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# Draft Regulations for Hazardous Chemical Agents, 2024

## == Regulation 14: “Medical Screening & Surveillance” ==

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**employment & labour**

Department:  
Employment and Labour  
REPUBLIC OF SOUTH AFRICA



## ▲ **Part 1: Preamble**

- What we set out to do
- What exactly is “medical surveillance”?

## ▲ **Part 2: Regulation 14 & related content**

- Some important new Definitions as applied to Occupational Health
- Quick review of Biological Monitoring & Biological Exposure Indices (BEIs)
- A look at the Regulation 14

## ▲ **Wrap up**



**What is the revised Regulation 14 trying to achieve?**

## **PART 1: PREAMBLE**



**Improve clarity** of certain issues, including:

- ▲ **Who does what** – employer, OHP and OMP
- ▲ The **conditions to be met** that warrant doing medical screening (NB: medicals must be really necessary, and risk-based! Then if medicals are warranted, let's get maximum value out of them!)
- ▲ The place for **Medical Certification (new definition, explicit purpose)**
- ▲ The place for **Biological Monitoring**;
  - much more explicitly covered, but **located in Regulation 13** (Exposure Monitoring) not Regulation 14 (Medical Surveillance)
  - relationship between **BEIs and OELs**



**Introduce some new thinking on old concepts, including:**

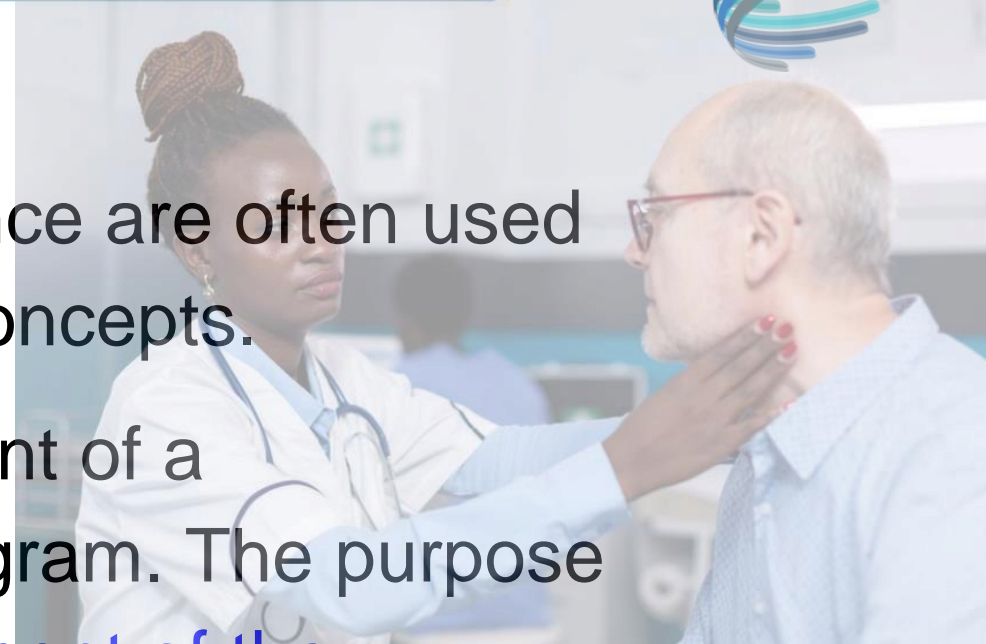
- ▲ Medical **Screening** vs Medical **Surveillance** (new perspectives)
- ▲ **Exit** Medicals (new to these Regs)
- ▲ **Appeal of a finding** of an occupational medical practitioner stipulated in the medical certificate of fitness (new to all the Regs)

Also – follow a similar format to the other Regulations (NIHL, HBA, PAR, Ergo, etc.)



## U.S. Department of Labour

- ▲ Medical screening and medical surveillance are often used interchangeably, they are quite distinct concepts.
- ▲ **Medical screening** is only one component of a comprehensive **medical surveillance** program. The purpose of screening is **early diagnosis and treatment of the individual** and thus has a **clinical** focus.
- ▲ The fundamental purpose of **surveillance** is to **detect and eliminate the underlying causes** such as hazards or exposures **of any discovered trends** and thus has a **prevention** focus.





## Centres for Disease Control & Prevention, USA (CDC)

- ▲ Medical surveillance is the ongoing, systematic collection, analysis and interpretation of health data ....
- ▲ To be effective, surveillance must be directly linked to preventive action.
- ▲ In the case of occupational health, the actions prompted by the surveillance system should be directed not only at the individual case or the affected group but also at the responsible workplace factors.





# Quick Summary: Medical Screening versus Medical Surveillance



## Medical Screening

### Key features:

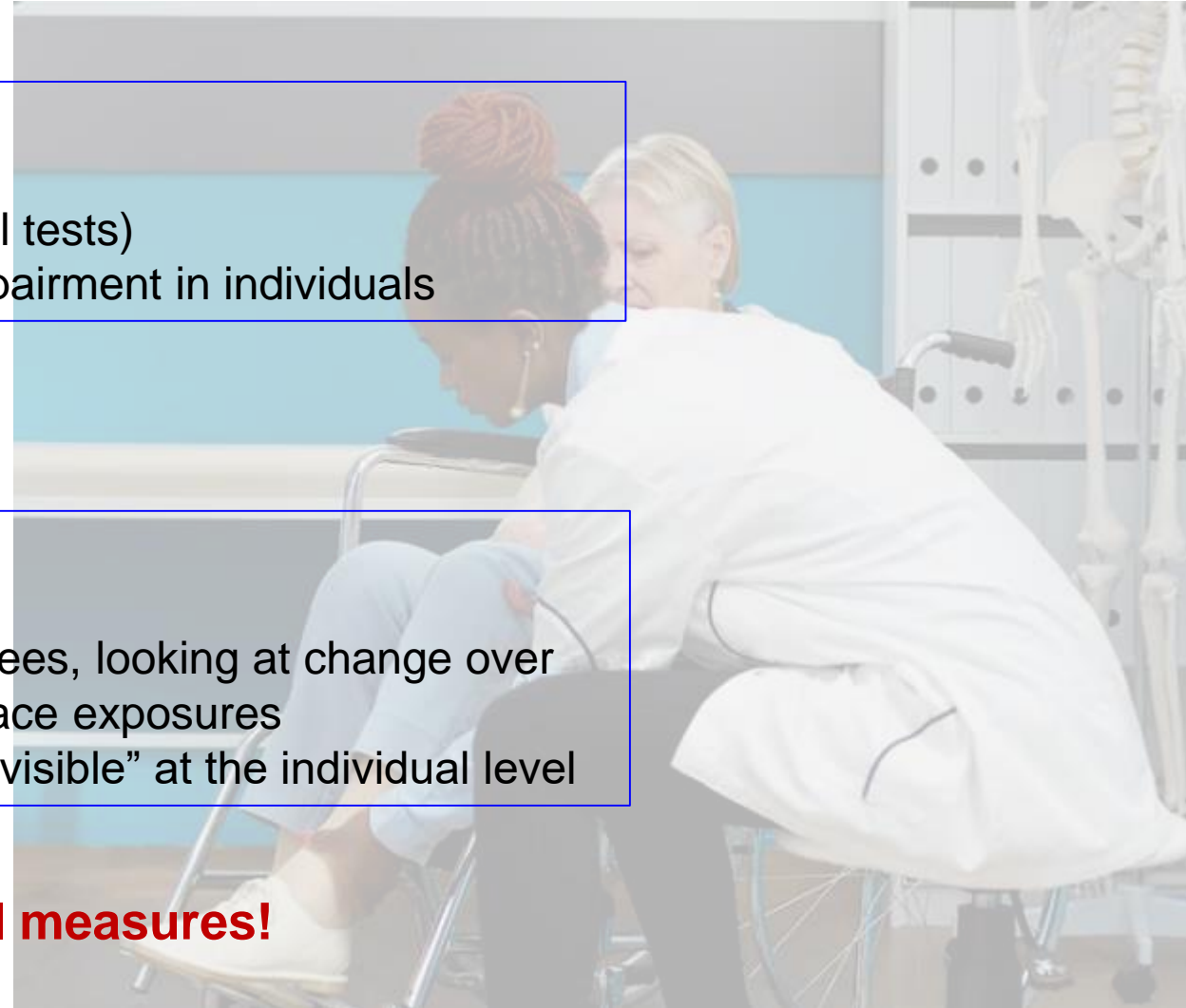
- Aimed at **individuals**
- Uses clinical tools (examination, interviews, medical tests)
- Purpose: early detection of clinically observable impairment in individuals

## Medical Surveillance

### Key features:

- Aimed at **groups**
- Assesses screening outcomes of groups of employees, looking at change over time, trends, clustering of findings, linked to workplace exposures
- Purpose: early detection of adverse outcomes not “visible” at the individual level

**Both are important as control measures!**







“**medical surveillance**” (Occupational Health & Safety Act, 85 of 1993)  
means a **planned programme** or **periodic examination** (which may include **clinical examinations**, **biological monitoring** or **medical tests**) of **employees** by an occupational health practitioner or, in prescribed cases, by an occupational medicine practitioner

Not a single event, but an organised series of screening events (“programme”) with multiple (or groups of) employees over time

The “**building blocks**” of surveillance include:

- “**clinical examinations**” (questionnaires, physical examinations)
- “**medical tests**” (audiograms, spirograms, chest x-rays, laboratory tests)
- “**biological monitoring**” (laboratory tests of very early biochemical interference and of exposure or internal dose)

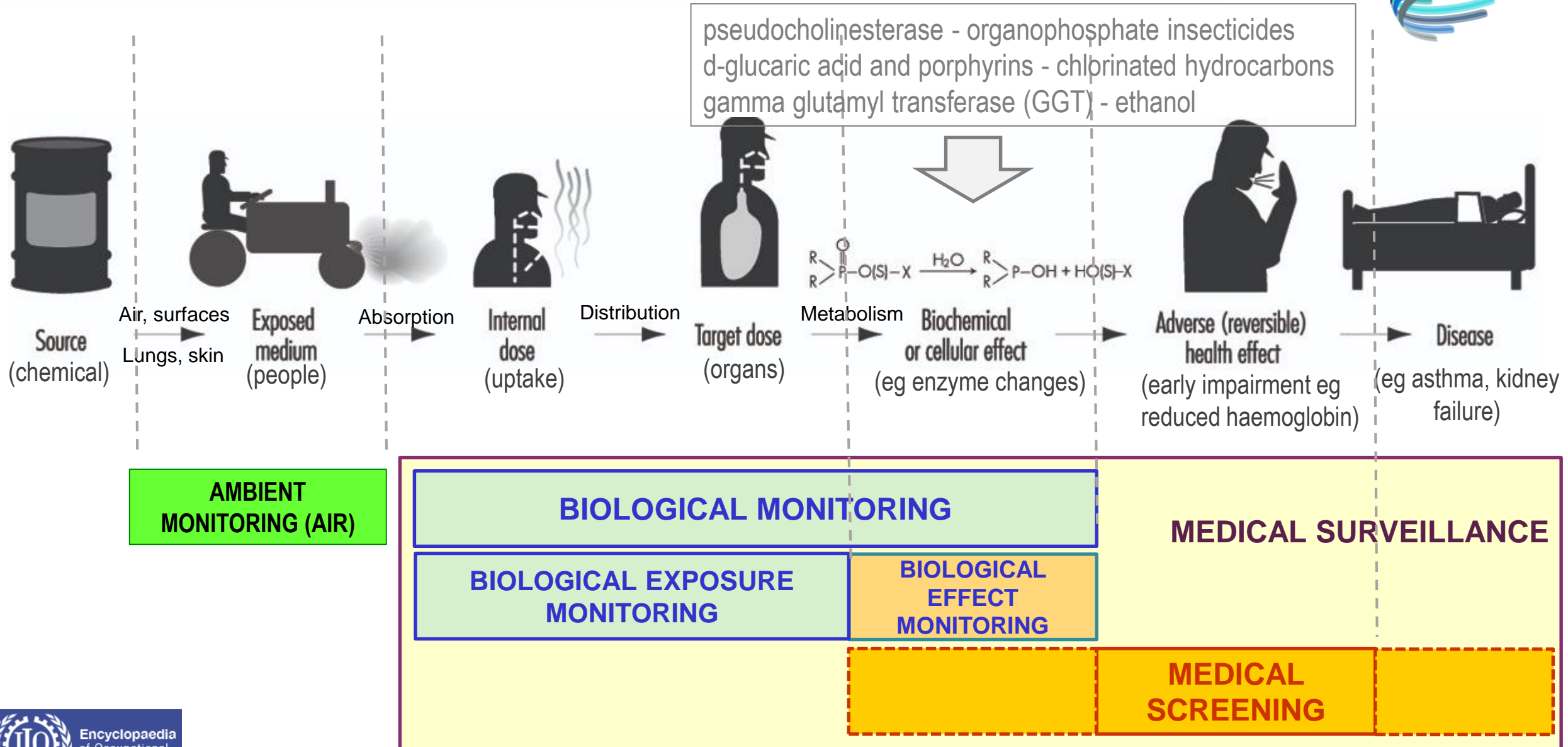
Screening for

impairment

exposure

signs of impairment or exposure in **individuals**, involving target organs of interest  
= “**medical screening**”

# Biological Monitoring, Medical Screening & Medical Surveillance



# “System of” Medical Surveillance in the various Regulations



Regulations	Wording
<b>Hazardous Biological Agents</b> Regulations	8.(1) An employer must establish and maintain a documented <b>system of medical surveillance</b> of employees, ... if-
<b>Asbestos Abatement</b> Regulations	17.(1) An employer must establish and maintain a <b>system of medical surveillance of employees</b> if-
<b>Physical Agents</b> Regulations ( <b>draft</b> )	8.(1) An employer must establish, implement and maintain a documented <b>system of medical surveillance</b> , ..., if;
<b>NIHL</b> Regulations ( <b>draft</b> )	9.(1) An employer must establish, maintain and document a <b>system of medical surveillance</b> for all employees exposed to:
<b>Hazardous Chemical Agents</b> Regulations ( <b>draft</b> )	7. The employer must, ..... (3), establish and maintain a documented <b>system of medical surveillance</b> including-

# “System” of medical surveillance?



Words from the **Mines Health & Safety Act...**

13. (2) Every **system of medical surveillance** must -

(a) be **appropriate**, considering the health hazards to which the employees are or may be exposed;

(b) be designed so that it **provides information** that the employer can use in determining measures to -

- (i) **eliminate, control and minimise the health risk** and hazards to which employees are or may be exposed; or
- (ii) **prevent, detect and treat occupational diseases**; and

(c) consist of an **initial medical examination** and other medical examinations at appropriate intervals.

Risk Assessment



Appropriate medical screening tests

**Data Analysis:**

Group data to identify trends, clusters (“hot spots”), etc.



Direct mitigation efforts

**Building Blocks:**

Screen individuals at entry & periodically



The **risk assessment** determines the need for medical surveillance

**RISK = (HARMFULNESS OF HAZARD) X (DEGREE OF EXPOSURE)**

**HAZARD**

(HCA, HBA, Noise, Ergo, Physical)

**X**

**EXPOSURE**

Duration, frequency intensity

**PERSON**  
vulnerability  
factors  
(influence  
response to  
exposure)

Medical screening helps identify the **vulnerable employee**.

Medical surveillance if...

- ✓ 1. Significant risk (harmfulness / toxicology), also considering the “vulnerable employee”
- ✓ 2. Hazard known to cause identifiable occupational disease or adverse effect
- ✓ 3. Reasonably likely to occur in the particular conditions of work
- ✓ 4. Techniques to diagnose indications of the disease (screening tools)

**ENVIRONMENTAL**  
factors  
(influence  
exposure, such as  
**synergistic**  
effects, **confined**  
space, wind, etc)

E.g. **ototoxic chemicals**  
or vibration + noise.



**The draft “Occupational Health” Regulation.**

## **PART 2: REGULATION 14**



## Definitions

Regulation 10 – Hazardous Chemical Agent Risk Assessment

Regulation 13 – Exposure monitoring of Hazardous Chemical Agents

Regulation 14 – Medical Screening & Medical Surveillance

Annexure 1 – Table 2: GHS hazard classes – health hazards

Annexure 2 – Table 4: Biological Exposure Indices (“BEI’s”)

Annexure 4 - Hazardous Chemical Agent Guidelines





- ▲ “**exposure monitoring**” means both air monitoring and **biological monitoring**;
- ▲ “**medical certificate of fitness**” means a written statement issued by an occupational health practitioner, or in prescribed cases by an occupational medicine practitioner, in which the practitioner certifies an employee’s **medical fitness** to perform a particular job function, after consideration of the **inherent requirements of the job** and the **hazards** to which the employee may be exposed;



- ▲ “**medical screening**” means the systematic application of a test or inquiry to identify individuals at sufficient risk of a specific disorder because of exposures in the workplace, identifying potential health effects before the employee exhibits any symptoms, to benefit from further investigation or direct preventive action;
- ▲ “**ototoxic chemical agents**” means chemical agents that can cause hearing impairment alone or in combination with noise, even below 85dBA;
- ▲ “**vulnerable employee**” means an employee who is at a higher risk of injury, disease or complications caused by exposure to an HCA;

## 10. Hazardous Chemical Agent Risk Assessment (1)



(1) Where an HCA is present in the workplace the employer must cause a documented risk assessment of an HCA to be carried out -

...

(e) taking into account at least the following-

...

(viii) **ototoxic chemical agents** acting synergistically with noise to cause hearing loss;

...

(x) additional information on **health effects**, including where available the OEL for that HCA;

...

(xvii) **records of adverse medical surveillance outcomes**, required by regulation 14(7), and where needed seek guidance from any Occupational Health Practitioner appointed by the employer;

(xviii) the **differing effects of exposure to HCA to men, women, young employees and vulnerable employees**, where such difference may exist;



- ▲ (3) The employer must indicate appropriate controls in the HCA risk assessment, in terms of regulation 11, where there is a risk to health indicated by-
  - ▲ ...
  - ▲ (d) **medical surveillance** carried out in accordance with regulation 14;
  - ▲ ...
  - ▲ (g) **where the BEI is likely to be exceeded**, then in terms of regulation 13(1) exposure monitoring must be conducted.

## 13. Exposure monitoring of HCA (1)



(1) Based on the HCA risk assessment for an SEG carried out in accordance with regulation 10, the employer must ensure that exposure monitoring is conducted –

...

(e) for **biological monitoring** of an HCA with a BEI listed in **table 4** of Annexure 2, when-

- (i) air monitoring alone is not likely to reflect total uptake through all **exposure pathways** and the BEI is likely to be exceeded;
- (ii) air monitoring results contemplated in subregulation (1)(a) **exceed 50% of the OEL**; or
- (iii) **recommended** by an occupational medicine practitioner.



## Bear in mind that:

- ▲ A **BEI** usually (not always) represents a level of an agent in a specimen (eg urine) collected from a healthy worker who has been exposed to the chemical at the **ACGIH TLV** (threshold limit value).
- ▲ This means that when an employee's biomonitoring level reaches the BEI value, we assume that employee's exposure has reached the level of the health-based (ACGIH) TLV.
- ▲ BEIs and ACGIH TLVs are both health based *non-enforceable* guideline values

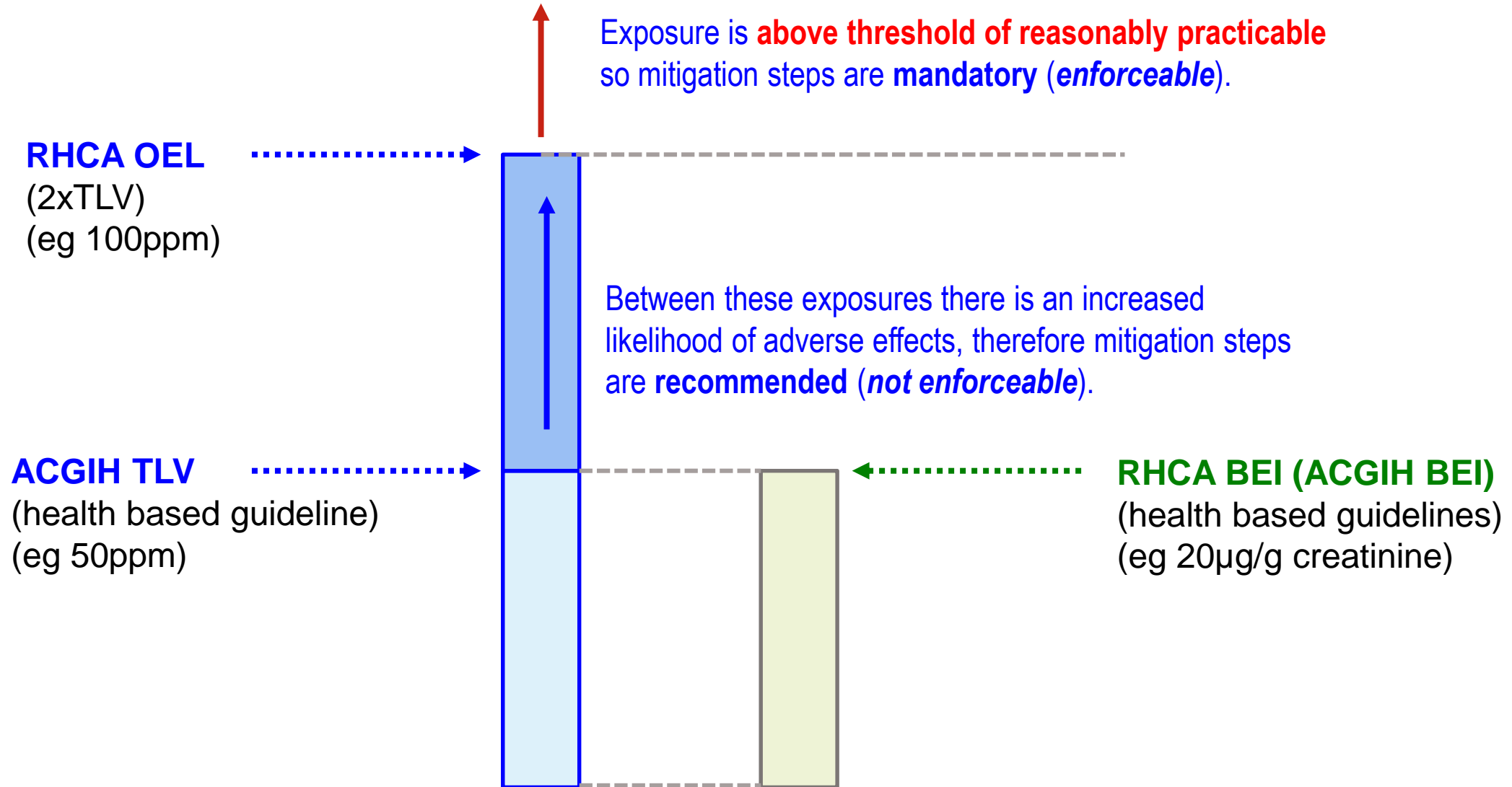
## Given the 2x relationship between the ACGIH **TLV** and the RHCA **OEL**:

- ▲ An employee who is exposed at the level of the (non-enforceable) **BEI** can be considered to be at approximately 50% of the RHCA'S (enforceable) **OEL**.

# Relationship between RHCA OEL, ACGIH TLV and RHCA BEI (2)



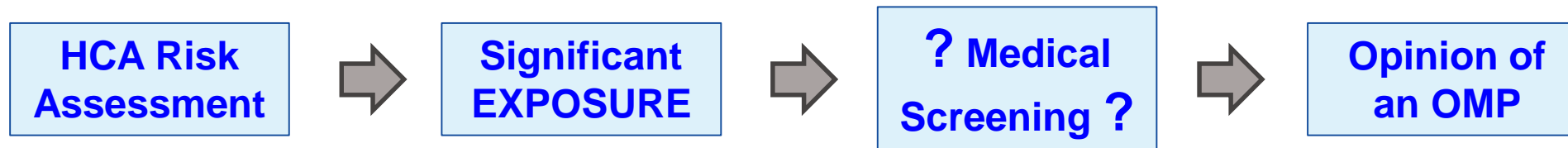
Using a fictitious chemical with a RHCA OEL of 100ppm and a BEI of 20µg/g creatinine







(1) Where the **HCA risk assessment**, including consideration of all routes of intake, or the exposure monitoring for HCA, comparative to an OEL or BEI as the case may be, identifies a **significant exposure risk** for an employee carrying out work using, handling, generating or storing HCA, the **employer** must obtain the opinion of an **occupational medicine practitioner** to determine whether it is necessary to conduct medical screening of employees.



## 14. Medical screening and surveillance (2)



(2) Where significant exposure risk is identified in terms of subregulation (1), **the occupational medicine practitioner must consider if-**

(a) there is **significant risk** to an employee's health;

Toxicological review of the HCA  
(harmfulness, target organs)

(b) an employee has a health condition that makes the **employee vulnerable** to an HCA, or which impacts the proper use of personal protective equipment;

(c) there is an **identifiable occupational disease** or adverse effect related to the HCA;

(d) there is a **reasonable likelihood** that the disease or effect may occur under the particular exposure conditions of their work; and

(e) there are **valid techniques to diagnose** indications of the disease or the effect, as far as is reasonably practicable.

## 14. Medical screening and surveillance (3)



(3) Where the need for medical surveillance has been determined as necessary by the occupational medicine practitioner, as contemplated in subregulation (2), the **occupational medicine practitioner** must specify **requirements for medical screening** including-

- (a) an evaluation of the employee's medical, occupational and exposure history;
- (b) the appropriate clinical examination and medical tests;
- (c) the **intervals** at which medical screening must be conducted, **appropriate to the health risks and health status of the employee**.

(4) The employer must ensure that medical screening contemplated in subregulation (3) is carried out by an **occupational health practitioner-**

- (a) immediately **before** or **within 14 days** after a person commences employment as is practicable; and
- (b) subsequently, at **intervals recommended by the occupational medicine practitioner**, but not exceeding 24 months.

## 14. Medical screening and surveillance (4)



(5) After the initial or periodic medical screening evaluation has been conducted, the occupational medicine practitioner must notify the employer in writing by means of a medical certificate of fitness, and inform the employee accordingly, **if-**

(a) the employee has a medical condition which;

(i) **prevents the wearing of other personal protective equipment**, where the employee's job requires the wearing of respiratory protective equipment or other any other personal protective equipment; or

(ii) is likely to be **aggravated by the exposures** at that workplace;

(b) the medical screening evaluation **identified an adverse health effect** caused by exposure to an HCA at that workplace.

Note: The Regulation **only** prescribes a Medical Certificate for **very specific circumstances**.  
(The employer may choose to require certification under a wider range of circumstances.)

Fitness to  
Work Issue

Occupational  
Disease

## 14. Medical screening and surveillance (5)



(6) **With respect to the medical certificate of fitness** contemplated in subregulation (5)-

(a) The certificate must indicate-

- (i) recommendations pertinent to the employee's **fitness to perform the inherent requirements of the job**, or the **presence of an occupational disease**, without including confidential medical information;
- (ii) if any **restrictions or conditions apply** to any specified duties performed by the employee;
- (iii) **the period** for which any restrictions or conditions, as applicable, should be applied;

(b) The **employer** must, as far as is reasonably practicable-

- (i) **accommodate** the conditions or restrictions recommended; and
- (ii) **only permit an employee who has been medically certified for restricted duties to return to normal duties if the employee has been certified fit for those duties by an occupational medicine practitioner.**



(7) The **employer** must, where medical screening has been determined necessary by the occupational medicine practitioner as contemplated in subregulation (3), establish and maintain a **documented system of medical surveillance** including-

- (a) an **analysis of the screening results over time, to look for abnormal trends in health status, potentially resulting from adverse effects of exposure to an HCA; and**
- (b) **must be overseen by an occupational medicine practitioner;**
- (c) **using the results of subregulation 7(a) to identify the need for targeted exposure prevention in the workplace.**



(8) The employer must **investigate and report** the **occupational disease** contemplated in subregulation (6)(a) in compliance with regulation 8 of the General Administrative Regulations, and section 25 of the Occupational Health and Safety Act, 85 of 1993.

(9) The employer must-

(a) ensure that the employee provides **written informed consent** for inclusion in the medical **screening**;

(b) ensure that the employee provides **written informed consent** for inclusion in the **surveillance programme**.





(10) The employer must ensure that an **exit medical screening** is carried out by an occupational health practitioner on termination of an employee's service.

(11) **An employee may appeal any finding of an occupational medical practitioner stipulated in the medical certificate of fitness to the chief inspector, in writing within 60 days of receiving the certificate.**



- ▲ Cut-off values for GHS (what makes a chemical “hazardous”)
- ▲ Cross reference between carcinogenic classification systems
- ▲ Absorption through the skin
- ▲ Wood dust, Sensitisers, Ototoxicants, Rubber fume and rubber process dust, Flour dust, Grain dust, Welding Fumes and gases.
- ▲ **Medical surveillance, medical screening (107-126)**
- ▲ **Biological monitoring (127-142)**



- ▲ Medical surveillance is an important control, but should only be triggered where appropriate
- ▲ “Medical surveillance” actually refers to systematic programme of medicals on multiple employees or groups of employees (as per the definition in the OHSA)

It is a powerful **strategic control measure**, as it identifies problems that may be invisible at the individual level

- ▲ “Medical Screening” refers to the assessments of individuals, aimed at identifying early adverse effects of exposure, and/or assuring fitness to work

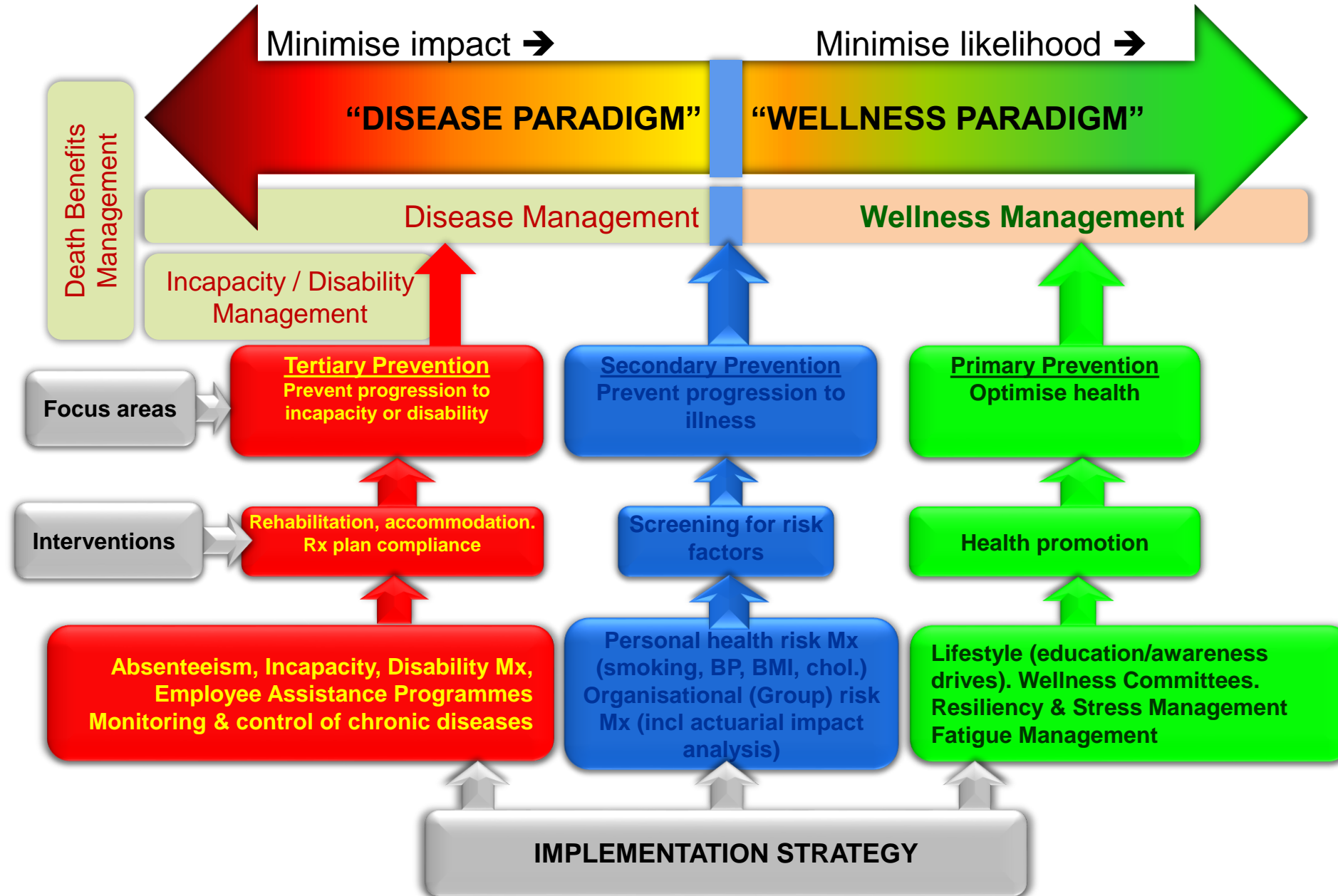
It is a powerful **operational control measure**, as it enables day-to-day risk mitigation as problems are identified



Thank you for your attention



# Integrated **Personal** Health Risk Management



# Integration between Workplace & Personal Health Risk Management

