 to 60,000. For the routine measurements an amount of DM 5,000 may be a fair guess. As a rule of thumb the yearly cost of routine monitoring is 10-20% of the cost of the working area analysis. Charges of course depend to a large extent on the cost of the analysis.

The calculation example in [16] itself does not convince to the authors. In a situation where 3 kg of a glue is used per shift with 25% of toluene in a workplace of 100 m^3 and an air change rate of 4 times/hour a simple calculation leads to a toluene concentration of 234 $mg.m^{-3}$. Because of the higher density of toluene compared to air and the limit of 375 $mg.m^{-3}$, the conclusion is compliance.

For the authors this conclusion would not be justified without personal exposure measurements. A change of a factor of two in the air change rate, which is not a big change in practice, could lead to a decision of non-compliance. In practice, situations of even mixing are not very common, and a cautious use of calculations would be prudent. If only calculations are used to determine compliance in order to be able to conclude the WAA, the routine monitoring should start immediately afterwards, and justification by measurements is automatically ensured.

8.4.3 United States of America

In order to minimise the burden of sampling, the NIOSH scheme recommends a two step procedure.

1. First select the employee(s) who may have the highest exposure and take one sample.
2. If the exposure of the maximum risk employee is ≥ AL, all employees possibly exposed to concentrations ≥ AL must be measured and identified. If the exposure of the maximum risk employee is < AL, there is no need for further measurements.

The selection of the maximum risk employee(s) (step one) is open to errors of judgement. A wrong selection is the more serious because only one representative exposure measurement is required for deciding whether follow-up monitoring (more employees, more days) is required.
To account for exposure variability, Tuggle [33] suggested that in step one at least two consecutive exposure estimates below the AL are required to make decisions. Corn [43] recommends that in any event a minimum of three samples should be taken before any statement of results is made. If the results of the measurements exceed a 25% spread, additional samples should be obtained.
Another approach for selecting the maximum risk employee, which is less prone to errors of judgement, is to sample a subgroup of potentially (high) exposed employees.
The advantage of this technique is that it offers additional insight into the between-worker variation, and so may help in decision making. When the selection of the maximum risk employee cannot be done with reasonable certainty, the NIOSH manual recommends the use of a distribution-free technique to estimate the size of a subgroup from a homogeneous risk group, so that there is a high probability that the subgroup will contain at least one worker with high exposure.

A distribution-free technique requires no assumptions on the actual distribution. However, the method is rather inefficient for small populations ($N < 20$). An alternative could be to assume a log-normal distribution of between-worker exposures.

Corn [43] suggests, in the absence of any sampling information, the use of a GSD of 2.2 to 2.5 to estimate the number of workers to be sampled in his zoning strategy. This approach can sometimes be more efficient than the distribution-free technique, but needs careful checks of the results.

Since in the second step the NIOSH scheme requires that all employees with exposures $\geq$ AL shall be identified once the maximum risk employee's exposure is $\geq$ AL, procedures for sampling subgroups from a homogeneous target population cannot be used.
Neither the AM nor the GM of a target population is a suitable indicator of an individual exposure, because the population average can significantly underestimate high exposures. Unless the group GSD is a minimum (GSD < 1.15), which is very unlikely, there is always a probability that one (unidentified) employee consistently has an exposure in the upper tail of the distribution above the AL.

When it is concluded that subsequent routine monitoring is necessary, the NIOSH scheme recommends a basic frequency of one sample every two months. However, monitoring can be terminated once two consecutive measurements are < AL. Corn [43] suggests the following monitoring frequencies (Table 4).

Table 4 Suggested monitoring frequencies for routine monitoring [43]

Situation	Sampling frequency (months)
Control system confidence low	3
Exposure level not far below the action level	3
Chemical a serious systemic poison	3
Odour threshold above the level of the hygienic standard	3
Control system confidence fair	6
Exposure level more than half the action level	6
Chemical a moderate systemic poison	6
Odour threshold and irritation level above the level of the hygienic standard	6
Control system confidence good	12
Exposure level less than half the action level	12
Chemical a simple upper respiratory irritant	12
Odour threshold well below the level of the hygienic standard	12

If inferences with a low uncertainty are to be made on the exposure distribution of a single employee (or a target population) a minimum number of 6-10 exposure estimates, randomly taken, are generally required [26].

As regards sampling duration on a single day, the NIOSH manual leaves the user much freedom in selecting a sampling strategy for estimating a 8-h TWA.
In practice the 'full period single sample' or the 'full period consecutive samples' is used.

For substances with acute hazards the sampling duration should cover the full period of the short term limit value. For those cases where no time period is assigned to the limit value (some of OSHA's adopted TLVs) no guidance is provided. Roach [44] suggested that sample duration (t) should be short relative to the biological half time (T). He concluded that as long as $t \leq 0.3 * T$ and the total dose during the interval is < 90% of its tolerable maximum there should be no undue risk to health. T values are not generally available for most acute toxic agents [45].
One solution would be to use direct-reading instruments. However, as real-time monitoring is used, the measured concentrations are less dampened relative to methods that average over longer periods [46].

Thus short sample durations effectively increase the highest concentration measured.
This has important implications to compliance monitoring, since ceiling values are usually interpreted as values never to be exceeded. In follow-up studies this point needs special attention.

In the NIOSH scheme the duration of a routine monitoring program is determined by the criterion that two consecutive measurements taken at least one week apart are both less than the regulatory action level.
Since exposure variability is only marginally accounted for in this way a better strategy would be to utilize all data previously collected for making a decision whether to terminate or continue monitoring. For non-regulatory routine monitoring Tuggle [14] proposed a statistical/graphical technique which takes account of all measurement data for decision making (see Section 8.7.3).

8.5 Check on results

8.5.1 United Kingdom

This has been discussed in 8.4.1 already.

8.5.2 Federal Republic of Germany

There is no special guidance on how to check on the results of measurements. That is a pity because of the nature of the WAA and the grouping together of different tasks deviations in concentrations may be expected.

In one of the bigger German firms the exposure of e.g. acrylonnytrile leads to a GSD between 1.6 and 7. This means there is a reasonable amount of fluctuation of exposure. From the experience of the authors with situations in Dutch industry such a range of GSD is often encountered.
To the authors a certain amount of grouping together of similar exposures into one WAA seems advisable. For when there is a certain limit to the fluctuations which are acceptable for a 'group' or WAA the chance of a misclassification and an injustified conclusion of compliance will be reduced.

8.5.3 United States of America

Inherent to the statistical analysis of multi-day or multiworker exposure data is the assumption of a distribution model. Although generally the log-normal distribution model is chosen, its appropriateness is seldom critically examined. In Section 6.5.3 a plotting technique to qualitatively check the distribution model is mentioned. In Appendix I of the NIOSH manual [24], some possible results and their interpretations are presented. In general practice other distributions occur. Reference [26] provides guidance on how to treat 3-parameter log-normal distributions. This type of distribution is usually due to a constant background concentration in a workplace.
Multimodal distributions point to a mixture of two or more log-normal distributions. One should try to reclassify the data into two or more distributions by examining the variables affecting the concentrations (see Section 4.2.1). Even if one decides that the log-normal model is appropriate, the problem remains that one still faces on unknown risks of incorrect decisions for the higher percentiles, particularly when limited sample sizes are available.

If no distribution model can be assumed, distribution-free methods have to be used. However, these methods require sample sizes substantially larger with respect to the log-normal model in order to achieve the same statistical power.

Another point to keep in mind is that statistical techniques require true independence of samples. Variability in occupational environments is not always random but is often influenced by time-dependent non-random factors [17, 44]. The random selection of sampling periods (intra or inter day) should be constructed to minimize the effects of autocorrelation [38].
One may have to refer to 'systematic random sampling' in order to avoid periods which are too much adjacent. However, if the exposure regime exhibits strong periodicity, then systematic random sampling at 'regular' intervals may introduce bias exceeding that from autocorrelation.
Actually non-randomisation is widely practiced either to assure that the sample is representative or to provide a more balanced profile of exposures (less outliers to both sides). Some safety factors should be included to allow for the possibility of bias arising on this account.

8.6 Calculation of TWA

8.6.1 United kingdom

The moment when professional judgement is very important at the calculation of TWA values is when a zero exposure is assumed during non-monitoring hours. EH-42 justly warns that this can be a tricky business.

A point in the calculation of TWA-values that is notably different from the situation in the Netherlands is that there are no legal provisions in the UK to restrict the number of working hours during one day. With mutual consent longer workdays than in Holland are possible, e.g. when a member of the following shift doesn't show up.

8.6.2 Federal Republic of Germany

The calculation of TWA values is quite straightforward. A possible source of error is the fact that a limited sampling time (minimum of two hours) can be used for the calculation of the TWA as a shift value (see Table 2). In the Netherlands, research has shown [13] that even for continuous processes a sampling time of 5 to 6 hours is necessary to reduce the additional error introduced by the shorter sampling time. This critical remark must not be taken amiss because with Table 2 the FRG has introduced a practical rule of thumb which is easy to use.

8.6.3 United States of America

Discussions can be raised how to assess the mean exposure over time and which criterion to use for decisions regarding safe and unsafe situations. For instance, is it appropriate to interpret an exposure limit as a limit to the mean exposure and if so, over what period of time?
This may be acceptable for chemicals with effects which are independent of dose rate because for these chemicals the mean exposure (or dose) is the most critical toxicological parameter. To express the mean exposure as the geometric mean (GM) has several advantages, (1) it is less sensitive to outlier values, (2) it can be reported with its companion geometric standard deviation to completely describe the

distribution. The NIOSH manual uses GM to assess whether a long term situation is acceptable.
However, from an epidemiological point of view, some authors suggest that the geometric mean is not a good indicator of cumulative exposures. They recommend to use the arithmetic mean (which is always greater than GM) [47, 48].
However, statistical theory fails to provide any means of obtaining exact confidence limits for the arithmetic mean of a log-normal distribution. The best estimate (the maximum-likelihood estimation) of the arithmetic mean ($\bar{x}$) is obtained from the two parameters of the log-normal distribution, the mean (m_l) and the standard deviation (s_l) of the logtransformed data [24, 47, 48].

$$\bar{x} = \exp. [m_l + 1/2 * s_l^2]$$

This is a better estimate of the arithmetic mean, because m_l is less influenced by outliers relative to a simple averaged value. Moreover, confidence limits for M can be estimated.
When s_l is high, the estimation becomes more imprecise. An alternative is to use the s_l of an interval of the log-normal distribution (Winsorisation procedure). This complex estimation technique yields slightly better estimates for distributions with outliers [47].

8.7 Interpretation

8.7.1 United Kingdom

The practical guidelines presented in 5.7 and 6.7 are followed by words of caution. This means that the interpretation scheme is flexible. The basis for the numerical values presented in 5.7.1 and 6.7.2 is professional judgement. There is no specific study to which these values can be traced.
Because of the vagueness of the interpretation scheme in the UK it is virtually impossible to estimate on the chance of arriving at an incorrect decision.

As a practical guideline for the industry compliance with the limits is assumed when 90% of the exposure values are below the limit.

8.7.2 Federal Republic of Germany

The FRG uses a fixed interpretation scheme, which is inflexible as to conclusions derived from a certain set of data. When he has to decide on compliance, non-compliance or permanently assured compliance, the professional judgement of the person conducting the evaluation is not taken into account. Anyone following the interpretation scheme should arrive at the same conclusion when starting with the same set of measurement data.
This approach has the advantage that it guarantees the uniformity of decisions, as well as possible legal and financial consequences, better than does the flexible scheme used in the UK.
One drawback is that it is more difficult to take into account what is reasonably practicable in a certain situation. Another is that all conclusions may seem evident with a fixed interpretation scheme, but as there are no strict rules for the establishment of the routine monitoring method a conclusion is not more reliable than the professional judgement of the person who established the procedure for the routine monitoring.
A very fixed interpretation scheme is not easily reconciled with one of the very important reconsiderations of the TRGS 402 that it has not to be taken too literally, but that it is to be interpreted more as a guidance note setting future goals.

The routine monitoring prescribes that a following measurement has to be done before a certain time has passed (16, 32 or 64 weeks). If within that period a measurement is done which gives a high result there is no proscription to do a new measurement, as long as it is within the fixed time period, and report that new measurements as the result of the routine monitoring. By chance alone one has to expect occasional high concentrations in a situation where as a rule there is compliance.

In the statistical interpretation in 5.7.2 of measurement data certain assumptions are made on the confidence of the test and the proportion of exposures which lie below the limit value.
In method B the OTL (one-sided tolerance limits) approach of Tuggle [14] is used.
In order to conclude to compliance a confidence level of 95% (the probability of making an incorrect decision is 5%) and proportion (p) of 95% tested to be less than the limit are used. As the standard devia-

tion of the measured values is used in the calculation, there is no specific assumption about the fluctuation of the data.

In method A it is not quite clear which GSD or which confidence level γ is assumed.

The statistical method presented in [7] to decide on compliance is much stricter than the interpretation scheme in the guidance note [3]. As ref. [7] is a guidance to a guidance note, presummably [3] has the preference. In practice it is highly improbable that people will go on monitoring to arrive at a conclusion by means of a statistical calculation if they can arrive at the same conclusion with one measurement.

The fact that the statistical approach is much stricter than the interpretation scheme, shows that the scheme leaves quite some room for incorrect decisions. These, of course, will become less when more measurements are done that indicate compliance.

In the interpretation scheme in the FRG (see Figure 3) there is a possibility to consider if corrective measures would be suitable before coming back for new measurements. In the text [3] this step is not elaborated any further, which is a pity. This could have been a link to the UK approach of keeping the levels as low as is reasonably practicable. In [15] there is some reference to this consideration. If the monitoring frequency is high because concentrations are near the limit, the cost of monitoring will be higher. A cost/benefit analysis can be used to evaluate if it is cheaper to reduce the concentrations and as a consequence the monitoring frequency.

The pre-condition for the use of a statistical method to determine compliance is that the measurement values are distributed log-normally. For large series of environmental data this mostly is the case [17, 13, 21] but for short series determination of log-normality is virtually impossible. In practice a test can be done if the possibility of a log-normal distribution is to be ruled out. This test has a low power.

In [16] two illustrative examples are given of the statistical method (B) of determining compliance.

If the TWA/MAK for three measurements is 0.2; 0.1 and 0.2 the conclusion must be non-compliance because 4.6 < 7.66, even though the measured values are between one tenth and one fifth of the MAK value. If there is a series of TWA/MAK of 0.7; 0.65 and 0.68 the conclusion is compliance because 10.5 > 7.66. In the last case all the measured values are between half the MAK value and the MAK, but because of the small fluctuation in the values the statistical approach leads to the conclusion of compliance.Even though the last situation from a hygienists point of view needs careful consideration of possible corrective measures.

Another statistical method which has been used in the FRG is based on the Markov-process [22]. It has been developed for the determination of compliance for the yearly average dust concentrations [18]. The result not only depends on the GM and GSD but also on the sampling time and the interval between the last two samples. As the new reference time is the shift length, this approach seems to be out of use now.

8.7.3 United States of America

In the regulatory NIOSH scheme interpretation of the initial assessment is strictly on the basis of professional judgement.
In the (non-)routine monitoring phase a rigid statistical method is used to classify exposures. Decisions are made according to a fixed decision scheme and no judgement of the person doing the interpretation is required.
Although this guarantees indisputable decisions, the ultimate conclusions can never be more reliable than the professional judgement, used to determine the need for monitoring and to select the target population.
In Section 8.1.3 we already pointed to some of the limitations of the NIOSH scheme. Since decisions are based on only one or, at most, two (consecutive) exposure estimates, a significant probability exists for making incorrect decisions.
Tuggle [14] proposed an argumented monitoring strategy that uses all the data collected, instead of only the last one and possibly the one preceding. He consideres exposure variability (GSD) and mean exposure (GM).
The procedure is based on one-sided tolerance limits (OTL) for decision making, assuming a log-normal distribution of exposures.

The OTL approach can answer such questions as: are we 95% confident that less than 5% of all exposures in a workplace are above the limit value. Any other criterion for a confidence level or fraction of exceedance can be chosen. A test criterion incorporating how much a mean exposure (x_1) is below or above a limit value (STD) and the exposure variability (s_1) are compared to an one-sided tolerance factor (K) found in standard tables (Figure 6).

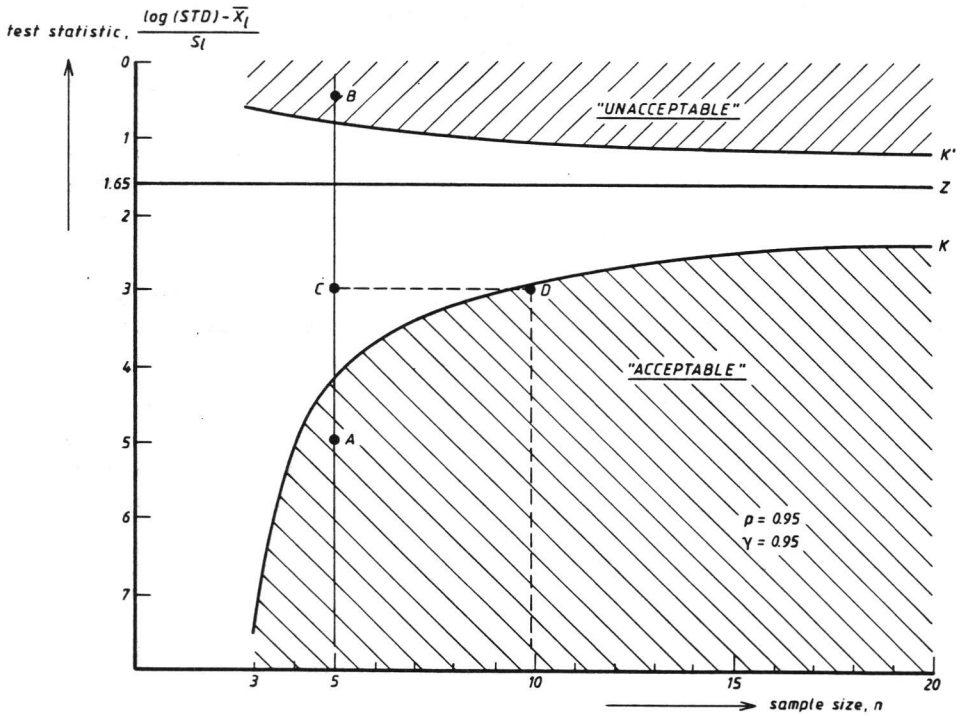


Figure 6 OTL decision criteria [14]. (Z is the normal standard variable, Z = 1.65 in the case $\gamma = 0.95$).

The OTL decision scheme is presented in Figure 7.

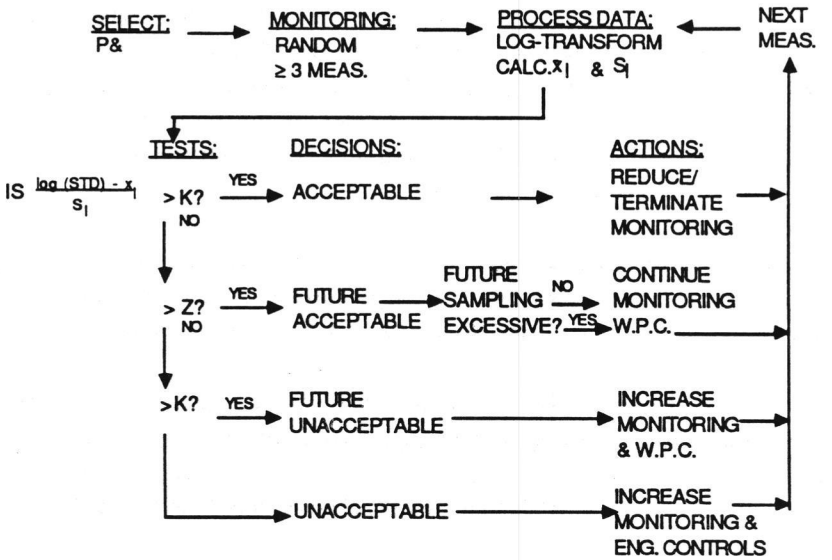


Figure 7 OTL decision scheme [14].

To start the scheme at least three random measurements are required. In the follow-up monitoring all previous samples are also considered, when making decisions.

Tuggle's OTL technique is incorporated in the recommended monitoring strategies in the Federal Republic of Germany and Belgium. The principle is incorporated in many 'in-house' strategies in the United States of America [39, 40, 41].

The advantage of the technique is that it combines a statistical and graphical technique.

For instance, one can easily estimate the expected number of samples required to reach the acceptable zone. Given point C (the result of five measurements), it can be seen that an expected number of 5 additional measurements are needed to reach a decision.

In the overall, the OTL scheme is rather conservative in the number of samples to be taken, particularly when the actual fraction of exposures above the limit value approaches the arbitrary limit (1-p = 0.05). Two factors contribute to this conservativeness, (1) the relative freedom of assumptions (no professional judgement is taken into account) and (2) the rather high confidence levels used [14].

If the exposure data are not stable over time, competent professional judgement may be used to censor some of the earlier exposure estimates. Thus, if more recent exposure data, instead of all data, are used the tolerance limits may become thighter and decisions can be

made more rapidly [26]. Several in-house strategies have also coped with the problem of the high number of samples required to achieve tight confidence limits around the fraction of exposure (p) below the limit value.
The Dow strategy makes distinction between chemicals with effects which are dose-rate independent and chemicals with effects which are highly dose-rate dependent [39].
In the latter case one should be 95% ($\gamma = 0.95$) sure of p (in this case $p = 0.95$) in the other case the best estimate of the median value of p is appropriate.

The ALCOA strategy is more permissive [40]. The one-sided tolerance level for $p = 0.90$ (90th percentile) is estimated at the confidence level $\gamma = 0.90$ for substances classified as highly toxic and at the confidence level $\gamma = 0.70$ for substances with low toxicity. However, any result exceeding the PEL is investigated. The minimum number of samples to estimate the tolerance levels is still five in this strategy. The ALCOA 'in-house' strategy is shown in Figure 8.

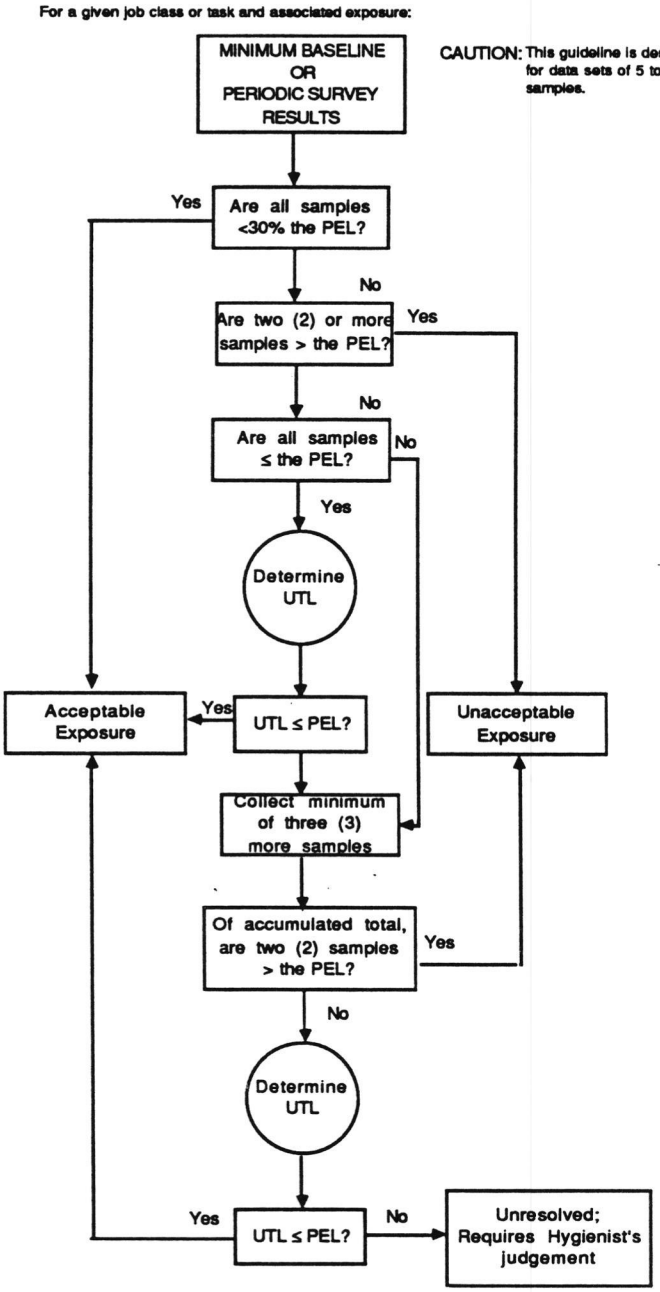


Figure 8 Criteria for exposure evaluation [40].

The minimum baseline describes the magnitude and range of exposures for a job class or task, based on at least five samples collected over

two different days. After a base line has been collected, routine monitoring is done according to a scheme presented in Table 5.

Table 5 Periodic sampling frequency and sample size for routine monitoring after baseline data have been collected [40].

PERIODIC SAMPLING FREQUENCY			PERIODIC SAMPLE SIZE		
Geometric mean of baseline data (GM)	Toxicity	Approximate sampling frequency in years	Number of employees in Job Class (N)	Geometric standard deviation of baseline data (GSD)	Minimum number of samples (n)
<50% the PEL	high	2	≤30	≤2.00	3
	low	3		>2.00	5
≥50% the PEL	high	0.5	>30	≤2.00	7
	low	1		>2.00	9

Since OTL schemes allow for some possible overexposure, Leidel and Busch [26] warned that the fraction (p) desired to be less than a limit value should be assessed by careful judgement taking account of:
- the nature of the health hazard (acute/chronic);
- the severity of the hazard (nuisance, carcinogen, lethal);
- the 'protection factor' of the limit value;
- possible economic and legal considerations.

In this respect an essential preliminary for this type of statistics is that the precise meaning of the occupational exposure limit is established. Are limits never to be exceeded or may they be exceeded at some finite frequency of occurrence? Will this frequency be different from one substance to another? Groups setting the limit standards do not usually specify all the parameters the statistician needs. Exposure limits have no precise meaning without the measuring strategy to be associated with it.

More recently Selvin [49] commented on the one-sided tolerance limits approach. Apart from the large numbers of observations necessary to

reach a statistical decision in most cases, perhaps the general weakness of the OTL approach is that it is not optimal for characterising mean exposure and its associated health risk. Since OTL focus on the right tail of the distribution important additional information on the mean and variance of the distribution is lost which may be of toxicological importance. That is, OTL cannot be used to differentiate between high-mean, low variance and low-mean, high variance distributions.

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ABBREVATIONS AND SYMBOLS

ACGIH	American Conference of Governmental Industrial Hygienists.
AgA	Ausschuß für gefährliche Arbeitsstoffe
AGS	Ausschuß für Gefahrstoffe
AL	Actionlevel
AM	Arithmetic mean
BAT	Biologische Arbeitsstoffetoleranzwerte
BAU	Bundesanstalt für Arbeitsschutz
BIA	Bundesgenossenschaftliches Institut für Arbeitssicherheit
C_1, C_2	Concentration of constituent 1, 2 etc, in air
c_1, c_2	Concentration of sampling period 1, 2 etc.
CEFIC	Conseil European des Federation de l'Industrie Chimique
CID	Center of Information and Documentation TNO
COSHH	Control of substances hazardous to health
DFG	Deutsche Forschungsgemeinschaft
EC	European Community
EH-42	Guidance note EH-42: monitoring strategies for toxic substances
FCG	Field Consultant Group
FRG	Federal Republic of Germany
Gefstoff V	Gefahrstoffverordnung
GM	Geometrical mean
GSD	Geometrical standard deviation
HQ	Headquarters
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSW Act	Health and Safety at work Act
I	Index of exposure to a mixture

K	One-sided tolerance factor
L	Limit value
L_1, L_2	Exposure limit value of constituent 1, 2 etc.
LCL	Lower confidence limit
LEV	Local exhaust ventilation
ln	Natural logarithm with 1 as a base
m_l	Mean of the logtransformed data
MAK	Maximalen Arbeitsplatzkonzentration
MAK_1,MAK_2	MAK-value of constituent 1, 2 etc.
MDHS	Methods for the determination of hazardous substances
MSDS	Material safety data sheet
n	Number of samples/number of workers in a subgroup
N	Number of workers in a homogeneous population
NEDB	National exposure data base of HSE
NIOSH	National Institute of Occupational Safety and Health
OHVR	Occupational hygiene visit report data base
OSHA	Occupational Safety and Health Agency
OTL	One-sided tolerance limit
p	Proportion of exposures tested to be less than the limit value
P	Probability
PAS	Personal air sampling
PEL	Permissible exposure limit
RPE	Respiratory protective equipment
s	Standard deviation by n-1 method
s_l	Standard deviation of log transformed data
STD	Standard (any occupational hygiene standard for a chemical)
STEL	Short time exposure limit value

T_1, T_2	Duration of exposure to constituent 1, 2 etc. in hours
t_1, t_2	Duration of sampling of period 1, 2 in hours
TLV	Threshold limit value
TRgA	Technische Regeln für gefährliche Arbeitsstoffe
TRGS	TEchnische Regeln für Gefahrstoffe
TRK	Technische Richtkonzentrationen
TWA	Time weighted average concentration
TWA_i	Time weighted shift average concentration on day i
TWA_i*	Natural logarithm of the quotient of TWA_i and MAK
$\overline{twa}$	Average of the log transformed quotient of TWA_i and MAK
8-h TWA	Time weighted average over 8 hours
UCL	Upper confidence limit
UK	United Kingdom
USA	United States of America
UTL	Upper Tolerance Limit
VCM	Vinyl chloride monomer
WAA	Working area analysis (=Arbeitsbereichanalyse)
WPC	Work practice control
$\overline{x}$	Average exposure
$\overline{x_l}$	Arithmetic mean of a lognormal distribution of exposures.
Z	Value of the standard normal variable
γ	Confidence limit of OTL-test
Σ	Sum

Health and Safety Executive

Environmental monitoring results

Appendix A

FCG file reference	Date of visit	Substance							
		Units							
Occupier	Total number of people on site	Monitoring procedure							
		In-house atmos. monitoring							
		In-house biol. monitoring							
		Males exposed							
		Females exposed							

	Reference number	Sample type	Sample description (eg name/process/job)	Sample period	Duration (minutes)	Result	TWA	Result	TWA	Result	TWA	Result	TWA
1													
2													
3													
4													
5													
6													
7													
8													
			Exposure limits	8 hour									
				10 min									

Appendix A

	HSE Area no.			
	SHIELD ID no.			
	Industry			
	Type of visit			
	OHVR reference no.			
	Exposure details		Control measures	
	Type	Pattern	RPE	LEV
1				
2				
3				
4				
5				
6				
7				
8				

Appendix B

Health and Safety Executive

FI9 Visit report —Summary sheet

FI9 File no.

OHVR Accession no.

Date of report

To

Subject of report
(block caps)

Initiation

Area no/PI group no.
(or other inspectorate)

Area (name)

Copies for : SSI (FCG)/PI/SEMA *(delete as appropriate)* Others :

Summary sheet to :SSI(FI9)/AD/OHVR

Name of firm
(block caps)

Address

Persons seen
(Names and positions)

Visited by

Date of visit

FCG file no.

Relevant papers

Abstract

BIA Berufsgenossenschaftliches Institut für Arbeitssicherheit, 5205 Sankt Augustin 2, Lindenstraße 80, Tel. (02241) 231724

Exemplar für Auftraggeber

Auftrag zur Untersuchung von Staub- und Gasproben zur Beurteilung von Arbeitsplätzen

Meßplan
☐ Erst-messung ☐ Wiederholungs-messung ☐ Sonder-messung
☐ Bestands-aufnahme ☐ Arbeitsbereichs-analyse ☐ Kontroll-meßplan

Berichts-Nr.

Probe ..... von .....

BG

Name
Str./Postf.
PLZ, Ort

Verfahrensbedingte Exposition (S = Schicht)
☐ 8 h/S | ..... h/S | ..... S/Jahr
Dauer pro Spitze ..... min
Anzahl der verfahrensbed. Spitzen/S .....
Zeitintervall zwischen den Spitzen ..... h

Materialprobe
(Kennzeichnung, Name, Spezifikation)

RegB

Name
Str./Postf.
PLZ, Ort

Schadstoffanalyse
Probenträger-Nr. .....
Probenahmeverfahren Codeangabe s. Bl. 4 ☐☐☐

Probenträger-Nr.: .....
Probenahmeverfahren Codeangabe s. Bl. 4 ☐☐☐

HBA

Art des Betriebes nach Meßstellenplan: .....

Expositionsmess. ☐ ja / ☐ nein
☐ repräs. Schichtw. / ☐ Kurzzeitw.
☐ stationär ☐ / personenbezogen

Expositionsmess. ☐ ja / ☐ nein
☐ repräs. Schichtw. / ☐ Kurzzeitw.
☐ stationär ☐ / personenbezogen

IBA

Indiv. betr. Arb.-Ber.: max. 5 numer. Zeichen

Anzahl Exponierten

Luftprobe
Prn.-Dauer ..... (h)
Durchsatz ..... (l/min)
Durchsatz ..... (m³/h)
Volumen ..... (l)
Volumen ..... (m³)
Anzahl der erfaßten Spitzen .....

Luftprobe (zugehörig zum selben Arbeitsbereich zur selben Schicht)
Prn.-Dauer ..... (h
Durchsatz ..... (l
Durchsatz ..... (m
Volumen ..... (l)
Volumen ..... (m
Anzahl der erfaßten Spitzen .....

AB

Nr. d. Arb.-Ber. (korresp. zu IBA) (entspr. Meßstellenpl.)

TBA

Teilbetriebsart (nur einzusetzen, falls abweichend v. HBA)

DPN

T T M M J J

Probenahme von ..... bis ..... Uhr

Raum	1	im Freien	2	teilw. offen < 50 m³	3	teilw. offen 50–500 m³	4	teilw. offen 500–5000 m³	5	teilw. offen > 5000 m³
	6	geschlossen < 50 m³	7	geschlossen 50–500 m³	8	geschlossen 500–5000 m³	9	geschlossen > 5000 m³		
Raumhöhe	1	< 3 m	2	3–6 m	3	> 6 m				
Lüftung Anlage Zust. schlecht	1	Fenster/Türen geschl.	2	Fenster/Türen offen	3	Dachreiter	5	Frischluft (techn.)	6	Abluft (techn.)
	7	Frisch- u. Abluft (techn.)	8	Umluft (techn.)	9	Um- u. Frischluft (techn.)	0	Abluft vorw. üb. Erfassungseinrichtung		
Absaugung Anlage Zust. schlecht	0	keine	1	Saugrohr	2	Saugschlitz	3	Saugschlitz/Haube mit Blasstrahl	4	Haube seitlich
	5	Haube oben	6	Saugwand	7	Teilkapselung	8	Vollkapselung mit Absaugung	9	Vollkapselung ohne Absaugung
Abstand Emissionsquelle/Absaugung			6	Punktabsaugung	7	flächenförmige Absaugung	8	weiträumige Absaugung		
Wetter	1	sonnig/bewölkt	2	Regen/Schnee	3	diesig				
Wind	4	schwach	5	mittel	6	stark, stürmisch/böig				
Temperaturdifferenz	innen/außen		7	< 10° C	8	10–20° C	9	> 20° C		
Entstaubung	0	keine	1	Naßarbeiten	2	staubarme Bearbeitung				
	3	Reinluftrückführung Raumluft	5	Reinluftrückführung Erfassungsluft	4	sonst. Wärmerück-gewinnung	6	Reinluftabführung		

Bemerkung:
Sondermeßprogramm: .....
**) Die oben bezeichneten Proben beziehen sich unmittelba auf die Beurteilung der Schadstoffexposition.

(Code-Nr. und Unterschrift des Auftraggebers)

Bitte freilassen | ZBA Eingang: | Bearbeiter: | Weiterl.: | E4: | E5: | E6:

Appendix D

EMPLOYEE EXPOSURE MEASUREMENT RECORD

Facility ..... Area .....

Sampled by ..... Date .....

Temperature ..... Altitude .....

Sample #..... Employee name ..... SS# .....

Operation(s) monitored .....

Type of sample: Personal ..... Breathing zone ..... Area .....

Operating conditions and control methods .....

.....

Time on ..... Time off .....

Elapsed time (min) ..... Indicated flow rate (LPM) ..... Volume (liters) .....

Calibration location ..... By ..... Date .....

Sampling/analytical method .....

Evidence of accuracy .....

.....

Remarks, possible interferences, action taken, etc. .....

.....

.....

Results of sample analysis or instrument reading .....

.....

Exposure of employee (indicate 8-hr average or 15 min) and sample numbers it is based on .....

.....

.....