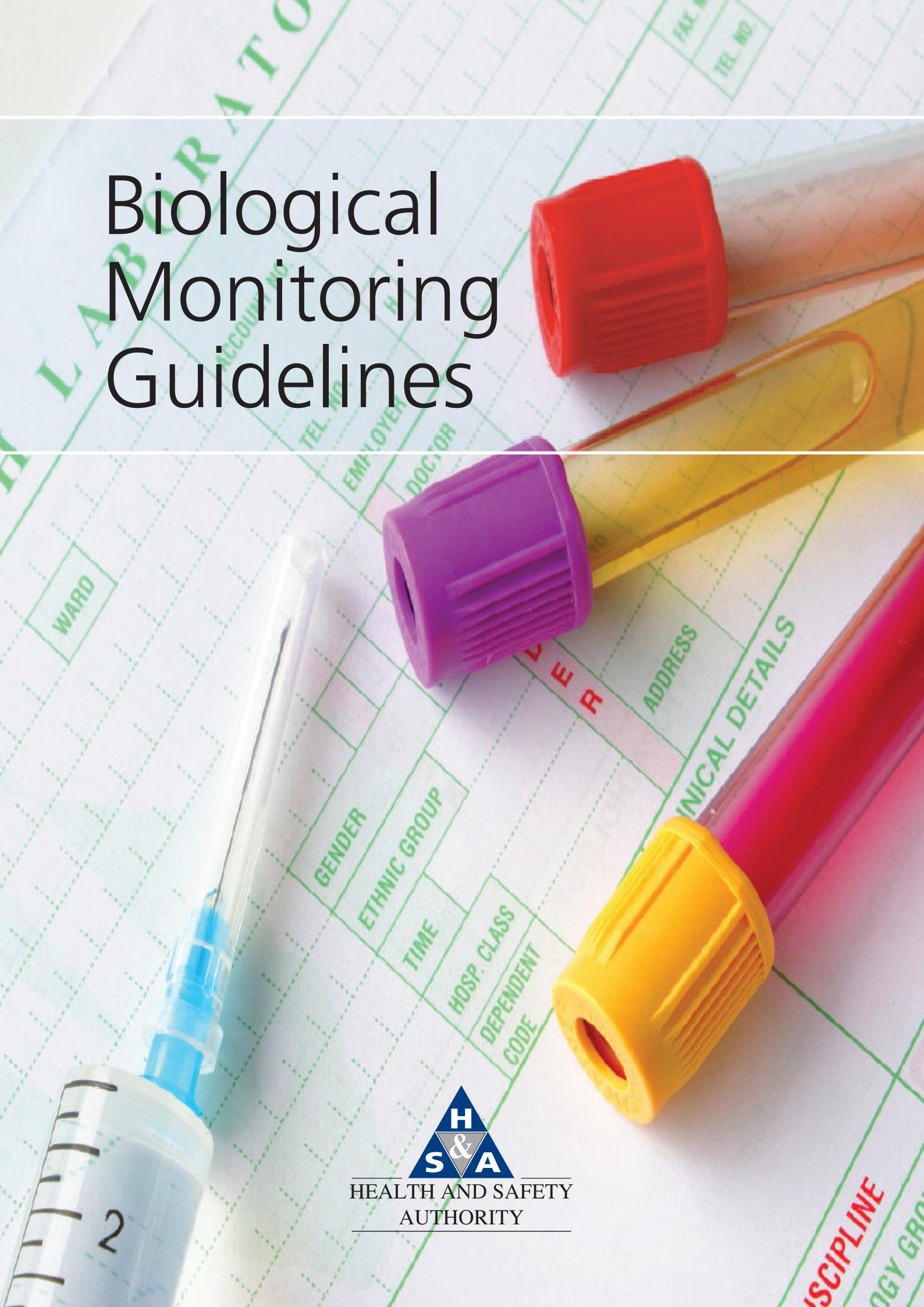
Biological Monitoring Guidelines



HEALTH AND SAFETY AUTHORITY

Our vision:
A national culture where all commit to safe and healthy workplaces and the safe and sustainable management of chemicals

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1.0 Introduction

These guidelines are primarily aimed at employers who are managing a workplace biological monitoring programme. It also aims to explain the process of biological monitoring to employees. Many tasks involve using chemicals which can be harmful to health if they are not properly controlled. The employer must ensure that exposure to chemicals is either prevented, or properly controlled. To do this he or she may need to measure the amount of chemical a person is exposed to. The most common method of determining exposure to chemicals is to measure how much of the chemical is present in the workplace air, in particular, in the employee's breathing zone. However, where there is a particular risk of skin absorption or ingestion of a chemical, biological monitoring for certain chemicals can provide a more precise estimation of exposure.

Biological monitoring in the workplace is an element of **health surveillance** which can be used in the assessment of the risks to health as an integral part of an occupational health and safety programme. Health surveillance is not a substitute for control measures.

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 and an occupational physician should be consulted in setting up a biological monitoring programme, particularly in establishing procedures for reporting results. They should also be available to offer medical interpretation of results.

These guidelines are not intended to be a legal interpretation of the Safety, Health and Welfare at Work (Chemical Agent) Regulations, 2001 (S.I. No. 619 of 2001) or the Safety, Health and Welfare at Work Act, 2005 (S.I. No 10 of 2005) but are issued to support employers to meet their obligation under the above legislation.

2.0 What is Biological Monitoring?

Biological monitoring is a chemical exposure assessment method involving the analysis of blood, urine, hair or exhaled breath samples from workers, for a hazardous substance or its metabolites (breakdown products in the body). It can be used as part of an overall strategy for controlling hazardous chemicals within the workplace, by reducing uncertainty in relation to the effectiveness of control measures in place (e.g. engineering control measures or PPE) and by monitoring work practices.

Biological monitoring data reflects the total absorption of a chemical by an individual through all routes of exposure (inhalation, ingestion, absorption through the skin or a combination of these routes) and thus represents the individual's actual exposure level.

The aim of biological monitoring is to detect hazardous substances in the body ***before*** adverse health effects occur. It is thus aimed to prevent rather than detect adverse changes.
This biological data can therefore provide a better measure of risk than is possible through air/environmental monitoring and is complementary to this.

3.0 What is a Biological Monitoring Guidance Value?

Biological Monitoring Guidance Values (BMGVs) are only available for a limited number of chemicals. BMGVs are used for assessing potential health hazards in the practice of occupational hygiene. They represent the limit of concentration of the particular chemical, its metabolite(s) or an indicator of effect in the appropriate biological medium. The BMGV represents the level most likely to be observed in specimens collected from healthy workers who have been exposed to the chemical through inhalation at the occupational exposure limit value (OELV).

The BMGV indicates a concentration below which nearly all workers should not experience adverse health effects. The BMGV is not intended for use as a measure of adverse effects or for the diagnosis of occupational illness. BMGVs are not an alternative or replacement for airborne OELVs. Biological Monitoring Guidance Values (BMGVs) are thus named to distinguish them from Biological Limit Values which are stated in the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 (see section 4.1).

Biological Monitoring Guidance Values have been sourced primarily from the Scientific Committee on Occupational Exposure Limit Values (SCOEL) which was set up by a Commission Decision (95/320/EC) with the mandate to advise the European Commission on occupational exposure limits for chemicals in the workplace; and also from Biological Indices as issued by the American Conference of Governmental Industrial Hygienists (ACGIH) and the UK Health and Safety Executive.

A table of Biological Monitoring Guidance Values are provided in Appendix 1.

4.0 Legal Requirements

4.1 Legislation

The existence of a BMGV does not necessarily indicate a need to conduct biological monitoring. Biological monitoring is a requirement of the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 where a biological limit value is listed in Schedule 2 or in an approved code of practice (Regulation 10 (3)). This currently only applies to one chemical agent- Lead and its ionic compounds. Where biological monitoring is mandatory employers must ensure that those employees are informed of the requirement to undergo health surveillance before the work commences whereby they may be exposed to that hazardous chemical agent.

4.2 Consent

When health surveillance involves obtaining biological samples, the procedure must be explained and acceptable to the employees concerned (informed consent). It is unethical for an occupational healthcare professional to perform additional tests on the biological specimen other than those specified when taking the sample without the knowledge and consent of the relevant employee. Workers should be informed that the biological monitoring is voluntary and for their benefit, what exposure is being assessed, what sample they will need to provide, what will be analysed in the sample(s) and when the results will be reported. An example of how the consent form may be laid out is provided in Appendix 2.

Employers must maintain an individual health record for each employee who undergoes biological monitoring at his/her place of work.

5.0 Managing a Workplace Biological Monitoring Programme

There are two main purposes of biological monitoring - health surveillance and exposure assessment. A competent person should be responsible for the monitoring programme.

5.1 Sampling

Different strategies/protocols may be used when sampling. Sampling is a critical step and a procedure should be established to avoid contamination of samples and to perform all sampling in a standardised way.

Due to the fact that the concentration of some substances can change rapidly, the specimen sampling time is very important and must be recorded. The different recommended sampling times are specified in Appendix 1. They are determined by the retention times of the chemical within the human body. Measurements are made either on samples of breath, urine, blood or hair or any combination of these depending on the properties of the substance being monitored.

5.2 Accidental Exposures

Biological monitoring can also be used following accidental exposures to hazardous substances, e.g. solvent spillages, especially if measurements of the workplace atmosphere are not available.

5.3 Specimen Acceptability

The World Health Organisation (WHO) in its series of publications Biological Monitoring of Chemical Exposure in the Workplace - Guidelines – includes guidance on sampling and analytical methods for various substances and their metabolites. The World Health Organisation has adopted guidelines for valid urine specimens for occupational monitoring. Specimens must have a creatinine

concentration of >0.3g/L and <3.0g/L or a Specific Gravity of >1.010 and <1.030. Specimens falling outside of these ranges should be discarded, as urine samples that are very dilute or very concentrated are usually not suitable for monitoring. Some BMGVs for chemicals, whose concentration is dependent on urine production levels, are expressed relative to creatinine concentration to correct for variable dilutions in spot samples, as urine concentration can vary widely due to changes in fluid intakes and fluid losses through sweating for example. Urinary biological monitoring is not suitable for individuals with renal disease.

In relation to exhaled breath specimens, these must be taken in an area free from of the chemical being measured.

5.4 Quality Assurance

All aspects of a biological monitoring program should be subject to a quality assurance programme. Due to the variable nature of concentrations in biological specimens, dependence should not be placed on the results of one single specimen. Action should be based on the results of multiple sampling. All analytical testing should be carried out by an appropriately accredited laboratory. The transportation and storage of samples prior to sending to the laboratory should be outlined in a protocol or procedure, as samples may require preservation e.g. at low temperatures prior to analysis.

5.5 Results

Biological monitoring results require interpretation by experienced medical practitioners. The results of biological monitoring should be interpreted by a physician or nurse, who has the ability to take into account the individual's physiology, health status and lifestyle.

They are used to assist the occupational health professional to detect exposure to the chemical agent and to determine the extent of absorption through the skin, gastro-intestinal system or by inhalation to assess overall body burden. Absorption via skin or by ingestion in particular can only be estimated by biological monitoring.

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

As with all monitoring, following the interpretation of the results, it may be necessary to re-evaluate the risk assessment and the control measures in place, take appropriate action and re-evaluate the improvements. These actions should be done in a reasonable time frame.

Appendix 1

Appendix 1: Table of Biological Monitoring Guidance Values

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Acetone	67-64-1	50mg acetone/L urine	ACGIH	End of shift	Ns
Acetylcholinesterase inhibiting pesticides	Various	Cholinesterase activity in red blood cells @70% of individual's baseline	ACGIH	Discretionary	Ns
Acrylamide	79-06-1	0.5nmol N-2-carbamoyl-ethyl-valine adduct/ g haemoglobin	SCOEL-SUM-139	Post shift towards the end of working week	Acrylamide is metabolised to form haemoglo-bin adducts
Aniline	62-53-3	0 mg p-aminophenol/L urine	SCOEL/SUM/153	0-2hr after exposure/shift	
Arsenic, elemental and soluble inorganic compounds	7440-38-2	35µg Inorganic As plus methylated metabolites /L urine	ACGIH	End of workweek	B
Benzene	71-43-2	25µg S-Phenylmercap-turic acid/g creatinine **or** 500 µg t,t-Muconic acid/g creatinine	ACGIH	End of shift	B

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
1,3-Butadiene	106-99-0	2.5mg 1,2 dihydroxy-4-(N-acetylcysteinyl)-butane/L urine **or** 2.5pmol mixture of N-1 and N-2-(hydroxybutenyl) valine haemoglobin adducts/g Hb	ACGIH	End of shift, Not critical	B, Sq
Butan-2-one	78-93-3	70µmol butan-2- one/L urine	HSE	Post shift	
2-Butoxyethanol	111-76-2	200mg BAA/ g creatinine	ACGIH	End of shift	
Cadmium and its inorganic compounds	7440-43-9	2µg Cd/g creatinine	SCOEL/SUM/136	Not critical	
Carbon Disulphide	75-15-0	1.5mg TTCA/g creatinine	SCOEL/SUM/82	End of Shift	TTCA= metabolite 2-thiothiazolidine-4-carboxylic acid

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Carbon monoxide	630-08-0	20ppm CO in end-exhaled air **or** 3.5%COHb of haemoglobin	ACGIH	End of Shift	
Chlorobenzene	108-90-7	100mg 4-chlorocatechol **or** 20mg p-Chlorophenol /g creatinine	ACGIH	End of shift at end of workweek	Ns
Chromium VI and water soluble compounds	7440-47-3	25µg total chromium/L urine **or** 10µg total chromium increase during shift/L urine	ACGIH	End of shift at end of workweek	
Cobalt	7440-48-4	15µg/L urine or 1µg/L blood	ACGIH	End of shift at end of workweek	B Sq
Cyclohexanone	108-94-1	8mg cyclohexanol/L urine or 80mg 1,2-Cyclohexanediol/L urine	ACGIH	End of shift	Cyclohexanol= metabolite Ns
4, 4-Diaminodiphenyl-methane	101-77-9	1µg/L urine	SCOEL/SUM/107		

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Dichloromethane/ Methylene Chloride	75-09-2	4% COHb; [0.3mg methylene chloride/L urine or 1mg methylene chloride/L blood]	SCOEL/SUM/130	Measure @ end of shift	COHb Limit may be exceeded in heavy smokers Sq
N,N-Dimethylac-etamide	127-19-5	30mg N-methylac-etamide/g creatinine	ACGIH	End of shift at end of workweek	
N,N-Dimethylfor-mamide	68-12-2	15mg N-methylfor-mamide/L urine	SCOEL/SUM/121	Post shift	
2-Ethyoxyethanol and 2-Ethoxyethyl acetate	110-80-5 111-15-9	50mg 2-ethoxyacetic acid/L urine (40mg 2-ethoxyacetic acid/g creatinine)	SCOEL/SUM/116	Measure at end of work week	

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Ethyl benzene	100-41-4	0.7g mandelic acid and phenylglyoxylic acid/g creatinine or Ethylbenzene in end-exhaled air	ACGIH	End of shift at end of workweek Not critical	Ns, Sq Sq
Fluorine, Hydrogen Fluoride and Inorganic Fluorides (not uranium hexafluoride)	109-86-4	2mg Fluoride/L urine 3mg Fluoride/L urine	ACGIH	Prior to shift End of shift	B, Ns
Furfural	98-01-1	200mg Furoic acid/L urine	ACGIH	End of shift	Ns
Glycerol trinitrate	55-63-0	15 µmol total nitroglycols/mol creatinine	HSE	At end of the period of exposure	
Hexane	110-54-3	0.4mg 2,5-Hexanedion/L urine	ACGIH	End of shift at end of workweek	
Isocyanates	Various	1 µmol urinary diamine/mol creatinine	HSE	Post task	

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Lead	**7439-92-1**	**Binding Limit Value (BLV): 70µg Pb/100ml blood; health surveillance carried out if a blood-lead level >40µg Pb/100ml blood is measured in individual employees Note lower SCOEL recommendation of: 30µg Pb/100ml blood**	**Safety, Health and Welfare at Work (Chemical Agents) Regulations SCOEL/SUM/83**	**Not critical**	**Mandatory monitoring required as per SHWW Chemical Agents Regulations for BLV**
Lindane	58-89-9	35nmol/L (10µg Lindane/L) in whole blood (equivalent to 70nmol/L of lindane in plasma)	HSE	End of shift or pre-shift	
Mercury	7439-97-6	10µg Hg/L blood or 30µg Hg/g creatinine	SCOEL/SUM/84		
Methanol	67-56-1	15mg methanol/L urine	ACGIH	End of shift	B, Ns
Methaemoglobin inducers		1.5% of haemoglobin as methaemoglobin in blood	ACGIH	During or end of shift	B, Ns, Sq
2-Methoxyethanol and 2-Methoxyethyl Acetate	109-86-4 110-49-6	8mg MAA/ g creatinine	SCOEL/SUM/120	Sampled @ end of work week after @ least two weeks work	MAA=Methoxy-acetic acid (Metabolite)

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Methyl n-butyl ketone	591-78-6	0.4mg 2,5 Hexanedione/L urine	ACGIH	End of shift at end of work week	
Methyl chloroform	71-55-6	40ppm methyl chloroform in end-exhaled air **or** 10mg TCA/L urine **or** 30mg trichloroethanol/L urine **or**1mg trichloroethanol/L blood	ACGIH	Prior to last shift of workweek End of Workweek-End of shift @end of workweek End of shift @end of workweek	TCA=Trichloroacetic acid (Metabolite) Ns, Sq Ns, Sq Ns
MbOCA 4,4'-methylene bis (2-chloroaniline)/2,2' dichloro-4,4' methylene dianiline	101-14-4	15µmol total MbOCA/mol creatinine	HSE	Post Shift	
Methyl isobutyl ketone (MIBK)/ 4-methylpentan-2-one	108-10-1	1mg MIBK/L urine	ACGIH	End of shift	

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
N-Methyl-2-Pyrrolidone	872-50-4	20mg 2-HMSI/g creatinine or 70mg 5-HNMP /g creatinine	SCOEL/SUM/119	End of shift	2-HMSI measured morning after shift (8hrs) or 5-HNMP measured 2-4hrs after the end of the shift
4,4'-Methylenedianiline (MDA)	101-77-9	50µmol total MDA/mol creatinine	HSE	Post shift for inhalation and pre-shift next day for dermal exposure	
Nickel	7440-02-0 and others	3µg Ni/L urine	SCOEL/SUM/85	After several consecutive working shifts	
Nitrobenzene	98-95-3	5mg p-nitrophenol/g creatinine or 1.5% of haemoglobin as methaemoglobin	ACGIH	End of shift at end of workweek End of shift	Ns B, Ns, Sq
Parathion	56-38-2	0.5mg p-nitrophenol /g creatinine or 70% cholinesterase activity in red blood cells from baseline	ACGIH	End of shift Discretionary	Ns B,Ns, Sq

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Pentachlorophenol	87-86-5	2mg Total PCP/g creatinine **or** 5mg Free PCP/L plasma	ACGIH	Prior to last shift of workweek	B
Phenol	108-95-2	120mg phenol/g creatinine	SCOEL/SUM/16	End of shift	8hr exposure to 2ppm phenol corresponds to an end of shift urine conc. of 120mg
Polycyclic aromatic hydrocarbons		4 µmol 1-hydroxypyrene/ mol creatinine	HSE	Post shift	
2-Propanol	67-63-0	40mg Acetone /L urine	ACGIH	End of shift at end of workweek	B, Ns
Propylene Oxide	75-56-9	3 nmol N-(3-hydroxypropyl) valine/g globin in blood haemoglobin	SCOEL/SUM/161		
Styrene	100-42-5	400mg mandelic acid plus phenylglyoxylic acid/g creatinine **or** 0.2mg styrene/L venous blood	ACGIH	End of shift	Ns Sq

Substance	CAS Number	BMGV	Source (ACGIH/SCOEL/HSE)	Sampling Time	Notes
Tetrachloroethylene	127-18-4	0.4mg tetrachloroethylene/L blood **or** 3ppm/0.435 mg TCE /m3 end-exhaled air	SCOEL/SUM/133	Prior to the last shift of a working week	
Tetrahydrofuran	109-99-9	2mg THF/L urine	ACGIH	End of shift	
Toluene	108-88-3	0.02mg toluene/L blood **or** 0.03mg toluene/L urine **or** 0.3mg o-cresol/g creatinine	ACGIH	Prior to last shift of workweek End of shift End of shift	B
Trichloroethylene	79-01-6	20mg TCA/L urine	SCOEL/SUM/142	By the end of the last shift of a workweek/shift period	
Xylene	1330-20-7	1.5g methylhippuric acids/g creatinine	ACGIH	End of Shift	

Notes:

Prior to Shift	Before shift commences and16 hours after possible previous exposure ceases
During shift	Anytime after two hours of exposure
End of shift	As soon as possible after exposure ceases
End of the workweek	After 4 or 5 consecutive working days with exposure
Discretionary	At any time

B **Background,** the analyte may be present in biological specimens collected from individuals who have not been occupationally exposed, at a concentration which could affect interpretation of the result. Such background concentrations are incorporated into the BEI value.

Nq **Non-quantitative,** biological monitoring should be considered for the substance based on the review; however, a specific BEI was not determined due to insufficient data

Ns **Non-specific,** the analyte is nonspecific, since it is also observed after exposure to other chemicals

Sq **Semi-quantitative**, the biological analyte is an indicator of exposure to the substance but the quantitative interpretation of the measurement is ambiguous. These analytes should be used as a screening test if a quantitative test is not practical; or as a confirmatory test if the quantitative test is not specific and the origin of the determinant is in question.

Appendix 2: Sample Consent Form

As your employer I must identify any risks to your health and ensure they are adequately controlled. To ensure that the risks are properly controlled I may need to carry out biological monitoring to measure to what extent you have been exposed to a hazardous substance. This may involve analysing samples of your blood, urine or exhaled breath.

The substance being measured is: .....

The results will help us to determine whether exposure to this hazardous substance has been controlled adequately and therefore whether further controls are required. You will be offered a copy of your results. If it is recommended that your family doctor be informed of the results, your permission will be sought before any information is passed on.

Further information may be obtained from:..... Ext:.....

To be completed by the employee:
The purpose of the monitoring has been explained to me and I understand the purpose of the programme.

I, ... agree to provide a sample of blood/urine/breath*, providing:

- The sample will only be analysed for .....
- The results will be sent to .....
- Access to the results will be restricted to.....
- The data can be stored electronically

I would/would not* like to receive the results and an accompanying explanation.
I am/am not* willing for the results to be sent to my family doctor.

Signature of employee: .....

Name (print): .....

Date: .....

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 applicable

Appendix 3: Conversion Table

FROM	TO	CONVERSION
mg/l	mmol/l	÷MW
mmol/l	mg/l	X MW
µg/l	nmol/l	X 1000 ÷MW
nmol/l	µg/l	X MW ÷1000
µmol/l	µg/100ml	X MW ÷10
nmol/l	µmol/mol creatinine*	÷12
µg/l	µmol/mol creatinine*	÷MW X 83
µg/g creatinine	µmol/mol creatinine	÷MW X 113
µmol/mol creatinine	µg/l*	X MW ÷83
mmol/mol creatinine	mg/l*	X MW÷83

MW= Molecular Weight

*= These are approximations

Note 1: 1 litre of urine contains approximately 1.36g of creatinine and this is equivalent to 12.02 mmol creatinine and the Molecular Weight of creatinine=113.1

Note 2: This table can assist with converting published data but should not be used for direct numerical conversion in reporting data

Appendix 4: Glossary

ACGIH American Conference of Governmental Industrial Hygienists

BMGV Biological Monitoring Guidance Value

SCOEL Scientific Committee on Occupational Exposure Limits

Further Information

American Conference of Governmental Industrial Hygienists (2011), TLVs and BEIs

British Occupational Hygiene Society-Technical Guide No. 9 (1994) Biological Monitoring Reference Data

Health and Safety Executive, UK HSG 167 (1997) Biological Monitoring in the Workplace. (Online). Available from: http://www.hse.gov.uk/

Health and Safety Executive, UK HSG 173 (2006) Monitoring Strategies for Toxic Substances. (Online) Available from: http://www.hse.gov.uk/

Health and Safety Laboratory-UK Guidance sheets available for various substances on biological monitoring guidance values

Health and Safety Laboratory-UK, Guidance on Laboratory Techniques in Occupational Medicine (11th Edition) (2009)

World Health Organisation, Biological Monitoring of Chemical Exposure in the Workplace: Guidelines (Volume 1 & 2) (1997) Geneva: World Health Organisation (Online) http://www.who.int

European Centre for Ecology and Toxicology Guidance for the interpretation of biomonitoring data. Document No.44, Brussels (2005) (Online).
Available from: http://www.ecetoc.org/technical-documents

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