ANNEXURE 4
HAZARDOUS CHEMICAL AGENT GUIDELINES

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Prevention and control of exposure

1. The advice in this document should be taken in the context of the requirements of the Regulations for HCA, especially regulation 10 (Hazardous Chemical Agent Risk Assessment), regulation 11 (Prevention or Control of Exposure to and hazardous chemical agent [HCA]), regulation 12 (Use, Maintenance, Examination and Testing of Control Measures) and regulation 13 (Exposure Monitoring of HCA). Agents hazardous to health are defined in regulation 1 and Annexure 1. There are separate regulations for both lead and asbestos. These agents are not covered in detail in this document. This document also does not apply to exposure in mines or exposure to hazardous biological agents.
2. Exposure of employees to agents hazardous to health should be prevented or, where this is not reasonably practicable, adequately controlled. This is a fundamental requirement of the Regulations for Hazardous Chemical Agents (HCA), 202X. Exposure can occur by inhalation, ingestion or absorption through the skin, but inhalation is usually the main route of entry into the body. Tables 2 and 3 of Annexure 2 list the OELs, which should be used in determining the adequacy of control of exposure by inhalation, as required by the Regulations for HCAs.
3. Adequate control of exposure, (when prevention is not reasonably practicable) should be achieved by one or more of a range of control measures described in regulation 11. Control measures should follow the hierarchy of control as per regulation 11.

Globally Harmonised System (GHS)

4. The UN GHS Purple Book is updated biennially (every 2 years) by the United Nations Sub-committee on GHS. In order for importers and manufacturers in South Africa to transition to updated revisions of the GHS Purple Book, a “phase-in” period is granted. New revisions of the

GHS Purple Book have a 2-year phase-in from the date the changes are approved by the UN Sub-committee (not published) to the date applicable. The "phase–in" period for South African Industry for a new revision, is 2 years and 6 months, after approval by the UN GHS Sub-committee, until 30 June of the applicable year.

Table 1: Phase-in timeframes for GHS Purple Book new revisions

Approved by UN GHS Subcommittee	Published by UN	Transition cut-off date for South Africa
Revision 10 of the GHS December 2022	July 2023	June 2025
e.g Revision 11 of the GHS December 2024	July 2025	June 2027
e.g Revision 12 of the GHS December 2026	July 2027	June 2029*
*Follow illustrated timeframe for future implementation		

5. Expert judgement on human case reports must guide use of classification for corrosive agents if irreversible damage to the skin was observed.
6. In the case of respiratory or skin sensitizers, subcategories may be applied where sufficient data is available.
7. The GHS requirements for classification, labelling and SDSs are not applicable to low level pesticide residue in foodstuffs, cosmetics or pharmaceuticals in their final form.
8. Hazard classes and categories provided in Table 3 for Environmental Hazards, in Annexure 1, are intended as a guideline only for the classification of chemical agents.

GHS Labelling

9. On any label of an HCA, the pictogram size must be at least 16 mm x 16 mm where practicable, with a red border and minimum letter size of 1,2 mm. For further guidance on labelling refer to the European Chemicals Agency (ECHA), Guidance on labelling and packaging in accordance with Regulation (EC) N^{o}. 1272/2008, as may be updated from time to time.
10. GHS pictograms on hazardous chemical agents not intended for export, may be provided with black and white pictograms, otherwise the diamond frame of the pictogram must be in red.
11. The inclusion of all ingredients or elements of an alloy that contribute to the hazard of the mixture or alloy, should be included on the label.
12. Where a mixture is supplied exclusively for workplace use, the chemical identities may only be provided on the SDS for the chemical. All pictograms for physical hazards must be used where a substance or mixture is supplied exclusively for workplace use.
13. Where the packaging of a substance or a mixture is either in such a shape or form or is so small that it is impossible to provide all elements on the labelling, the following minimum information must be provided; product identifier, signal word, name plus telephone number of suppliers and hazard pictogram.
14. The GHS label for HCA at the workplace must be maintained on the supplied container in the workplace.

Special labelling arrangements

15. The communication of hazard information must be provided for carcinogens, reproductive toxicity and specific target organ toxicity (STOT) through repeated exposure, on the label and on

the SDS. For metals and alloys, communication of the hazard information may be provided through the SDS alone when supplied in the massive, non-dispersible, form.

16. Where a substance or mixture is classified as corrosive to metals but not corrosive to skin and/or eyes, the hazard pictogram linked to "corrosive to metals" must be provided on the label of such substances or mixtures which are packed in its finished state.

Additional SDS (safety data sheet) considerations

17. An SDS should be developed for mixtures which are not classified for acute toxicity or aquatic toxicity as a result of the application of the additivity formula, but which contain acutely toxic or toxic to the aquatic environment ingredients, in concentrations equal to or greater than 1 .
18. None of the 16 SDS headings /sections, except heading 16 (other information), may be left without text. Where information is not applicable or not available this should be indicated, thereby confirming that this information is either not applicable or not available.

Cut-off values for GHS

19. The term "cut-off" values are used and can also mean concentration limits. Generic cut-off values adopted in the UN GHS, apply. If a manufactures/classifier has information that the hazard of an ingredient will be evident below the generic cut-off, the mixture containing that ingredient must be classified accordingly.
20. An SDS must be provided based on the generic cut-off values in Table 2 of this guide. *(Table 1.5.1 in the UN GHS Purple book).*

Table 2: Generic cut-off values for health and environmental hazard class

Hazard class	Cut-off value
Acute toxicity	≥ 1.0 %
Skin corrosion/Irritations	≥ 1.0 %
Serious eye damage/eye irritation	≥ 1.0 %
Respiratory/Skin sensitization	≥ 0.1 %
Germ cell mutagenicity (Cat1)	≥ 0.1 %
Germ cell mutagenicity (Cat2)	≥ 1.0 %
Carcinogenicity	≥ 0.1 %
Reproductive toxicity	≥ 0.1 %
Specific target organ toxicity (Single exposure)	≥ 1.0 %
Specific target organ toxicity (Repeated exposure)	≥ 1.0 %
Aspiration Hazard (Cat 1)	≥ 1.0 %
Aspiration Hazard (Cat 2)	≥ 1.0 %
Hazardous to the aquatic environment	≥ 1.0 % (Guideline)

Precautionary statements

21. The GHS label should include appropriate precautionary statements, the choice of which is with the manufacturer/ labeller. General precautionary statements not linked to a certain hazard class or category shall also be used where relevant. Precautionary statements that appear on labels or in safety data sheets may incorporate minor textual variations if these variations assist in communicating safety information and do not compromise the information. These may include spelling variations or use of synonyms.

Cross reference between carcinogenic classification systems

22. The Regulations for Hazardous Chemical Agents uses the GHS carcinogenic classification as notations in the Tables in Annexure 2. Table 3 below provides a "read-across" to the classification systems of International Agency for Research on Cancer (IARC) and the American Conference of Governmental Industrial Hygienists (ACGIH).

Table 3: Approximate equivalences between carcinogenic classification systems

GHS	IARC	ACGIH
Category 1A	Group 1	A1
Category 1B	Group 2A	A2
Category 2	Group 2B	A3
	Group 3	A3
	Group 4	A5

23. Health hazards: Category 1 (skin corrosion) can be further divided into three sub-categories namely, 1A, 1B and 1C.

UN number and proper shipping name

24. The UN Number is a 4-digit number assigned to a specific chemical or article, or group of chemicals or articles, which can be found in the Dangerous Goods List (DGL) Chapter 3.2 of Volume I of the UN Transport of Dangerous Goods Orange book. Each UN number has a corresponding Proper Shipping Name – (PSN). The UN PSN is the standard technical name to describe the hazard properties and the composition of dangerous goods. Select the UN number (4 digits) and a proper shipping name from the UN Transport of Dangerous Goods, Dangerous Goods List that can most accurately describe the dangerous goods. The UN number and a proper shipping name should also be included in the Dangerous Goods Declaration and section 14 of the SDS.

GHS Competent Authorities

25. South African GHS Competent Authorities other than the Department of Employment and Labour;
    - Department of Forestry, Fisheries and the Environment: Environment House, Cnr. Steve Biko and Soutpansberg Road, Arcadia, Pretoria, South Africa e-mail: callcentre@environment.gov.za
    - Department of Agriculture, Land Reform and Rural Development: 20 Steve Biko (formerly Beatrix) Street, Arcadia, Pretoria. e-mail queries@dalrrd.gov.za
    - Department of Health: Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, South Africa. e-mail: healthhotline@health.gov.za

Exposure in mines

26. The Regulations for HCAs and the OELs in this publication do not apply to exposure to agents hazardous to health in mines where the Department of Mineral Resources and Energy has mandate.

Lead and asbestos

27. Work with asbestos or lead is not subject to the Regulations for HCA. The exposure limits for various types of asbestos and lead are specified in the Asbestos Abatement Regulations and the Lead Regulations.

Constitution of Similar Exposure Groups (SEGs)

28. In practice it is usually not possible to measure the exposure of each employee during each working day. To obtain quantitative data on exposure measurements that allows assessment for compliance with OEL's, an effective approach shall be taken that allows the most efficient use of resources. This approach, based on the observation of working conditions, permits measurement of exposure of a small number of employees belonging to an SEG for comparison with OEL's. Where exposure measurements on monitored employees of the SEG indicate that the OEL's are met, then it is considered that this is so for all employees in the SEG.

29. The SEG shall be constituted with information on the profile of exposure and duration of the tasks performed during the working shifts throughout the year. This requires occupational hygiene expertise. The information should include at least the following:
    (a) company industry sector;
    (b) the job classification of the SEG;
    (c) the inventory of tasks within a job;
    (d) the task specific exposure profile;
    (e) the duration and location of the exposure within the shift;
    (f) exposure history determined by the frequency and period of the tasks;
    (g) experience of the workforce.

30. For an SEG which is constituted by one employee, that employee's exposure is monitored in the same manner as a SEG, constituted by more than one employee.

Background to occupational exposure limits

31. Two types of OELs are defined in the Regulations for HCAs. These are OEL - Maximum Limit (OEL-ML) and OEL - Restricted Limit (OEL-RL), as listed in Tables 2 and 3 of Annexure 2.
32. There is no fixed timeframe for the update and publication of new or revised OELs or BEIs.
33. The lists of OELs given in Table 2 and Table 3 of Annexure 2, unless otherwise stated, relate to personal exposure to agents hazardous to health in the air of the workplace.

Setting occupational exposure limits

34. OEL-MLs and OEL-RLs are proposed by the Standing Technical Committee No. 7, (TC7). The OELs proposed by TC7 are reviewed by the Chief Inspector, approved by the Advisory Council for Occupational Health and Safety and promulgated by the Minister.
35. For both OEL-MLs and OEL-RLs, as listed in Tables 2 and 3 of Annexure 2, the intent is to provide a level of minimum protection for all employees within the mandate of the Department of Employment and Labour.
36. An OEL-ML is typically assigned to an agent with serious adverse implications for the health of employees exposed to the agent. Such effects are related to an agent being a carcinogen, sensitiser, teratogen or mutagen. However, those with lower orders of potency may not necessarily be assigned an OEL-ML.
37. The American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs) represent a scientific opinion, which are health-based values where exposure at these limits does not create an unreasonable risk of disease or injury. The TLVs and BEIs are established by committees that review existing published and peer

reviewed literature in various scientific disciplines. These disciplines include occupational hygiene, toxicology, occupational medicine and epidemiology.

38. The primary method for setting an OEL is to double the ACGIH TLV. This provides a uniform and systematic method that considers the principle of reasonably practicable, including both health risk and socio-economic impacts. Guideline values such as the ACGIH TLVs and NIOSH RELs consider only health risk and not socio-economic impacts, so it follows that these are not comparable to the OEL-ML and OEL-RL.
39. For exposure to agents that are predominantly associated with mining operations, consideration where practicable, will be given to align OEL-MLs and OEL-RLs with the Department of Mineral Resources and Energy. An example is setting of the OEL for crystalline silica. Whilst consideration has been given to align OEL-ML and OEL-RL values to the Department of Mineral Resources and Energy limits, it may not be practicable to do so, in which case the limits may differ.
40. With the extensive number of OELs and industry processes, it is beyond the resources of TC7 to consider all socio-economic impacts on industry as well as the range of use of the OELs within industry.
41. The final OEL-MLs and OEL-RLs will form a combination of these outcomes.

Units of measurement

42. For OELs, concentrations of gases and vapours in air are usually expressed in parts per million (ppm), a measure of concentration by volume, but may also be expressed in milligrams per cubic metre of air (mg/m^3), a measure of concentration by mass. Concentrations of airborne particles (fume, dust, etc.) are usually expressed in mg/m^3. In the case of airborne particulates, the limits, where applicable, in Annexure 2, Table 2 and Table 3 refer to the inhalable particulate matter, unless specifically indicated as referring to the respirable particulate matter. In the case of synthetic vitreous fibres (man-made mineral fibres), the limit is expressed as fibres per millilitre of air (f/ml).
43. OELs for prohibited agents are not provided, as these agents may not be used within the workplace.

Occupational exposure limit - maximum limit: OEL-ML (Table 2 of Annexure 2)

44. An OEL-ML is the maximum concentration of an airborne agent, averaged over a reference period, to which employees may be exposed by inhalation under any circumstances, and is specified together with the appropriate reference period in Table 2 of Annexure 2.
45. Regulation 11 of the Regulations for HCA, when read in conjunction with the Act, imposes a duty on the employer to take all reasonable precautions and to ensure that exposure is kept as far below an OEL-ML as is reasonably practicable.

Occupational exposure limit - restricted limit: OEL-RL (Table 3 of Annexure 2)

46. An OEL-RL is the concentration of an airborne agent, averaged over a reference period, at which, according to current knowledge, there is no evidence that it is likely to be injurious to employees if they are exposed by inhalation, day after day, to that concentration.
47. Control of a hazardous chemical agent, with an OEL-RL, as prescribed in regulation 11 can always be regarded as adequately controlled as far as exposure from inhalation is concerned. However, due to the variations in process control and fluctuations in agent concentrations in the workplace, it will be prudent for employers to reduce exposure below an OEL-RL to ensure that the exposure of all employees does not exceed that OEL-RL.

48. For an agent which has been assigned an OEL-RL, exposure by inhalation should be reduced to that limit. However, if exposure by inhalation exceeds the OEL-RL, the employer must identify the reasons for the exceedance, provide the appropriate RPE as an interim measure and take appropriate steps to reduce airborne concentrations to levels below the OEL-RL. The risk assessment as contemplated in regulation 10 will determine the urgency of the necessary action, considering the extent, cost and available technology of the required measures in relation to the nature and degree of exposure involved.

8 hour (long-term) and short-term exposure limits

49. Effects of exposure to agents hazardous to health vary considerably depending on the nature of the agent and the pattern of exposure. Some effects require prolonged or accumulated exposure. The long-term (eight-hour TWA) exposure limit is intended to control such effects by restricting the total intake by inhalation over one or more work shifts, depending on the length of the shift. Other effects may be seen after brief exposures. Short-term exposure limits (usually 15 minutes) may be applied to control these effects. For those HCAs without a short-term limit specified, it is recommended that a figure of three times the long-term limit be used as a guideline for controlling short-term peaks in exposure. Some workplace activities give rise to frequent short periods (less than 15 minutes) of elevated exposure which, if averaged over time, should not exceed either an eight-hour TWA or a 15-minute STEL. Such exposures have the potential to cause harm and should be subject to reasonably practicable measures to protect the employee.
50. Ceiling limits are set for HCAs that predominantly have acute effect and whose OELs are more appropriately based on this particular response. HCAs with this type of response are best controlled by a ceiling limit (OEL-C) that should not be exceeded at any time. It is implicit that the manner of sampling to determine non-compliance with the OEL-C for each similar exposure group must differ. Consequently, a single, brief sample that is applicable to an OEL-C is not appropriate for comparison with the OEL-TWA; here a sufficient number of samples are needed to permit determination of a TWA concentration throughout a complete cycle of operation or throughout the work shift. Whereas the OEL-C places a definite boundary that exposure concentrations should not be permitted to exceed, the OEL-TWA requires an explicit limit to the excursions which are acceptable to the promulgated OEL-TWAs. HCAs with ceiling limits are identified in Table 2 and 3 in Annexure 2, in the column "STEL/C", by means of a "C" notation.
51. Both the long-term and short-term exposure limits are expressed as airborne concentrations averaged over a specified period of time. The period for the long-term limit is normally eight hours, when a different period is used, this is stated. The averaging period for the short-term exposure limit (STEL) is normally 15 minutes, such a limit applying to any 15-minute period throughout the working shift. Exposure to agents hazardous to health should be calculated according to the approved method.

Limitations to the application of exposure limits

52. The list of OELs, unless otherwise stated, relates to personal exposure to agents hazardous to health in the air of the workplace. The limits cannot be adapted readily to evaluate or control non-occupational exposure, e.g. levels of contamination in the non-industrial environment. OELs are approved only for application to people at work. Although OELs are developed for atmospheric pressures between 85 kPa and 101,325 kPa, there are areas in South Africa where the atmospheric pressures are below 85 kPa. For practical purposes, uncorrected OELs may be used at atmospheric pressures as low as 80 kPa. Where higher atmospheric pressures may be

encountered, for example, in tunnelling or underwater hyperbaric chambers, such situations will require special assessments. Guidance may be sought in the Health and Safety Executive (HSE) guidance document from the United Kingdom, "Occupational exposure limits for hyperbaric conditions", which is a hazard assessment document.

53. The OELs, as set out in Tables 2 and 3 of Annexure 2, are intended to be used for normal working conditions in workplaces. Employers should also take into account their duties and the provisions of the National Environmental Management Act, 1998 (Act No. 107 of 1998). OELs are not however, designed to deal with serious accidents or emergencies, particularly where employees may be exposed to rapidly rising concentrations of gas, as may arise from a major escape due to plant failure. Over and above their responsibilities to ensure that the requirements of the Regulations for HCAs are met, employers also have a clear responsibility to ensure that the plant is designed, operated and maintained in a way that avoids accidents and emergencies. Where appropriate, detection, alarm and response measures should be used in order to minimise the effect of any such unplanned events. To help maintain adequate operational control, employers may find it helpful to select their own indicators of control when undertaking investigations or corrective action.

Calculation of exposure for specified reference periods

54. The following guidance is provided as an approved method for the calculation of exposure in relation to the eight-hour and short-term reference periods.

The 8-hour reference period

55. The term "8-hour reference period" relates to the procedure whereby the occupational exposures in any 24-hour period are treated as equivalent to a single uniform exposure for eight hours [the 8-hour time weighted average (TWA) exposure].

The eight-hour TWA may be represented mathematically by:

$$\frac{C_1T_1 + C_2T_2 + \ldots C_nT_n}{8}$$

where C_1 is the occupational exposure value (concentration) and T_1 is the associated exposure time in hours in any 24-hour period.

Examples

56. An operator works for 7 hours 20 minutes on a process in which he is exposed to an agent hazardous to health. The average exposure during that period is measured as 0,12 mg/m³. No exposure occurred during the remaining 40 minutes of the shift.

The 8 – hour TWA therefore is calculated as follows:

7h20min (7.33h) at 0.12mg/m^3 and 40min (0.67h) at 0mg/m^3

$$\frac{(0.12 \times 7.33) + (0 \times 0.67)}{8}$$

= 0.11mg/m^3

57. An operator works for eight hours on a process in which he is exposed to an agent hazardous to health. The average exposure during that period is measured as 0,15mg/m³.

The eight-hour TWA therefore is:

$$\frac{0.15 \times 8}{8}$$

$= 0.15 mg/m^2$

58. Working periods may be split into several sessions for the purpose of sampling to take into account e.g. rest and meal breaks. This is illustrated by the following example:

Table 4: Eight hour TWA calculation

Exposure is assumed to be zero during the period 10:30 to 10:45, 12:45 to 13:30 and 15:30 to 15:45.

Working period	Exposure (mg/m³)	Duration of sampling (hrs)
08:00-10:30	0,32	2,5
10:45-12:45	0,07	2
13:30-15:30	0,20	2
15:45-17:15	0,10	1,5

The 8-hour TWA therefore is:

$$\frac{(0.32 \times 2.5) + (0.07 \times 2) + (0.20 \times 2) + (0.10 \times 1.5) + (0 \times 1.25)}{8}$$

$= 0.19 mg/m^3$

59. An employee works for eight hours during the night shift on a process in which he is intermittently exposed to an agent hazardous to health. The employee's work pattern during the working period should be known and the best available data relating to each period of exposure should be applied in calculating the eight-hour TWA. This data should be based on direct measurement, estimates based on data already available or reasonable assumptions.

Table 5: Eight hour TWA calculation

Working period	Task	Exposure (mg/m³)
22:00-24:00	Helping in workshop	0,1 (known to be the exposure of full-time group in the workshop)
24:00-01:00	Cleaning elsewhere in factory	0 (assumed)
01:00-04:00	Working in canteen	0 (assumed)
04:00-06:00	Cleaning up after breakdown in workshop	0,21 (assumed)

The 8-hour TWA therefore is:

$$\frac{(0.10 mg/m^3 \times 2hrs) + (0.21 mg/m^3 \times 2hrs) + (0 mg/m^3 \times 4hrs)}{8}$$

= 0.078 mg/m^3

60. An employee works a 12-hour shift each day for five days, and then has seven days' rest. The exposure limits are based on an eight-hour reference period in each 24 hours in which an exposure occurs; the seven days' rest makes no difference. While at work, the employee is exposed to 4 $mg.m^{-3}$.

$$\frac{(4 \times 12)}{8}$$

The eight-hour TWA = 6 mg/m^3

The short-term reference period

61. Exposure should be recorded as the average over the specified short-term reference period, normally 15 minutes, and should be determined by sampling over that period. For short emissions of less than the reference period, which still may have the potential to cause harm, appropriate action should be taken to ensure that a suitable and sufficient risk assessment is carried out to ensure that there is no risk to health from such exposures.

Example where the short-term reference period is 15 minutes.

Exposure period is less than 15 minutes

62. The sampling result should be averaged over 15 minutes. For example, if a 5-minute sample produces a level of 600 ppm and is immediately followed by a period of zero exposure, then the 15-minute average exposure will be 200 ppm.

Exposure period 15 minutes or longer

63. Measurements should be taken over a 15-minute period and the result is the 15-minute average exposure. Measurements for periods greater than 15 minutes should not be used to calculate a 15-minute average exposure. If the average exposure over the longer period exceeds the 15-minute exposure limit (OEL STEL), then OEL STEL must have been exceeded over some 15-minute period within the longer sampling time period.

Airborne particulates

64. Airborne particulate matter is a mixture of particles and droplets in the air, consisting of a variety of components such as organic compounds, metals, acids, soil and dust. The general approach necessary to control occupational exposure to airborne particulates is as follows: Not all airborne particulates have been assigned OELs, but the lack of such limits should not imply an absence of hazard. In the absence of a specific exposure limit for a particulate, exposure should be reasonably controlled, as defined in the HCA Regulations. Where there is no indication of the need for a lower value, personal exposure to Particulates Not Otherwise Specified (PNOS) should be kept below both 10 mg/m^3, eight-hour time-weighted average for inhalable airborne particulates and 5 mg/m^3, eight-hour time-weighted average for respirable particulates. Such, or greater particulate concentrations should be taken as excessive concentrations.
65. Where airborne particulates contain components which have their own assigned OELs, all the relevant limits should be complied with.

66. The employer may provide respiratory protective equipment as an additional layer of control even when exposure to an HCA is reasonably controlled, with particular consideration given to an HCA with an OEL-ML.

Particle size selective criteria for sampling of total airborne particulates and respirable particulates

Inhalable Particulate Matter

67. Unless specified otherwise, OELs for all airborne particulates (HCAs comprising of airborne particulates) refer to the inhalable particulate matter of that agent. Sampling of these airborne particulates must be carried out with a method specifically designed to collect the inhalable particulate matter of the HCA. Inhalable particulate matter approximates to the particle size fraction of particulates that can be suspended in air, with an upper size limit of approximately 100 micrometres (µm) in aerodynamic diameter.

Respirable particulate matter

68. Respirable particulate matter refers to materials that are hazardous when deposited in the gas exchange region of the lung. Respirable particulates generally have an aerodynamic diameter of less than 10 µm and a median of 4 µm. These materials are sampled with a respirable particulate matter sampler with a median cut point of 4 µm.

Inhalable fraction:

The mass fraction of total airborne particles which is inhaled through the nose and mouth, measured by a size-selective device conforming to a sampling efficiency curve which passes through the points in Table 6 below.

Table 6: Aerodynamic diameter and inhalable fraction

Aerodynamic diameter (µm)	Inhalable fraction (%)
0	100
1	97
2	94
5	87
10	77
20	65
30	58
40	54,5
50	52,5
100	50

Thoracic fraction:

The mass fraction of inhaled particles which penetrate beyond the larynx, measured by a size-selective device conforming to a sampling efficiency curve which passes through the points in the Table 7 below.

Table 7: Aerodynamic diameter and thoracic fraction

Aerodynamic diameter (µm)	Thoracic fraction (%)
0	100

Aerodynamic diameter (µm)	Thoracic fraction (%)
2	94
4	89
6	80,5
8	67
10	50
12	35
14	23
16	15
18	9,5

Respirable fraction:

The mass fraction of inhaled particles which penetrate to the unciliated airways, measured by a size-selective device conforming to a sampling efficiency curve which passes through the points in Table 8 below.

Table 8: Aerodynamic diameter and respirable fraction

Aerodynamic diameter (µm)	Respirable fraction (%)
0	100
1	97
2	91
3	74
4	50
5	30
6	17
7	9
8	5
10	1

Wood dust

69. Wood dust is a general term covering a wide variety of airborne wood dusts. The health effects of wood dust differ between the dust generated from the processing of different species of trees. Specific species of both hard and soft woods induce sensitisation and so the categorisation of woods into hard and soft woods to indicate relative toxicity is not useful. For this reason, OELs are indicated by species and not hard/soft wood categorisation. Oak and beech are listed under Group 1 by the International Agency for Research on Cancer (IARC) and Category 1A (confirmed human carcinogenic potential) by GHS. Birch, mahogany, teak and walnut are listed under Group 2B (IARC) and Category 2, (suspected human carcinogenic potential) by GHS. Reference table 1 of paragraph 7. for further information on the health effects of woods the ACGIH TLVs and BEIs, which provides information on tree species suspected of inducing sensitisation. Dust is generated by the machining and working of wood and wood-containing materials such as chipboard and fibreboard. Operations such as sawing, turning and routing produce relatively coarse dust, while sanding and assembly operations generate fine dust.

Fume

70. The word fume is often used to include gases and vapours. This is not the case for exposure limits where fume should normally be applied to solid particles generated by chemical reactions or condensed from the gaseous state, usually after volatilisation from melted substances. The generation of fume is often accompanied by a chemical reaction such as oxidation or thermal breakdown.

Absorption through the skin

71. In general, for most agents the main route of entry into the body is by inhalation. The OELs given in these regulations relate solely to exposure by this route. Certain agents such as phenol, aniline and certain pesticides have been identified in Tables 2 and 3 of Annexure 2, with a SKIN notation. These HCAs have the ability to penetrate intact skin and thus become absorbed into the body. Absorption through the skin can result from localised contamination, for example, from a splash on the skin, clothing or footwear, or in certain cases from exposure to high atmospheric concentrations of vapour. Serious effects may result with little or no warning; therefore, it is necessary to take special precautions to prevent skin contact when handling these agents. Where the properties of the agents and the methods of use provide a potential exposure route via skin absorption, these factors should be considered in determining reasonably controlled.

    The absorbed dose of skin exposure of agents such as phenol, aniline, and acetone may be monitored in body fluids such as urine or blood. This is known as biological monitoring. Chemical agents with these properties are listed in Table 4 of Annexure 2 with their Biological Exposure Indices.

Sensitisers

72. Certain agents may cause sensitisation of the respiratory tract if inhaled or if skin contact occurs. Respiratory sensitisers can cause asthma, rhinitis or extrinsic allergic alveolitis. Skin sensitisers cause allergic contact dermatitis. Agents which cause skin sensitisations are not necessarily respiratory sensitisers or vice versa. Only a proportion of the exposed population will become sensitised, and those who do become sensitised will not have been identified in advance. Individuals who become sensitised may produce symptoms of ill health even after exposure to minute concentrations of the sensitiser.
73. Exposure to sensitisers should be prevented. Where this cannot be achieved, exposure should be kept as low as is reasonably practicable and activities giving rise to short-term peak-concentrations should receive particular attention. As with other agents, the spread of contamination by sensitisers to other working areas should also be prevented.
74. RSEN and DSEN notations (Tables 2 and 3 of Annexure 2) have been assigned only to those sensitisers that may cause sensitisation by inhalation and skin respectively. Other agents not contained in these Tables may act as sensitisers.

Interaction with physical agents

75. Working conditions which impose additional stress on the body, such as exposure to ultra-violet radiation and high temperatures, pressures and humidity, may increase the toxic response to an agent. In such cases, specialist advice may be necessary to evaluate the effect of these factors.

Mixed exposures

General

76. The majority of OELs listed in Tables 2 and 3 of Annexure 2 are for single compounds or for HCAs containing a common element or radical, e.g. tungsten and compounds, and isocyanates. A few of the limits relate to HCAs commonly encountered as complex mixtures or compounds, e.g., rubber fume, coal tar pitch volatiles and asphalt as petroleum fumes. However, employees are frequently subject to other mixed exposures involving solids, liquids, fumes, aerosols or gases. These exposures can arise as a result of work with materials containing a mixture of agents, or from work with several individual HCAs, simultaneously or successively, in a work shift. Mixed exposures require careful assessment of their health effects and the appropriateness of control standards. The following paragraphs provide a brief summary of the advice on the application of exposure limits in these circumstances. In all cases of doubt, specialist advice should be sought.

Effects of mixed exposures

77. The ways in which the constituent agents of a mixed exposure interact, vary considerably. Some mixed exposures involve agents that act on different body tissues or organs, or by different toxicological mechanisms, these various effects being independent of each other. Other mixtures will include agents that act on the same organs, or by similar mechanisms, so that the effects reinforce each other and the agents are *additive in their effect*. In some cases, the overall effect is considerably greater than the sum of the individual effects and the system *is synergistic*. This may arise from mutual enhancement of the effects of the constituents or because one agent potentiates another, causing it to act in a way which it would not do alone.

Assessment and control

78. With all types of mixed exposures, it is essential that assessments be based on the concentrations of each of the constituents in air to which employees are exposed. Depending on the nature of the constituents and the circumstances of use, the relative concentrations of the constituents in air may differ considerably from those in the liquid or solid source material. The composition of the bulk material should not be relied on for assessment unless there is good evidence for doing so.

(a) Additive agents:

Where there is reason to believe that the effects of the constituents are additive, and where the exposure limits are based on the same health effects, the mixed exposure can be assessed by means of the following formula:

$$E_m = \frac{(C1)}{(OEL1)} + \frac{(C2)}{(OEL2)} + \frac{(Cn...)}{(OELn...}$$

Here E_m is the exposure for the mixture, and C1, C2, etc. are the time-weighted average (TWA) concentrations of constituents in air. OEL1, OEL2, etc. are the corresponding exposure limits. The use of this formula is only applicable where the additive agents have been assigned OELs which relate to the same reference period in the list of promulgated OELs. If the equation generates a result that is > 1, then the exposure limit for the mixture (E_m) has been exceeded. If one of the constituents has been assigned an OEL-ML, and the result is <1, then the additive effect should be taken into account and exposure should be controlled to a ALARP;

***(b) Independent agent**:*

Where no synergistic or additive effects are known or considered likely, the constituents can be regarded as acting independently. It is then sufficient to ensure compliance with each of the OELs individually.

79. The above steps provide basic protocol for assessment of mixed exposures. All non-synergistic systems should be treated as if they were additive. This avoids the need to distinguish between additive and independent systems and can be regarded as the most prudent course, particularly where the toxicity data are scarce or difficult to assess.

Monitoring mixed exposure

80. The number of components of a mixed exposure for which routine air monitoring is required can be reduced if their relative concentrations in air can be shown to be representative. This involves the selection of a key or marker, which may be one of the constituents, as a measure of exposure. Exposure to the marker is controlled at a level selected so that exposures to all components will be assessed in accordance with the criteria in paragraphs 78. However, if one of the components has been assigned an OEL-ML, the level of the exposure to that agent should always be reasonably controlled. If this approach is to be used, it should take place under the guidance of a competent person.

Complicating factors

81. Several factors that complicate the assessment and control of exposure to individual agents will also affect cases of mixed exposures and will require similar special consideration. Such factors include:
    (a) exposure to an agent for which there is no established limit or for which an OEL-ML has been set;
    (b) the relevance of factors such as alcohol, medication, smoking, noise and additional stresses;
    (c) exposure of the skin to one or more agents that can be absorbed by this route, as well as by inhalation; and
    (d) agents in mixture may mutually affect the extent of their absorption, as well as their health effects, at a given level of exposure.

Monitoring exposure by inhalation

82. Aspects such as the frequency of sampling, number of samples to take and percentiles with associated confidence levels (as guided in EN 689 by 5.5.2 Preliminary test and 5.5.3 Statistical test, or guided in AIHA use of an upper 90^{th}, 95^{th} or 99^{th} percentile exposure at a chosen confidence level such as 95% for an SEG), covered in these guidance documents DO NOT override requirements embedded in the regulation. Rather both the percentile and confidence level are embedded in Regulation 13(2)(a) and (b), specifically: "at least three air measurements must be taken for each SEG and if all three air measurement results are below the OEL ML or RL, then it is considered that there is compliance with the limit".

    Percentile and confidence levels are embedded in Regulation 13(2)(a) and (b), specifically: "*at least three air measurements must be taken for each SEG and if all three air measurement results are below the OEL ML or RL, then it is considered that there is compliance with the limit*".

Any aspects of exposure monitoring by inhalation, that are not provided within regulation 13 should be guided by good occupational hygiene practice. There are several documents that provide guidance (not mandatory requirements) on testing compliance with exposure limits and are considered to represent good occupational hygiene practice. These documents include but are not limited to:

(a) EN: 689 Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values

(b) AIHA: A Strategy for Assessing and Managing Occupational Exposures

The frequency of sampling, the number of samples to be taken and the statistical percentiles along with their associated confidence levels, as delineated in these guidance documents, shall not be construed as obligatory mandates under this regulation.

Methods of measurement and calculation for determining fibre concentrations of synthetic vitreous fibre

Refractory ceramic fibre (RCF)

83. RCFs are synthetic vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18% by weight. The term RCF also includes non-oxide ceramic fibres such as boron and silicon carbides and nitrides.

Cotton dust

84. Cotton is the cellulose fibre that grows inside the seed pods (or bolls) of the cotton plant. When mature, the boll breaks and the cotton appears as a soft wad of fine fibres. After picking, the cotton is separated from the seed, packed and compressed into bales.

85. The OELs, which are based on personal sampling, applies to exposure to dust during the handling of raw and waste cotton, including blends containing raw or waste cotton, with the following exceptions:

(a) cotton dust from weaving, knitting, braiding and subsequent processes;

(b) cotton dust from bleached or dyed cotton; and

(c) cotton dust from finished articles, for example, garments.

(*Where the OEL does not apply, exposure should still be adequately controlled*.)

Two OELs apply:

(a) Cotton dust less fly (thoracic fraction); and

(b) Cotton dust inhalable airborne particulate **Cotton dust less fly**

86. Area concentrations of cotton dust less fly must be measured using a vertical elutriator in accordance with OSHA Analytical Method, Appendix A 29 CFR 1910.1043, as updated from time to time.

Cotton dust inhalable airborne particulate

87. Personal exposure concentrations must be measured by means of an Institute of UK Occupational Medicine (IOM) inhalable dust sampler in accordance with MDHS14/3 or any other sampler giving equivalent results, as updated from time to time.

Confined Space entry / Toxicity

88. It is important to note that the presence and accumulation of toxic chemical agents in the form of gases, vapours and fumes, can have serious health effects, including respiratory problems, eye and skin irritation and even death. In addition to the typical confined space safe entry protocols, it is critical to also assess the potential chemical toxicity of a confined space before entry, and to take appropriate measures to prevent employee exposures to hazardous chemical agents. This may include using the appropriate personal protective equipment, sufficient ventilation and air monitoring, to ensure that the atmosphere inside the confined space is safe for entry. The employer must ensure that the appropriate respiratory equipment is worn, that employees have been trained on the hazards associated with confined spaces and the appropriate measures are taken to reduce the risk of chemical toxicity exposure.

Compressed Air

89. Consequences of use of compressed air in the workplace include but are not limited to, causing air embolisms under the skin of employees. The use of compressed may also cause HCA particles to become airborne thereby increasing inhalation exposure.
90. The hazardous chemical agent risk assessment must assess the use of compressed air in the workplace. It is permitted in the workplace to use compressed air to clean equipment that has high operational heat or is difficult to access, where it is not possible to clean the equipment by any other method. Where these specified criteria are met and the risks associated with the use of compressed air have been assessed, recommendations should be made to mitigate risk.
91. No HCA provided with a RSEN (respiratory sensitization) notation may be removed from equipment using compressed air.

Ototoxicant

92. The designation “OTO” for hearing disorders in the “Notations” column highlights the potential for a chemical to cause hearing impairment alone or in combination with noise, even below 85 dBA. The OTO notation is reserved for chemicals that have been shown, through evidence from animals or humans, to adversely affect anatomical structure or auditory function, manifested as a permanent audiometric threshold shift and/or difficulties in processing sounds. Some substances appear to act synergistically with noise, whereas others may potentiate noise effects. The OTO notation is intended to focus attention, not only on engineering controls, administrative controls and PPE needed to reduce airborne concentrations, but also on other means of preventing excessive combined exposures with noise to prevent hearing disorders. Specifically, affected employees may need to be enrolled in hearing conservation and medical surveillance programs to closely monitor auditory capacity, even when noise exposures do not exceed the OEL for Audible Sound.

Pesticides/ Agrochemicals

93. Agents used as active ingredients in pesticides (including herbicides, insecticides and fungicides) and fertilisers are listed under their chemical names and/or their common names. These names may sometimes be used as parts of the names of proprietary pesticide formulations. In all cases, the exposure limit applies to the specific active ingredients and not to the formulation as a whole.

Simple Asphyxiants

94. Some gases and vapours, when present at high concentration in air, act as simple asphyxiants by reducing the oxygen content by dilution or displacement to such an extent that life cannot be supported. Many asphyxiants are odourless, colourless and not readily detectable. Monitoring

the oxygen content of the air is often the best means of ensuring safety. The oxygen content of air in the workplace should never be allowed to fall below a minimum of 19% by volume under normal atmospheric pressure. Particular care is necessary when dense asphyxiants, e.g. argon, are used since very high localised concentrations can arise due to their collecting in pits, confined spaces and other low-lying areas where ventilation is likely to be poor. Additionally, many asphyxiants present a fire or explosion risk. The concentrations at which these risks can arise are likely to be well below those levels at which asphyxiation is likely to occur and should be considered when assessing the hazards.

Chemical asphyxiants

95. In addition to reducing the oxygen content by dilution or displacement to such an extent that life cannot be supported. Chemical asphyxiants can be highly toxic and cause serious health effects, such as respiratory problems, headaches, dizziness, unconsciousness and death. Some chemical asphyxiants are flammable and pose a fire hazard in the presence of an ignition source. Chemical asphyxiants can accumulate in confined spaces, such as tanks, vessels, silos, pipelines, road transport tankers and in particular sewerage systems i.e. manholes, pump stations, sewage tanks and pits wherein hazardous atmospheric conditions are often encountered. Chemical asphyxiants can also have unpredictable reactions with other chemicals and cause hazardous reactions, such as the release of toxic gases. It is important to assess the potential hazards of chemical asphyxiants and to take appropriate measures to reduce the risk of injury or death before entering a confined space.

Rubber fume and rubber process dust

96. Rubber fume is fume evolved in the mixing, milling and blending of natural rubber or synthetic elastomers, or of natural rubber and synthetic polymers combined with chemicals, and in the processes which convert the resultant blends into finished products or parts thereof, and including any inspection procedures where fume continues to be evolved.
97. Rubber process dust is evolved during the manufacture of intermediates or articles from natural rubber and/or synthetic elastomers. This definition does not include dusts, which, for occupational purposes, can be dealt with individually. In each case the relevant OEL will apply.
98. Dust produced by the abrasion of cured rubber should be dealt with as particles (insoluble or poorly soluble) not otherwise specified [PNOS], i.e. dust of any kind when present at a substantial concentration in air.

Flour dust

99. Flour dust is taken to be finely ground particles of cereals or pulses (including contaminants) that result from any grinding process and from any subsequent handling and use of that flour. Any additives (e.g. flour improvers) are included in this definition only after they have been added to the final product mix.
100. Flour dust may contain allergens such as proteins from wheat, rye, barley and other grains. When inhaled, these allergens can trigger an immune response in susceptible individuals, causing inflammation and damage to the respiratory tract. The allergens in flour dust can also cause the release of histamine and other chemicals that can irritate the airways and cause symptoms such as coughing, wheezing and shortness of breath. Over time, repeated exposure to flour dust can result in the development of Baker's lung, a type of occupational lung disease characterized by chronic bronchitis, asthma and fibrosis (scarring) of the lung tissue.

Grain dust

101. Grain dust is taken to be dust arising from the harvesting, drying, handling, storage or processing of barley, wheat, oats, maize and rye, including contaminants.

102. Grain dust can contain various hazardous components, including:
    (a) Allergens: Grain dust can contain proteins from the grain that can trigger an allergic reaction in susceptible individuals, causing symptoms such as itching, sneezing and runny nose.
    (b) Microorganisms: Grain dust can contain mould spores, yeast and bacteria that can cause respiratory infections and other health problems.
    (c) Toxins: Some strains of mould that are commonly found in grain dust can produce toxic substances such as mycotoxins that can pose serious health risk if inhaled or ingested.
    (d) Dust particles: The dust particles in grain dust can irritate the respiratory tract and cause symptoms such as coughing, wheezing, and shortness of breath. Over time, repeated exposure to grain dust can result in the development of occupational lung diseases, such as Farmer's lung.

Halogeno-platinum compounds

103. These are co-ordination compounds in which a platinum atom or ion is directly co-ordinated to one or more halide (i.e. fluoride, chloride, bromide or iodide) ions. These compounds are subject to an OEL and cause sensitisation.

104. For substances which, although they contain platinum and halide ions, the halogen is not directly co-coordinated by a chemical bond to the platinum, the OEL for soluble platinum compounds is applicable.

Welding Fumes and gases

105. Welding fumes and gases are by-products produced during the welding process. Welding fumes are tiny particles that are generated when the metal is heated and volatilised. They then condense in the air as very fine solid particles. Welding gases on the other hand, are gaseous by-products such as toxic oxides of nitrogen, ozone and carbon monoxide. Both welding fumes and gases could pose serious health risks to employees if they are inhaled in high concentrations over a prolonged period. The composition of welding fumes and gases may vary depending on the type of metal being used for welding and the type of metal being welded.

Silicosis Elimination Plan

106. A documented silicosis elimination plan outlines the employer’s commitment to silicosis elimination and must include at least the role and responsibilities of the following stakeholders in the elimination of silicosis; the employer, employees, OHS representatives and committees, suppliers, manufacturers and approved inspection authorities. Timeframes for the assessment, monitoring, reporting, control and reduction or elimination of crystalline silica exposure must be indicated.

Medical surveillance, medical screening and biological monitoring

Medical screening

107. Medical screening and medical surveillance are two fundamental strategies for optimizing employee health. Although the terms are often incorrectly used interchangeably, they are quite

distinct concepts. Medical screening is only one component of a comprehensive medical surveillance program. It focuses on the individual worker and may consist of a detailed personal and work history, physical exam, and any number of tests such as blood tests, radiological imaging, pulmonary function tests (spirometry), and more. It is performed prior to employment and periodically during employment. It provides a snapshot in time which may be useful in identifying potential health effects of an employee potentially exposed to a known workplace hazard before the employee even exhibits any symptoms or has any idea that there may be an issue. The fundamental purpose of screening is early diagnosis and intervention for the individual and thus has a clinical focus.

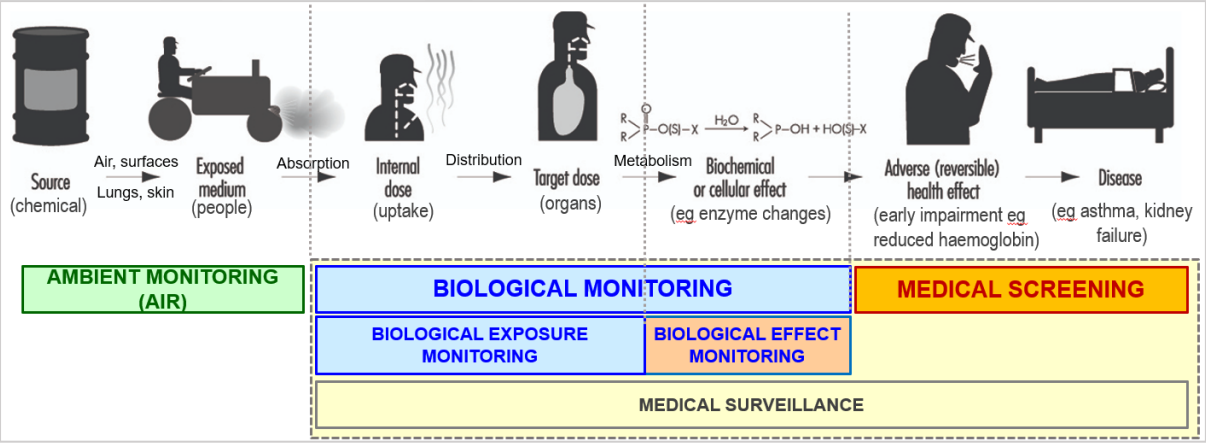
108. Medical surveillance refers to the overall monitoring of employees to identify changes in their health status because of exposure to chemical agents. Monitoring activities are not limited to only medical testing, but also importantly include the monitoring and analysis of the individual and group outcome data, including historical data, derived from the medical testing.

Medical surveillance

109. Medical surveillance is a broader activity, and its focus is on the entire group, not just the individual. It is a systemic process of collecting health information (such as the outcomes of medical screening in conjunction with outcomes of risk assessments and exposure monitoring) over time, and this information is used to analyse trends in work groups. Review of group results helps to identify potential problem areas and the effectiveness of existing worksite preventive strategies and controls. Thus, medical surveillance serves as a feedback loop to the employer. Not only is medical surveillance useful in evaluating known exposures, but it can be critical in identifying new and emerging trends in the workplace. The fundamental purpose of surveillance is to detect and eliminate the underlying hazards or exposures of any discovered trends and thus has a prevention focus.

110. This information is included in this section only to highlight the relationship between biological monitoring, medical screening and medical surveillance.

Figure 1: The relationship between biological monitoring, medical screening and medical surveillance.



Source: https://www.iloencyclopaedia.org/part-iv-66769/biological-monitoring-65407.

111. From figure 1 above, the following important features are evident:

(a) Biological monitoring comprises two categories of tests; biological exposure monitoring which estimates the absorbed or target organ dose of a HCA, and biological effect monitoring which estimates the earliest biochemical effects of exposure to an HCA.

Biological monitoring therefore provides an additional means to assess the exposure to an HCA; it does not represent an adverse health effect or an occupational disease.

(b) Medical screening aims to identify adverse effects of exposure, from the earliest signs of impaired function or structural damage, to established disease.

(c) Medical surveillance includes the evaluation of the outcomes of all biological monitoring as well as medical screening.

(d) The distinction between early biological effects and established disease is not always clear, there tends to be a severity gradient in which biological effects blend into established disease. An occupational disease is present when the adverse biological effect progresses to clinically detectable organ damage requiring treatment or permanent impaired function. The categorisation of the condition is at the discretion of the occupational medicine practitioner.

(e) The decision to categorise an outcome as a disease has important statutory implications because in terms of Section 25 of the Occupational Health and Safety Act, 85 of 1993 as amended and Compensation for Occupational Injuries and Diseases Amendment Act, N^{o}. 10 of 2022, all occupational diseases must be reported by the medical practitioner to the Chief Inspector.

112. The presence of chemical agents in the workplace does not automatically require medical screening to be carried out. Certain criteria must be met for medical screening to be necessary.

113. Work-related adverse health findings, identified by medical surveillance, must trigger certain actions by the employer, as described below under "outcomes management".

Indications for conducting medical screening

114. Medical screening must be provided if an employee:

(a) is generating, using, handling, storing, transporting, disposing or otherwise exposed to an HCA that is known to cause adverse health effects;

(b) the level of exposure is such that an occupational disease or adverse effect may reasonably be expected to occur; and

(c) valid medical testing techniques are available to detect the adverse effect on the employee's health.

115. This means the employer must ensure that a health risk assessment is conducted to determine the likelihood of exposure to an HCA, in conjunction with the known health effects of the HCA, which the occupational medicine practitioner can use to decide if medical screening is necessary.

Designing and implementing a programme of medical surveillance

116. The following steps should be included in any programme of medical surveillance:

(a) ***Risk assessment*****:** this will determine the potential exposure to and routes of absorption of an HCA, and identify potential target-organ toxicity to inform medical surveillance requirements.

(b) ***Test selection:*** medical screening & biological monitoring tests should have the desirable operating characteristics of appropriate sensitivity, specificity, reliability and predictive value.

(c) ***Test schedule:*** the frequency of testing is laid down in general terms by regulation 13, but should in any case be based on an understanding of the nature of the hazard and the natural history of any adverse effects that may develop in specific target organs.

(d) ***Development of action criteria:*** interpretative criteria for various types of medical tests have been published in the medical literature. However, the occupational medicine practitioner must develop pragmatic action criteria in the context of the specific workplace.

(e) ***Standardisation of test process:*** quality control needs to be exercised both at the testing site and in the laboratory contracted to carry out analyses. Consistency over time should be sought to make longitudinal measurements comparable.

(f) ***Ethical considerations:***

i. Information and training of employees as required by regulation 17 should include the rationale for doing medical surveillance, and the consequence of abnormal findings.

ii. Written informed consent should be obtained for medical tests to be conducted, in accordance with requirements prescribed by the National Health Act (61 of 2003) and regulation 14.

iii. An employee must be notified of the results and interpretation of his/her tests and any recommendations made, including, where appropriate, the need for medical referral for confirmation of diagnosis and related actions.

iv. The confidentiality of personal medical records is laid down by regulation 14 of these regulations.

(g) ***Outcomes management - determination of steps to be taken in the event of identifying a work-related health problem:*** Cooperation of employees can be best secured by a policy of protection of conditions of service in case of medical removal from a particular job.

(h) ***Evaluation of exposure controls:*** an abnormal finding in an employee, or a pattern of findings in a group of employees, may point to inadequate primary control of exposure(s). In such cases the employer needs to be notified of such details of the medical findings as are necessary to evaluate the workplace problem and take remedial action to prevent the continued exposure of the employee and yet unexposed employees.

(i) ***Record keeping:*** this includes both medical records and exposure information for every employee. While the employer is responsible for record keeping in terms of regulation 20, access to the contents of personal medical records should be restricted to the occupational health practitioner, the employee, and any person nominated by the employee in writing.

(j) ***Data Analysis***: conduct an analysis of the biological monitoring and medical screening results over time, to look for evidence of excessive exposure or trends in exposure-related health status and use this to identify the need for targeted exposure prevention.

117. The medical surveillance programme should be described in a written document with the key issues addressed.

118. The employer must provide the occupational health practitioner with the following information about the work to be performed, which has triggered the requirement for medical surveillance:

(a) the work the employee is, or will be, carrying out;

(b) if the employee has started that work, how long the employee has been carrying it out;

(c) a list of the HCAs to which the employee is, or will be, exposed, as detailed in the risk assessment and relevant SDSs;

(d) relevant risk assessment reports and results of air monitoring carried out at the workplace; and

(e) the type of personal protective equipment being used by the employee.

Outcomes Management: Non-work-related findings

119. Non-work-related findings include various health conditions that may be identified by the medical testing process, such as hypertension and diabetes. These findings should be shared with the employee (preferably in writing) by the occupational health practitioner to enable the employee to take appropriate action to improve his or her general health. In addition, the occupational health practitioner should refer the employee to their own healthcare provider for further treatment, if necessary.
120. Where the non-work-related health condition increases the affected employee's vulnerability to a workplace hazard, this may require additional actions.
121. The presence of non-occupational disease does not require notification to the employer.

Outcomes Management: Work-related findings

122. Work-related findings include two categories:
    (a) ***Occupational disease:*** These are adverse health effects related to exposure to a HCA. Section 25 of the Occupational Health and Safety Act requires that those health effects which have progressed to occupational disease must be communicated to the employee, employer and the Chief Inspector of the Department of Employment and Labour.
    (b) ***Medical fitness to work:*** Health conditions either caused by work or not caused by work may impact on an employee's medical fitness for work. Additionally, health conditions not caused by work may impact on the vulnerability of the employee who may be exposed to an HCA, or which may be aggravated by workplace exposures. For example, an employee who has had asthma since childhood and is performing work that may result in exposure to a respiratory irritant or allergen. In these circumstances, the occupational medicine practitioner must carefully consider the risks and convey the appropriate task or workplace restrictions to the employer in the form of a written certificate of fitness, without disclosing the actual diagnosis. The employer may not allow the employee to return to normal duties until cleared by an occupational medicine practitioner.

Medical fitness and Incapacity

123. A medical incapacity is present when an employee is unable to fulfil the inherent requirements of a job for the reasons of ill health. This is the case whether or not the underlying health condition was caused by exposure to workplace hazards. The presence of an occupational disease is not necessarily an incapacity and therefore not a reason to automatically declare that the employee is medically unfit to perform their job.
124. Where a medical incapacity is present all options for accommodation should be considered, as prescribed by the Labour Relations Act, 1995 Act No. 66 of 1995 and the Employment Equity Act, 1998 Act No. 55 of 1998.

Legal duties in occupational disease identification

125. The medical practitioner must notify the chief inspector as prescribed in section 25 of the Act. The prescribed format is the use of the WCL forms used for the submission of claims for an occupational disease under the Compensation for Occupational Injuries and Diseases Amendment Act, N^{o} 10 of 2022.
126. The medical practitioner (usually an occupational medicine practitioner) must facilitate the submission of a claim for compensation under the Compensation for Occupational Injuries and Diseases Amendment Act, N^{o} 10 of 2022, by completing the necessary medical reports and following the procedure prescribed by the Compensation Commissioner. These are described in the "Internal Instruction" documents published by the Compensation Commissioner.

Biological monitoring

Distinction between biological monitoring, biological exposure monitoring and biological effect monitoring

127. As illustrated in Figure 1 above, biological exposure monitoring and biological effect monitoring are subdivisions of biological monitoring.
128. Biological exposure monitoring is the measurement and assessment of chemicals or their metabolites (substances the body converts the chemical into,) in exposed employees. These measurements are made on samples of exhaled air, urine, blood or other biological materials, or any combination of these. These measurements reflect the total uptake of a chemical by an individual by all routes (inhalation, ingestion, absorption through skin or by a combination of these routes). Biological exposure monitoring, therefore, does not represent an adverse effect or an occupational disease – it only reflects exposure.
129. Biological effect monitoring is the measurement and assessment of early non-adverse reversible subclinical physiological effects caused by the absorption of chemicals (i.e. prior to functional or structural impairment). It typically involves measuring biochemical responses. For example, measuring plasma and erythrocyte cholinesterase activity in employees exposed to organophosphate pesticides; or measuring increases in urinary protein following exposure to cadmium; or changes in functioning of enzymes.
130. Biological effect monitoring should be distinguished from medical testing for established clinical disease, which is sometimes also referred to as effect monitoring. For example, measuring changes in blood cell counts following exposure to bone marrow toxins does not constitute biological effect monitoring.
131. Biological effect monitoring responses may have potential health implications for the individual and may also arise from causes other than occupational exposure.

Objectives and uses of biological exposure monitoring

132. The main objective of biological exposure monitoring is to provide a complementary method to air monitoring when air sampling methods alone may not give a reliable indication of exposure. Biological exposure monitoring may be useful in the following situations:
    (a) to detect and determine absorption via the skin or gastrointestinal system, in addition to that by inhalation;
    (b) to test the efficacy of personal protective equipment and monitor work practices;
    (c) to compliment air monitoring in circumstances when work practices are not normal, such as abnormally long or variable working hours or very strenuous work (high breathing rates = increased chemical intake)
    (d) to detect non-occupational exposures;
    (e) to assess total body burden;
    (f) to reconstruct past exposure in the absence of other exposure measurements for chemicals with long half-lives; and
    (g) to assess the effectiveness of medical removal procedures.

Important considerations in biological exposure monitoring

133. In choosing a test to meet the objectives, it is important to understand the relationship between environmental exposure and the concentration of an HCA in biological samples. This includes an

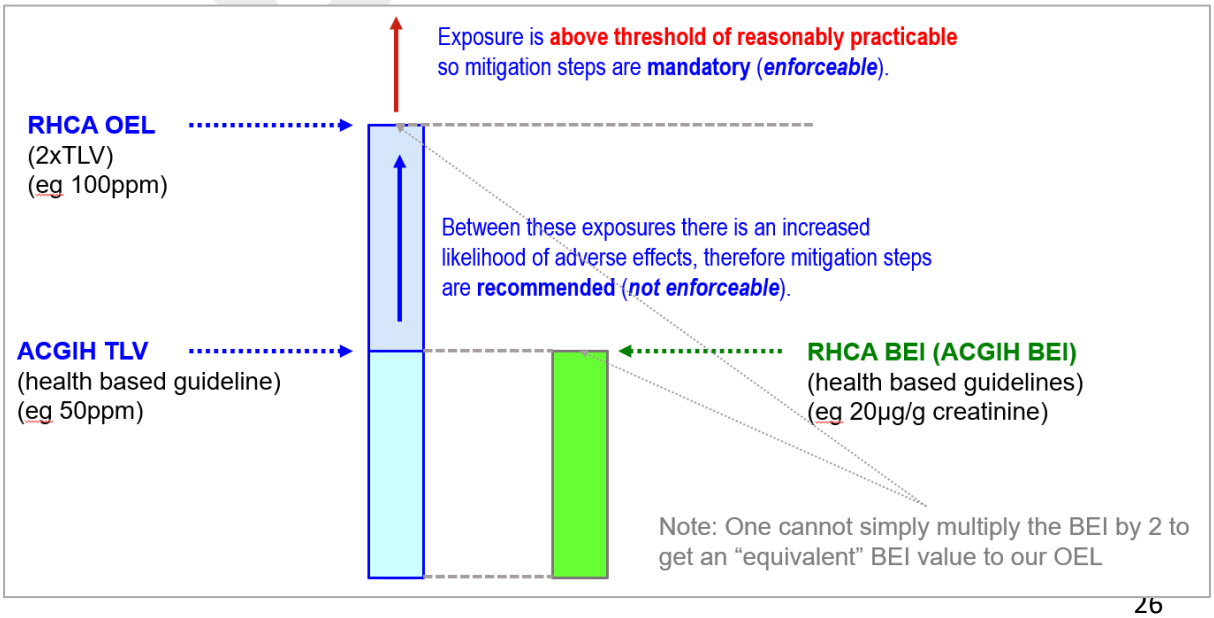
understanding of the principles of absorption, biotransformation, distribution and excretion of the HCA or its metabolites.

134. In addition, there should be (1) analytical methods available with sufficient sensitivity and specificity to detect concentrations of the agent in biological media in the range of exposure likely to be associated with the process in industry and (2) reference values against which to infer occupational exposure with reasonable reliability. The HCAs listed in Table 4 of Annexure2 are those for which extensive documented research has been done and where these criteria are deemed to have been met.

Biological exposure indices

135. Biological exposure indices (BEIs) are values against which to compare biological monitoring results, intended as a reference guideline for the likelihood of adverse health effects.
136. A BEI represents in theory the level of an HCA or metabolite most likely to be observed in a specimen collected from a healthy employee who has been exposed to an HCA to the same extent as an employee with inhalation exposure to half the OEL-TWA. They are health-based values, meaning that they represent the levels at which the earliest signs of adverse effect may occur.
137. BEIs do not represent a sharp distinction between hazardous and non-hazardous exposures. For example, owing to biological variability, it is possible that an individual's measurements can exceed the BEI without incurring an increased health risk. There are also some susceptible individuals who may be harmed at levels below the BEI.
138. BEIs are guidance reference values, not legal reference values. If measurements in specimens obtained from an employee on different occasions persistently exceed the BEI, or if measurements in specimens obtained from a group of similarly exposed employees, the employer must investigate the cause of the excessive values and take proper action to reduce the exposure.
139. BEIs apply to eight-hour exposures, five days a week.
140. BEIs should not be applied, either directly or through a conversion factor, in the determination of safe levels for *non-occupational* exposure to air and water pollutants, or food contaminants. BEIs are not intended for use as a measure of adverse effects or for diagnosis of occupational disease.
141. The level of a hazardous chemical or its metabolites in the body does not *necessarily* correlate with exposure to the hazardous chemicals (there may be other non-occupational sources of exposure), symptoms or damage to health.

Figure 2: The relationship between the RHCA OEL, ACGIH TLV and RHCA BEI.



Biological monitoring sampling strategy

142. Several approaches may be considered, depending on the circumstances.
    a) 100% Sampling-This means selection of all employees exposed to a HCA listed in Annexure 2, Table 4 and where the risk assessment indicates the need for biological monitoring. The rationale for this approach is not to miss anybody who may be individually at risk. This is best suited to circumstances where the target group(s) is small, and exposures are highly variable.
    b) Purposive sampling -This means the selection of the employees who will give the most useful information about exposure, and which accounts for various routes of exposure and use of PPE. This is best suited to circumstances where the target group(s) is small, and specific issues are being addressed, such as effectiveness of PPE.
    c) Statistical sampling (epidemiological approach) -This means the collection of a minimum number of samples to achieve statistical representativeness in a group of similarly exposed employees, in the same manner that statistical representativeness is achieved via occupational hygiene sampling strategy. The rationale for this approach is that biological monitoring is directly analogous to personal dosimetry in occupational hygiene monitoring. Data obtained from biological monitoring of groups of employees can be used in cross-sectional studies. These can be used to compare the situations existing in different departments of the factory, or in similarly exposed groups (SEGs), in order to set up risk maps for manufacturing processes. This is best suited to circumstances where the target group(s) is large, and it will be prohibitively expensive to biologically monitor all the exposed employees. Analysis of a group becomes especially important when the results of the biological indicators used can be markedly influenced by factors independent of exposure (diet, concentration or dilution of urine, etc.) and for which a wide range of "normal" values exists. In order to ensure that the group study will furnish useful results, the group must be sufficiently numerous and homogeneous as regards exposure and sex. The more the exposure levels are constant over time, the more reliable the data will be.

Consultation with health and safety committee/ representatives

143. The employer must consult with the relevant health and safety committee or representative as the case may be on the following matters:
    (a) conducting and the outcomes of the risk assessment,
    (b) control measures implemented in the workplace,
    (c) exposure monitoring (both occupational hygiene and biological) programs/sampling participation required by employees,
    (d) the programme of medical screening and medical surveillance to be implemented, and
    (e) training, instruction and information to be provided, including frequency of training.