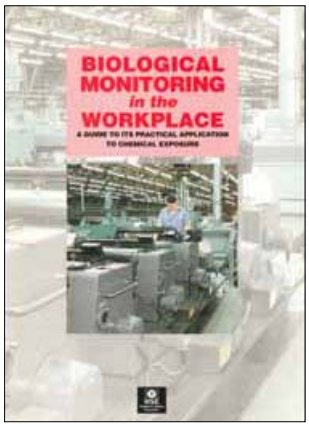
Biological monitoring in the workplace

A guide to its practical application to chemical exposure



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This guide is for occupational hygienists, occupational health professionals and managers who are considering setting up and/or managing a biological monitoring programme for chemical exposure in the workplace. It may also be helpful to employee health and safety representatives.

It gives practical advice on setting up a programme, how to protect employees' rights, what the law says, the role and use of biological monitoring guidance values and contains an Appendix about the technical aspects of biological monitoring.

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This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

Contents

Introduction

1 This guide is for occupational hygienists, occupational health professionals and managers who are considering setting up and/or managing a biological monitoring programme in the workplace. It may also be helpful to employee health and safety representatives. We recommend that you read it in conjunction with the Control of Substances Hazardous to Health Regulations 1994 (COSHH). The guide provides you with information on when and how biological monitoring should be used in the workplace. It also describes the proper and effective management of a biological monitoring programme. In particular, it gives you advice on:

- relevant health and safety legislation;
- the role and use of biological monitoring guidance values (BMGVs);
- the practical aspects of operating a biological monitoring programme;
- the steps you need to take to ensure individuals' rights are protected; and
- technical aspects of biological monitoring.

2 Biological monitoring involves analysis of breath, urine or blood samples collected from employees. There are sensitive ethical issues involved in the collection, analysis and reporting of results from such samples. Occupational physicians play a crucial role in handling such sensitive issues. We therefore strongly recommend that you involve an occupational physician in setting up a biological monitoring programme, particularly in establishing procedures for reporting results. They should be available to offer medical interpretation of results. However, normally they may not need to be involved in the day-to-day sample collection and analysis. This guide explains the need for professional advice in the design and management of a biological monitoring programme.

3 This guide covers the use of biological monitoring for exposures to chemicals in the workplace for the purposes of health surveillance and exposure assessment. It is not intended to give detailed advice on its use in other areas, for example overdose, research or pre-employment screening. However, some of the principles and technical information are common to these other uses.

4 Since biological monitoring involves measurements on biological samples collected from individuals it is essential that the rights of the individual giving the sample are safeguarded. This guide explains in detail the steps needed to set up an effective biological monitoring programme which will protect the rights of the individual participants.

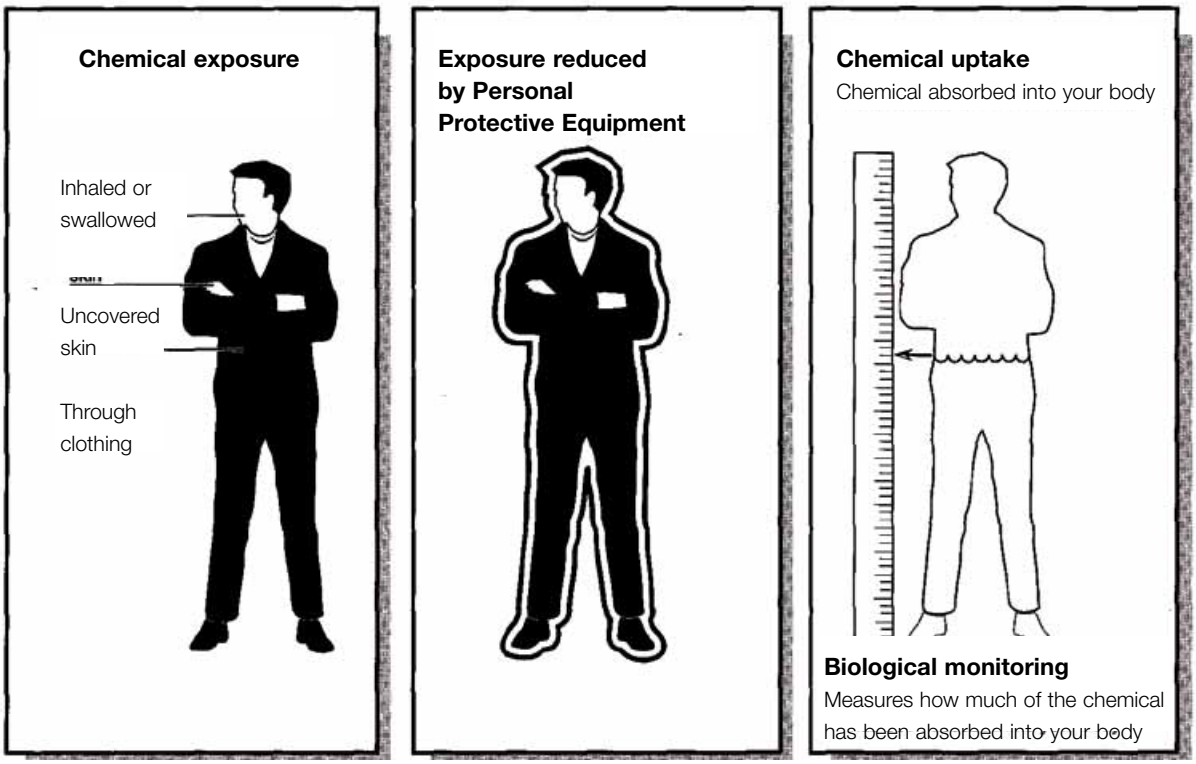
What is biological monitoring?

5 Biological monitoring is the measurement and assessment of chemicals or their metabolites (substances the body converts the chemical into) in exposed workers. These measurements are made on samples of breath, urine or blood, or any combination of these. Biological monitoring measurements reflect the total uptake of a chemical by an individual by all routes (inhalation, ingestion, through the skin or by a combination of these routes). Thus it differs from environmental monitoring which measures an individual's exposure (see Figure 1). Table 1 gives examples of chemicals that can be assessed by biological monitoring.

Table 1 Examples of chemicals that can be assessed by biological monitoring

Biological monitoring (measuring the chemical itself)		
In blood In urine In breath	Lead, cadmium, polychlorinated biphenyls Cobalt, nickel, 4,4'methylenebis-(2-chloroaniline) Tetrachloroethylene, carbon monoxide	
Biological monitoring (measuring a metabolite)		
In blood In urine	Bromide Mandelic acid Trichloroacetic acid	From methyl bromide exposure From styrene From trichloroethylene

Figure 1



What is biological effect monitoring?

6 Biological effect monitoring is the measurement and assessment of early biological effects caused by absorption of chemicals. It normally involves measuring biochemical responses (for example, measuring plasma and erythrocyte cholinesterase activity in workers exposed to organophosphorus pesticides; or measuring increases in urinary protein following exposure to cadmium). These responses may have potential health implications for the individual, and may arise from causes other than occupational exposure. Consequently, biological effect monitoring should always be carried out with the close involvement of an occupational health physician.

How are biological monitoring and biological effect monitoring related?

7 Although biological effect monitoring and biological monitoring are often included under the umbrella heading of biological monitoring, we have used the terms separately in this guide. The advice in the guide is primarily about the use of biological monitoring in exposure assessment, although many of the principles are also applicable to biological effect monitoring and other applications of biological monitoring.

The role of biological monitoring

8 Biological monitoring for chemical exposure contributes to the aim of preventing unacceptable health risks by providing information on the control of occupational exposure. It can give an indication of absorption by all routes of exposure, consequently, it is often used to complement personal air monitoring (which measures the concentration of a chemical in the air in a person's breathing zone). Therefore biological monitoring may be particularly useful for those chemicals which are easily absorbed through the skin or taken in by ingestion, or where exposure is controlled by personal protective equipment. The value of biological monitoring is illustrated by Case Studies 1 and 2. The first case study shows how biological monitoring revealed significant uptake of N,N'-dimethylacetamide as a result of skin absorption, despite very low airborne levels and the use of personal protective equipment. The second shows how biological monitoring demonstrated the effectiveness of gloves used to prevent skin contamination by 4,4'-methylenedianiline.

CASE STUDY 1

BIOLOGICAL MONITORING REVEALED FLAW IN PERSONAL PROTECTIVE MEASURES

Periodic plant maintenance during polymer manufacturing involved dismantling process equipment and exposing large quantities of warm polymer solution, containing the volatile solvent N,N'-dimethylacetamide (DMAc), to air within an enclosed working area. It was recognised that this could result in very high levels of exposure by inhalation and the possibility of skin absorption of DMAc. Control measures included providing all potentially exposed maintenance workers with appropriate airline breathing apparatus and full protective clothing (gloves, PVC suits and boots). Although procedures to control exposure appeared exemplary, before long early symptoms of over-exposure occurred. Biological monitoring for DMAc showed very high levels of absorption. A thorough investigation showed that because the protective suits were not sealed at the neck and cuffs etc, vigorous activity during maintenance work caused solvent loaded air to be 'pumped' underneath the suits. Positive pressure suits supplied with fresh air were then introduced and further biological monitoring confirmed that absorption had been almost entirely eliminated.

Biological monitoring allowed the effectiveness of personal protective equipment used to control uptake to be assessed and improved in a way no other technique could have done.

CASE STUDY 2

BIOLOGICAL MONITORING SHOWS DIFFERENT ABSORPTION BY TWO PEOPLE DOING THE SAME JOB

Two workers were employed in a formulation process which involved emptying sacks of 4,4 '-methylenedianiline (MDA) into a mixing drum and then adding solvents and other chemicals. There was exhaust ventilation over the mixing drum and it was considered that there was only limited potential for inhalation of MDA. The main route of exposure was considered to be the skin. The two workers performed the same task but one of them wore gloves and the other did not. Biological monitoring showed that the worker who wore gloves had urinary MDA levels less than 100 mmol MDA/mol creatinine whereas the worker who did not wear gloves had levels ranging from 180 to 320 mmol MDA/mol creatinine. This finding resulted in the second worker adopting improved occupational hygiene procedures and a consequential lowering of MDA uptake.

These figures were recorded several years ago, and both workers showed high urinary MDA levels. MDA is no longer used in this process. However this case study shows how biological monitoring demonstrated to the workers the importance of wearing gloves.

Health and safety law

The Control of Substances Hazardous to Health Regulations 1994 (COSHH)

9 The COSHH Regulations aim to protect the health of workers, and others, exposed to hazardous substances at work. The COSHH General Approved Code of Practice (ACOP)[1] gives practical guidance on how to comply with the Regulations. To comply with COSHH employers have to:

- assess the risks to employees' health arising from their work with chemicals (regulation 6);
- decide what precautions they need to take (regulation 6);
- prevent or control risk (regulation 7);
- ensure the control measures are properly used and maintained (regulations 8 and 9);
- monitor the exposure of workers, where necessary (regulation 10);
- provide health surveillance, as appropriate (regulation 11); and
- inform, instruct and train employees about the risks and any necessary precautions (regulation 12).

Biological monitoring under COSHH regulations 6, 7 and 10

10 Biological monitoring can make a valuable contribution to exposure monitoring under regulation 10, in circumstances where air sampling alone may not give a reliable indication of exposure. It can also be used to support measures taken under regulations 6 and 7, by contributing to health risk assessment and the evaluation of control measures. As Case Studies 1 and 2 illustrate, biological monitoring is valuable where, for example:

- there is likely to be significant skin absorption; and/or
- there is likely to be significant uptake following ingestion of the chemical; and/or
- control of uptake depends on personal protective equipment.

Biological monitoring guidance values (BMGVs)

11 Clear criteria for interpreting the results of biological monitoring are essential to their effective use in exposure assessment. We have established a system of non-statutory biological monitoring guidance values (BMGVs) to provide an authoritative guide to the interpretation of biological monitoring results. There is no requirement in the COSHH Regulations for compliance with BMGVs. Their purpose is as guidance in the interpretation of biological monitoring data. There are two types of guidance value:

- ***Health guidance value*** (HGV). HGVs are set at a level at which there is no indication from the scientific evidence available that the substance being monitored is likely to be injurious to health. Values not greatly in excess of a HGV are unlikely to produce serious short or long-term effects on health. However, regularly exceeding the HGV does indicate that control of exposure may not be adequate. Under these circumstances employers will need to look at current work practices to see how they can be improved to reduce exposure.
- ***Benchmark guidance value*** (BGV). BGVs are not health based. They are practicable, achievable levels set at the 90th percentile of available biological monitoring results collected from a representative sample of workplaces with good occupational hygiene practices*. If a result is greater than a BGV it does not necessarily mean that ill health will occur, but it does indicate that control of exposure may not be adequate. Under these circumstances employers will need to look at current work practices to see how they can be improved to reduce exposure.

12 BMGVs have been established for a number of chemicals, a full list is contained in the HSE publication *EH40: Occupational exposure limits*[2]. We now routinely consider whether it is appropriate to establish a BMGV when chemicals are reviewed for an occupational exposure limit (see paragraph 10). Our first priority is to set a HGV, however a BGV may be set if there is insufficient data to derive a HGV. The data supporting proposals for new BMGVs will be published in *EH64: Criteria document summaries*[3] before it is listed in EH40. EH40 and EH64 are updated annually ..

Comparison of BMGVs with occupational exposure limits (OELs)

- An HGV can be considered as equivalent, in health protection terms, to the appropriate occupational exposure standard (OES).
- A BGV is not health based. It is set at a level achievable by good occupational hygiene.
- A BGV may be set for a substance assigned an OES, when there is insufficient data to derive a HGV.
- A BGV may be set for a substance assigned a maximum exposure limit (MEL). However a BGV would not be set at a level which would result from inhalation exposure above the MEL.

*That is, BGVs are set at levels achieved by 90% of these workplaces.

Biological monitoring as part of health surveillance (COSHH regulation 11)

13 Suitable health surveillance, as set out in regulation 11 of COSHH, can include biological monitoring. Health surveillance is considered appropriate under regulation 11 either in specific situations set out in Schedule 5 to the Regulations, or more generally where:

> *the exposure of the employee to a substance hazardous to health is such that an identifiable disease or adverse health effect may be related to the exposure, there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his work and there are valid techniques for detecting indications of the disease or the effect.* (COSHH regulation 11 (2)(b)).

Thus, biological monitoring may be appropriate under regulation 11 of COSHH where it is possible to link results from biological monitoring to an adverse health effect.

Biological monitoring and the Control of Lead at Work Regulations 1980 (CLAW)

14 While the general philosophy of exposure control for lead is consistent with COSHH, lead is subject to separate legislation, CLAW*. However, unlike COSHH, CLAW specifically requires biological monitoring and lays down biological monitoring limits in its Approved Code of Practice (ACOP)[4].

*These Regulations are to be replaced by new lead regulations from April 1998.

How to set up and manage a biological monitoring programme

15 This section considers the main elements of a biological monitoring programme. You need to think these through carefully *before* you start. It gives practical guidance on how these elements translate into the operation of a biological monitoring programme.

16 You are likely to find it helpful to discuss new programmes with someone already involved with an existing one. In particular, we suggest you involve an occupational physician. Information on programmes already in place can help you ensure that your own is applicable and consistent with appropriate industry practices and experience.

17 If you are considering setting up a biological monitoring programme but do not have the expertise in-house, you may wish to seek help from an organisation which does have the appropriate expertise and specialises in providing a biological monitoring service.

18 The main steps involved in a biological monitoring programme are:

Step 1 Define the purpose of the programme
Step 2 Appoint a competent person to manage the programme
Step 3 Define the monitoring strategy
Step 4 Consult on the programme with employees or their representatives
Step 5 Discuss and agree the programme with the individual employees concerned
Step 6 Establish procedures for sample collection, storage, transportation, analysis and quality assurance
Step 7 Establish procedures for feedback, including interpretation or results
Step 8 Ensure arrangements are in place for acting on the results and evaluating the effectiveness of the programme

Step 1 Define the purpose of the programme

19 You need to establish from the beginning the main purpose of the biological monitoring programme. This guide considers two main purposes of biological monitoring in the context of the COSHH Regulations - health surveillance and exposure assessment. These two are not mutually exclusive but are considered separately to reflect the requirements of the Regulations.

Health surveillance under COSHH regulation 11

20 Health surveillance is the protection of an employee's health through the detection of any adverse health effects at as early a stage as possible. It is carried out on an individual basis. Paragraph 13 sets out the circumstances under which health surveillance is appropriate. If you are considering biological monitoring as part of health surveillance under the COSHH Regulations you should refer to regulation 11 and the associated text in the Approved Code of Practice (ACOP)[1].

Exposure assessment

21 The key issue for you to consider is whether biological monitoring will be of practical value in assessing risks from, and/or controlling exposure to, chemicals. As explained in paragraphs 10-12, we recommend that you *consider* using biological monitoring for exposure assessment to support measures taken under the COSHH Regulations, where all of the following apply:

- it will give you information in addition to that already available through complying with the COSHH Regulations;
- it will provide you with useful information on exposure assessment which will assist in evaluating control measures;
- there is an appropriate sampling strategy and analytical technique which preferably involves non-invasive sampling (ie urine or breath rather than blood);
- you have clear criteria for interpreting the results, for example a BMGV (where no BMGV is available you may wish to set an in-house standard or use standards from other countries - but be aware that HSE has not assessed these); and
- you can adequately address the issues listed in paragraphs 22-52.

Step 2 Appoint a competent person to manage the programme

22 The competent person should be someone who understands this guide and has:

- the relevant experience and knowledge to act on it themselves; or
- access to appropriate specialist expertise able to act on it. For example, if blood samples are unavoidable you will need an appropriately qualified person to take them.

23 Where biological monitoring is being carried out as part of health surveillance under COSHH regulation 11 it should be carried out either under the supervision of a registered medical practitioner, or where appropriate by a suitably qualified person (for example an occupational health nurse) or a responsible person with the necessary information, instruction and training (in accordance with regulation 12(3) of COSHH). These people should be conversant with the relevant biological monitoring techniques. Please note the role of the occupational health physician outlined in paragraph 2. Where health surveillance is undertaken because of exposure to one of the substances or work in one of the processes specified in Schedule 5 of the COSHH Regulations this must include medical surveillance under the supervision of an Employment Medical Adviser or an appointed doctor.

24 When biological monitoring is used solely for exposure assessment the competent person may be an occupational hygienist or a health and safety manager. But note we recommend you have an input, in particular in setting up the programme, from an occupational physician (see paragraph 2).

Step 3 Define the monitoring strategy

25 The monitoring strategy depends on what you are measuring. You need to consider who to monitor, how often and when to take the samples. For substances which have been assigned a BMGV advice on when to take samples is given:

- alongside the BMGVs in the HSE publication *EH40: Occupational exposure limits*[2]; and
- from leaflets detailing suggested analytical methods for chemicals which have a BMGV. These are available, free of charge, from the Health and Safety Laboratory (see Appendix 3).

26 For chemicals not assigned a BMGV, the strategy needs to be established with knowledge of the absorption and metabolism of the substance and any factors which influence them. You will also need to consider how the substance is used in the workplace. More technical information on these aspects is contained in Appendix 1.

Step 4 Consult on the programme with employees or their representatives

27 It is important you consult with employees directly or with elected representatives of employee safety before the biological monitoring programme starts*. Consultation should include all elements of the programme. For example, you will need to discuss and agree arrangements for:

- gaining the employees' consent to provide samples and their processing by occupational health or hygiene staff;
- gaining specific consent for further disclosure of the results;
- giving assurance on how workers will be affected if results suggest their exposure should be reduced;
- briefing new workers;
- the periodic review of the programme.

28 Employees or their representatives will be able to provide you with valuable input into all of these areas and help ensure the programme is implemented successfully. You should remember that employees are not obliged to participate in a biological monitoring programme†.

* There are requirements for consultation with employees on matters relating to their health and safety. You can get further information on this from the Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996.

† Under some circumstances, where an employer is required under health and safety law to carry out a biological monitoring programme, there is an obligation on employees to co¬operate. In particular, employee participation is required under CLAW.

Step 5 Discuss and agree the programme with the individual employees concerned

29 As biological monitoring involves measurements on an individual's body fluids (or breath) it is important to ensure that individuals' rights are protected. To do this you need to ensure that:

- employees give informed consent before samples are taken;
- samples are only analysed for the substances for which informed consent was given (strict controls will be needed to guarantee that this is adhered to);
- individual measurements are treated as confidential and released only to people for whom consent has been given;
- employees are offered their result(s) and an explanation of what it means before it is passed to anyone else.

30 Occupational hygienists, occupational health physicians and nurses are bound by ethical obligations imposed by their professional bodies, whose role is to ensure that these principles are adhered to. However, this may not be the case with other people involved in a biological monitoring programme. You will therefore need to make sure that everyone involved with the biological monitoring programme is aware of, and operates to, the principles given in this guide. It is essential for the protection of an individual's rights that you gain their informed consent. You need to make sure that they understand what is being done, the purpose of the programme and how the results will be used.

31 If an employee consents to give a sample, it is implicit that the person running the programme will have access to the individual's result. You will require specific consent if it is proposed that others, for example, business or functional managers, should have access to individual as opposed to anonymised results. In some instances there may be a case for making the results known to an individual's family practitioner. You should first offer the employee the opportunity to see them. Release of results is best handled by an occupational physician, and will need the employee's consent.

32 When seeking informed consent from individual employees you will need to provide information on:

- the purpose of the programme (and whether it is a legal requirement*);
- what will be involved (taking a sample of blood/urine/breath) and any associated risks;
- their rights on consenting to sample taking and use of results;
- interpretation of the results - you should emphasise when appropriate, that the results do not have direct significance for their health, but do provide information on the effectiveness of control measures;
- what action might be taken on the basis of the results (including how they will be affected if results suggest their exposure should be reduced);
- the benefit to the individual in taking part.

* Under some circumstances, where an employer is required under health and safety law to carry out a programme, there is an obligation on employees to co-operate. In particular, employee participation is required under CLAW.

When seeking informed consent you will need to gain permission for:

- taking a specified sample;
- analysis of the sample for the specified purpose and any ancillary tests (for example, creatinine);
- access to results by specified third parties, ie specified people not involved in running the biological monitoring programme (for example employer, other employees, supervisor, trade union representative);
- making the result known to their family practitioner (see paragraph 31).

33 Employees are more likely to participate fully and allow disclosure of results if they:

- have been fully consulted;
- understand the purpose, consequences and benefits of the programme to them;
- are confident that agreed procedures will be followed; and
- are given clear feedback on the results and their interpretation.

34 You need to decide whether you want to use group data, individual data or both in the biological monitoring programme, and seek appropriate consent from the employees. Group results can provide an overall picture of a group of workers with similar exposure. This may be useful in assessing general controls in the workplace. However, greater benefit in ensuring exposure control can often come from the use of individual data. Case Study 3 illustrates how biological monitoring can be used effectively to promote improved occupational hygiene practice. The options for interpretation are discussed further in paragraphs 42-48.

35 The elements you need to consider when obtaining informed consent are demonstrated through an illustrative consent form in Appendix 2. However, it is up to individual establishments to discuss with employees the details and the most appropriate approaches for the particular circumstances. It is important that any consent form you use is in simple and clear language and is understood by the individual who is being asked to give their consent (you should be mindful of any literacy or language barriers). You will need to provide two copies of the consent form, a copy for each person who signs the form. Each person will need to sign both copies.

CASE STUDY 3

GRAPHS OF BIOLOGICAL MONITORING RESULTS ENCOURAGE GOOD PRACTICE

A company involved in the production of a urethane product containing 4,4 'methylenebis-(2-chloroaniline) (MbOCA) had difficulty in adequately controlling exposure. MbOCA is easily absorbed through the skin and exposure was assessed by the measurement of MbOCA in worker's urine together with air and surface contamination monitoring. All workers who were potentially exposed to MbOCA were covered by the biological monitoring programme. Graphs of group and individual results were produced, including results going back over several years. These allowed identification of trends in MbOCA absorption at both the group and individual level. When results were returned by the analysing laboratory, workers were given a printout showing the most recent result and a graph of past and current results. This arrangement was agreed with both the trade union and the workers being monitored.

This was a well-implemented biological monitoring programme. The employees were kept fully informed at all stages of the programme. Consequently they allowed their results to be used in the assessment of the effectiveness of exposure control measures. The scheme encouraged good occupational hygiene practices with consequential lowering of exposure.

Step 6 Establish procedures for sample collection, storage, transportation, analysis and quality assurance

36 We recommend you obtain detailed information about sample collection, storage, transportation, analysis and quality assurance from the laboratory you select to perform the analysis. However, the following general guidance may be useful to you.

Sample collection

37 For urine sample collection, you need to use the correct type of contamination-free container and ensure the required volume is collected at the time determined by your monitoring strategy (see paragraphs 26-27). You will need to ask employees to change out of their work clothes and wash their hands before providing a sample, otherwise there is the possibility of inadvertent contamination of the sample.

38 Blood sample collection involves the puncturing of a vein and so must be carried out by someone qualified to do so (a physician, suitably qualified nurse or venepuncture technician). Again consideration needs to be given to the type of container and the volume needed. You can obtain further advice on the procedures to be followed when taking blood from the publication *Safe working and the prevention of infection in clinical laboratories*[5] by HSC's Health Services Advisory Committee. This includes advice on the provision of separate accommodation, the use of protective measures to guard against spillage or splashing of blood and the need to properly label samples. Because of the additional risks associated with taking blood, *we recommend that urine or breath (ie non-invasive techniques) are used for biological monitoring wherever possible*.

Sample storage

39 When you are not able to send the sample to the laboratory immediately, you should make sure that the samples are stored properly while awaiting dispatch. If you fail to do this your biological monitoring results may be inaccurate and misleading. You can obtain advice on storage conditions from the analysing laboratory and from the free leaflets available from the Health and Safety Laboratory (see Appendix 3 for details), where the chemical has a BMGV.

Sample transportation

40 You can get advice on this from the analysing laboratory. The packaging of samples sent by post must comply with the rules laid down by the carrier in relation to the transportation of biological material. These are usually intended to prevent the sample container from breaking in transit and to contain any sample leakage which may occur.

Sample analysis and quality assurance

41 Analysis of the samples must be carried out properly, otherwise the results are meaningless. You therefore need to select carefully the analysing laboratory. Methods need to be reliable and well validated. As mentioned in paragraph 39, for chemicals which have been assigned a BMGV, information on suggested analytical methods is contained in free leaflets produced by the Health and Safety Laboratory. Laboratories offering biological monitoring analytical services should ideally be able to demonstrate their participation in internal and external analytical quality assurance schemes and that they operate to a recognised quality standard. Before contracting an organisation to undertake analysis, you may wish to seek reassurance of participation in such schemes together with evidence of satisfactory performance.

Step 7 Establish procedures for feedback, including interpretation of results

42 You should inform the employees being monitored of their own results and what they mean. This needs to be done by someone who understands the results and can explain what they mean. Guidance on the interpretation of individual results in the context of existing BMGVs is given in paragraph 11.

43 Analysis of results from serial sampling either on an individual or group basis may allow the identification of trends, either upward (towards inadequate control) or downward (indicating improved control).

44 When there is a possibility of non-occupational exposure to a chemical (for example, solvents in DIY materials) it may be necessary to compare a sample obtained after work exposure with a pre-work level. Mixed exposures may also affect how a chemical is handled by the body and may therefore affect the levels recorded by biological monitoring.

45 When you interpret results it is important that you are aware of any inherent limitations of the method used to analyse the samples.

Interpreting data for health surveillance

46 Where biological monitoring is being used as part of health surveillance under the COSHH Regulations this needs to be in accordance with the requirements of regulation 11 of COSHH (see paragraph 13). The interpretation of biological monitoring results for health surveillance will need to be done by an occupational physician competent in the use of the relevant biological monitoring techniques in occupational health.

Interpreting data for exposure assessment

47 When results are used for exposure assessment you will need to ensure they are interpreted by someone competent in occupational hygiene. Individual medical interpretation may not be necessary. Nevertheless, we recommend that an occupational physician should be available to give advice if a problem, or potential problem comes to light. In many cases they may not need to see the employee. It may be sufficient for the occupational physician to see the results and be available to discuss their significance with employees if necessary. We recommend that you discuss with an occupational physician, at the beginning of the biological monitoring programme, the circumstances under which it will be appropriate for them to be consulted. These may include:

- where levels for an individual are above the BMGV (or other interpretation criteria) despite good occupational hygiene practice; or
- where an individual reports symptoms of ill health that may be related to the exposure; or
- where medical interpretation is requested by an individual; or
- where there is concern, based on reliable information, that the levels recorded may be associated with harm. Where this type of information is available it will be contained in any specific guidance on the chemical such as the HSE publication *EH64: Summary criteria for occupational exposure limits*[3].

Case Study 4 illustrates the role of the occupational physician where workers exposed to mercury had urinary levels above the Health Guidance Value.

48 Individuals need to be informed of their results with reference to any BMGV (or any other criteria used for interpretation) and what action or follow-up will take place. If the result is high it does not necessarily mean that the individual will become ill. However, it does indicate that control of exposure may not be adequate, so you will need to look at how the substance is being handled and options for reducing exposure. For substances with BMGVs, the HSL leaflet for that substance gives information on how to interpret the results in relation to the BMGV (see Appendix 3 for details about HSL leaflets).

CASE STUDY 4

BIOLOGICAL MONITORING IDENTIFIES POSSIBLE HEALTH IMPLICATIONS IN WORKERS EXPOSED TO MERCURY

In 1996 HSE introduced a biological monitoring health guidance value for mercury in urine. Regular biological monitoring of urinary mercury in a group of workers engaged in the manufacture of barometers showed levels near or above the health guidance value. Consequently the occupational physician responsible for the monitoring programme instigated further monitoring which confirmed that their mercury levels were occasionally above the health guidance value. Since mercury is known to damage the kidneys, the physician instituted a programme to monitor protein in the workers' urine. Laboratory results showed all the workers had normal urinary protein levels. After a clinical examination the physician was then able to reassure the workers that no kidney damage had occurred. However, in view of the relatively high urinary mercury levels the physician advised that control measures be improved.

Step 8 Ensure arrangements are in place for acting on the results and evaluating the effectiveness of the programme

49 There is no point in carrying out a biological monitoring programme unless:

- you consider what action to take in response to the results;
- appropriate action is then taken; and
- the effectiveness of this action is evaluated.

50 Where the results indicate that you are likely to need to reduce exposure (for example where a BMGV is exceeded, or where accumulated data shows a trend towards this) you will need to look at how the substance is being handled. This will include looking at current control measures and work practices, in particular:

- whether current measures and handling methods are working effectively and properly; and
- whether additional measures need to be introduced. Further information on control measures is contained in COSHH (regulations 6 and 7).

51 You will need to consider follow-up monitoring, or increasing the frequency of monitoring, to ensure that any changes made to control measures have been effective. Where specific guidance is available for a chemical this may contain further information on what action is necessary.

52 You may find it helpful to keep records of your biological monitoring programme. Numerical records should be cross-referenced to the task performed and any other occupational hygiene information.

Appendix 1: Technical advice

Sampling strategy for biological monitoring

1 This appendix contains technical information on the establishment of a biological monitoring strategy for substances not assigned a BMGV. If you are not familiar with the concepts underlying the absorption, metabolism and excretion of chemicals you should seek specialist advice.

2 The rates at which chemicals are absorbed into the body and the rates at which they are distributed to different tissues, metabolised and excreted differ markedly and you must take this into account when devising a sampling strategy. For example dichloromethane can be detected in the breath for only a few hours after the end of exposure, whereas tetrachloroethylene remains detectable for up to a week. The concentrations of cobalt and chromium in urine mainly reflect levels of exposure in the previous shift, mercury in urine follows exposure over the previous two to three months while cadmium in urine gives a measure of a lifetime's absorption.

3 Your sampling strategy must therefore be based on a knowledge of the timing of the appearance, breakdown and disappearance of the substance to be measured in the appropriate sample, ie the kinetics of its absorption, metabolism and elimination. This knowledge will enable you to make a decision on:

- the most suitable medium (blood, urine, breath);
- whether to sample before, after or at any time during the shift; and
- whether to sample on the first or last day of the working week or at any time during the week.

For example, trichloroacetic acid (for trichloroethylene exposure) should be measured in urine at the end of shift on the fourth or fifth day of the week, but blood can be taken for polychlorinated biphenyl (PCB) or cadmium measurements at any time.

4 The rate at which a chemical or its metabolites disappear from blood, breath or urine after the end of exposure is described by its half-life. The half-life of a substance or its metabolite is the time taken for its concentration to fall to 50% of its original value after the end of exposure and this can be minutes, hours or days. However, a substance may have several half-lives. For example, the concentration of a solvent in blood may fall rapidly immediately after the end of exposure as much of it is cleared by the lungs (half-life measured in minutes). Then the rate of fall slows as remaining solvent is washed out of muscle and other tissues (half-life measured in hours), but some of the solvent may be retained in fat tissues for many days.

5 Although many chemicals can be shown to have several half-lives, in practice one main half-life dominates the absorption and excretion of a substance or its metabolite during a working shift and this is usually the one that has to be considered in developing a sampling strategy.

6 For chemicals with very short half-lives biological monitoring measurements are markedly influenced by short-term changes in workplace exposure. The strategy for sampling can be conveniently related to the main half-life of the material to be measured in the biological sample of choice (see Table 2).

Table 2

Half-life	*Optimum time for taking samples*
Less than 2 hours	Concentrations of the agent change too fast, consider measuring a metabolite with a longer half-life
2-10 hours	End of shift or next morning
10-100 hours	End of shift at end of week
Greater than 100 hours	Random samples are acceptable

7 The choice of sampling medium (blood, breath or urine) depends on a range of factors. These include the concentration of the material in the medium, its kinetics in that medium and the convenience of collection from the exposed person. Urine and breath may be sampled non-invasively and should be used preferentially. Collection of blood carries a risk of blood-borne infections to the occupational health professional and laboratory analyst. Accurate breath sampling and analysis can be performed with, for example, a transportable respiratory mass spectrometer but these instruments are not generally available. Other breath sampling methods are readily available but none is very convenient.

8 With urine samples there is the problem of dilution and concentration effects. The concentration of a chemical or its metabolites is greatly dependent on the rate of urine production. Measurement of the concentration of a chemical in either very dilute or very concentrated urine specimens can give the wrong picture of absorption and excretion. Various means have been used to correct for concentration and dilution effects. These have usually involved correcting the concentration of the analyte to a urinary constituent that is excreted at a constant rate, independent of water output. Urinary measurements have been adjusted to an agreed specific gravity, to an osmolarity or to the amount of creatinine excreted. None of these correction factors is without criticism; however, correction to a constant amount of creatinine is widely accepted. Urinary results are expressed as mass per mole of creatinine.

Factors influencing the absorption of hazardous substances

9 Workers vary in build and fitness, so they may inhale very different amounts of air while performing similar tasks and thus receive different doses of airborne chemicals. Work practices and the extent of use of respiratory protection and its efficiency have a major influence on the amount of material inhaled. However, the respiratory pathway is not necessarily the major route for the absorption of all substances. Many chemicals, including some solvents and pesticides, can be absorbed through the skin and for some substances and circumstances of use this is the major route of entry into the body. In Tables 1 and 2 of *EH40: Occupational exposure limits*,[2] a skin notation (Sk) is assigned to substances that can be absorbed through the skin. The total absorption and retention of fat soluble materials is also affected by an individual's amount of body fat.

10 The interplay of these various biological factors with the behaviour and work activities of individual employees results in considerable variability in the extent of absorption during any specified task. The measurement of personal exposure to airborne material will not reflect these differences in absorption, particularly when personal protective equipment is worn. Under these circumstances biological monitoring is a valuable adjunct to air monitoring in the assessment of individual risk.

11 Consideration also needs to be given to any confounding factors; reference baseline measurements will be needed where non-occupational exposures are possible or pre-exposure status can affect levels. Mixed exposures are often seen in occupational settings and any possible interactions between substances and/or their biological effects need to be considered (for example, alcohol may delay excretion of metabolites). This is particularly important when interpreting results. Baseline pre-exposure levels may be necessary if there is a possibility of cumulative body burden.

Appendix 2: Illustrative consent form

CONSENT FORM

Many jobs involve the use of chemicals which can harm your health if they are not used properly. As your employer I have to identify the risks to your health and ensure that they are properly controlled. To do this I may need to measure the amount of chemical in the air you breathe. Some chemicals can be absorbed through your skin and when this is the case measuring the amount of chemical present in the air may not give an accurate picture of your exposure. Under these circumstances biological monitoring can be used to indicate how much of a chemical you are exposed to at work has entered your body.

You can find out more about biological monitoring in the free HSE leaflet *Biological monitoring in the workplace: Information for employees on its application to chemical exposure*.

A biological monitoring programme is about to begin in your workplace. The results will be used to check that your exposure to ..... at work is being adequately controlled. You do not have to take part in this programme. If you decide not to take part, this will not affect your conditions of employment. Similarly, if you do take part, the result of your test will not affect your conditions of employment.

You will be offered a copy of your results. They will be used by ..... to assess whether your exposure to ..... needs to be reduced. Your permission will be sought before results are passed to any other person. On occasions it may be useful for your family practitioner to know the results. Your permission will be specifically sought before information is passed to your doctor.

If you require more information at any time, or have any concerns about the programme or your results, you can contact ..... on .....

Completion of this form

Section A should be completed by the employee.

Section B should be completed by the biological monitoring programme manager.

Note: A signed copy of the form should be held by the employer and employee.

Note: you may need to simplify this form, particularly question 3, to suit individual circumstances

Section A: To be completed by the employee

The purpose of this biological monitoring programme and the actions which might be taken to control my exposure have been explained to me by …… and I …… agree to provide a sample of blood/urine/breath* for the measurement of …… under the following conditions:

1. The sample I provide will **only** be analysed for ……

2. The result of my test will be sent to ……

3. Further access to the results will be restricted to the following persons in the indicated forms:

Person to receive results**	Individual results (not anonymised)	Individual results (anonymised)	Group results (anonymised)

4. I would/would not* like to receive my own result and have it explained to me.

5. I am / am not* willing for my results to be passed to my family practitioner.

Signature of Employee: …… Date: ……

Section B: To be completed by the biological monitoring programme manager

I agree to abide by the above conditions.

Signature of biological monitoring programme manager:

Name (print): …… Date: ……

* Delete as appropriate.

** This box should be completed by the programme manager following discussion and agreement with employees or their representatives. Recipients may be supervisors, employers, health and safety managers, trade union representatives or occupational health staff not involved in running the programme.

Appendix 3: References and further reading

References

1 *General COSHH ACOP and Carcinogens ACOP and Biological Agents ACOP: Control of Substances Hazardous To Health Regulations 1994* L5 (rev) HSE Books ISBN 0 7176 1308 9

2 *EH40: Occupational exposure limits* (lists all current BMGVs, updated annually) EH40/97 1997 HSE Books ISBN 0 7176 1315 1

3 *EH64: Criteria document summaries* (summaries of scientific data available for individual substances) EH64 1995 HSE Books ISBN 0 7176 0883 2

4 *Control of Lead at Work Regulations 1980 (CLAW)* (to be replaced by new lead regulations in 1998) SI 1980/248 1980 HMSO ISBN 0 11 007248 0

5 *Safe working and the prevention of infection in clinical laboratories* HSC's Health Services Advisory Committee 1991 HSE Books ISBN 0 11 885442 9

Further reading

Other relevant information on biological monitoring can be obtained from the following sources:

Biological monitoring in the workplace: Information for employees on its application to chemical exposure INDG245 1997. Available in priced packs of 15 from HSE Books, ISBN 0 7176 1450 6 or as single free copies

Biological monitoring of workers exposed to organophosphorus pesticides MS 17 1987 HSE Books ISBN 0 11 883951 9

Control of lead at work COP2 (rev) 1985 HSE Books ISBN 0 7176 1046 2

Health and Safety (Consultation with Employees) Regulations 1996 SI 1996/1513 1996 HMSO ISBN 0 11 054839 6

Health surveillance under COSHH: Guidance for employers 1990 HSE Books ISBN 0 7176 0491 8

Safety Representatives and Safety Committees Regulations 1977 SI 1977/500 1977 HMSO ISBN 0 11 070500 9

Surveillance of people exposed to health risks at work HSG61 1990 HSE Books ISBN 0 7176 05256

Free leaflets describing the suggested analytical method for substances with BMGVs are available from the Health and Safety Laboratory, Broad Lane, Sheffield S3 7HQ.

Further information

HSE priced and free publications can be viewed online or ordered from www.hse.gov.uk or contact HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165 Fax: 01787 313995. HSE priced publications are also available from bookshops.

For information about health and safety ring HSE's Infoline Tel: 0845 345 0055 Fax: 0845 408 9566 Textphone: 0845 408 9577 e-mail: hse.infoline@natbrit.com or write to HSE Information Services, Caerphilly Business Park, Caerphilly CF83 3GG.

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