

GijimaAst Occupational Hygiene and Environmental Services

A Presentation on:

Regulations for Hazardous Biological Agents –
Professional opinion by a non-expert

Presented by: Jaco van Rensburg

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Introduction



- **Regulations for hazardous Biological Agents, 2001, under the OHS Act; Act 85 of 1993.**
 - Another “Modern Style” Regulation under the OHS Act, similar in approach to the:
 - Noise Induced Hearing Loss regulations, 2003, and
 - Regulations for Hazardous Chemical Substances, 1995.
- **Based on the broad principles of:**
 - Assessment (Anticipate and Recognize), followed by
 - Evaluation (Exposure quantification), and
 - Control (Exposure management)
 - » For all practical Purposes, the Regulations consist of 2 parts; Regulations and Annexures/Guidelines (Seemingly developed separately)



Similarity with Regulations for Hazardous Chemical Substances goes as far that one could almost merely replace the term “Hazardous Chemical Substance” with “Hazardous Biological Agent”

Terminology and Definitions



- **Biological Agent** means any micro-organism, cell culture or human endoparasite, including any which have been genetically modified, which may cause an infection, allergy or toxicity, or otherwise create a hazard to human health;
- **HBA** means hazardous biological agents which are micro-organisms, including those that have been genetically modified, pathogens, cells, cell cultures and human endoparasites that have the potential to provoke an infection toxic effects.

(these Regulations are limited to HBAs, despite the definition for Biological Agents being “better”.)

- The difference between a Biological Agent and HBA, is that it must be capable of causing infection (communicable disease) or a toxic effect to be considered a HBA. (However the terms infection and toxic are not further explained). From HCS Regs. We know that “Hazardous” also include toxic, harmful and irritant.

Terminology and Definitions



- **HBAs** are, subdivided into the following groups:
 - Group 1; HBA that is unlikely to cause human disease (which I suppose makes it a Biological Agent and not a HBA – as per def. on previous page);
 - Group 2; HBA that may cause human disease and be a hazard to exposed persons, which is unlikely to spread to the community and for which effective prophylaxis and treatment is usually available;
 - Group 3; HBA that may cause severe human disease, which presents a serious hazard to exposed persons and which may present a risk of spreading to the community, but for which effective prophylaxis and treatment is available;
 - Group 4; HBA that causes severe human disease and is a serious hazard to exposed persons and which may present a high risk of spreading to the community, but for which no effective prophylaxis and treatment is available.

Application



- These Regulations are applicable where:
 - HBA is deliberately produced, processed, used, handled, stored or transported.
 - Micro-biology laboratories
 - Research facilities
 - ?

Application



- These Regulations are applicable where:
 - **An incident, for which an indicative list is given in Annexure A to this Regulation occurs that does not involve a deliberate intention to work with a HBA but may result in persons being exposed to HBA in the performance of his or her work**
 - Health Care Facilities (humans and veterinary), pathology labs,
 - OH Nurses (Spirometry, urine and blood sampling)
 - Traveling to “Malaria area” for work purposes
 - Water/Sewage system maintenance and treatment works employees
 - General Workplace (common flu?, “Sick Building Syndrome”, infected colleagues?)
 - ??
 - How practical is this?

Application



- These Regulations are applicable where:
 - Regulations 8, 14, 15, 16 and 17 shall not apply to an employer or self-employed person at a workplace where the exposure is restricted to a Group 1 HBA;
 - Reg. 8 – Medical Surveillance
 - Reg. 14 – Labeling, Packaging and Transport
 - Reg. 15 – Special Measures (Veterinary)
 - Reg. 16 - Special Measures (Labs., Industrial Processes...)
 - Reg. 17 – Disposal of HBA.
- » Meaning that common, good hygiene practices and housekeeping/cleanliness of facility will suffice.

Regulations



- 6. Risk Assessment
 - Reads almost word-for-word exactly as Regulations for Hazardous Chemical Substances (with “HCS” being substituted with “HBA”)
 - One would thus assume that the same principles for performing a RA should apply.
 - Wrong!

Risk Assessment



- Why not the same as with HCSs?
 - With HCSs we perform, Probability vs. Severity based Risk Assessments, utilizing 2 main principles:
 - Dose (the dose makes the poison; HCSs usually have known/predictable dose-response relationships)
 - Severity of Response (inherent hazard potential of the HCS)
 - With HBAs, there is only Severity of Response with virtually no (or very unpredictable) Dose-response relationships
 - To how many HI Viruses must you be exposed to become HIV+, or to contract AIDS?

Risk Assessment



- Then How?
 - Where the Regulations itself lack in terms of practicality, it makes up in control guidelines; guidelines for specific HBAs as well as (and/or) conditions where exposure to any variety of HBAs could occur.
 - Therefore, instead of Assessing Risk in the conventional sense, rather identify potential for exposure and audit compliance to the required control actions.

Risk Assessment – Step 1



- Identify your situation:
 - 1) HBA is deliberately produced, processed, used, handled, stored or transported.
 - 2) An incident, for which an indicative list is given in Annexure A to this Regulation occurs that does not involve a deliberate intention to work with a HBA but may result in persons being exposed to HBA in the performance of his or her work
 - Health Care Facilities (humans and veterinary), pathology labs,
 - OH Nurses (Spirometry, urine and blood sampling)
 - Traveling to “Malaria area” for work purposes
 - Water/Sewage system maintenance and treatment works employees
 - General Workplace

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Regulation 16



- Step 1:
 - Identify/List the HBAs by name and award “Hazard Category”, in terms of Annexure B to the Regulations, in terms of:
 - Class (Class 1, 2, 3 & 4)
 - “Physical Condition” (Liquid/suspension, dry/powder, spore-forming/airborne potential)
 - Notations (A, T & V)
 - A = allergic effect
 - T = Toxic Effect
 - V = Vaccine Available
 - » All Viruses (with humans as host) not Listed under Annexure B are classed as Class 2 as a minimum (with exceptions).

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Regulation 16



- Step 2 – for all Class 2, 3 & 4 HBAs:
 - Critically Assess all Tasks and Procedures to identify any potential for exposure to each individual HBA, in terms of:
 - **Exposure Potential:**
 - Incidental (excluding the protection offered by PPE)
 - Unavoidable (excluding the protection offered by PPE)
 - **Route of Exposure:**
 - Dermal
 - Inhalation
 - Eyes (droplets and spores can cause infection via eye contact)

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Regulation 16



- Step 3 – “Risk Rating”:
 - Use the following Matrix – to determine the “Risk Rating”/Level of Containment required:

Rating/Containment Level

Exposure	Unavoidable	Level 3	Level 4	Level 4
	Incidental	Level 2	Level 3	Level 4
		2	3	4

HBA Classification (HBA Regs. Annexure A)

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Annexure E.



- Step 4 – Audit the Facility’s Containment Measures, in terms of the Risk/Containment Levels awarded in Step 3 (as deemed appropriate):

Containment Measures	Containment Levels		
	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
1. The workplace is to be separated from any other activities in the same building.	No	Recommended	Yes
2. <i>Input air and extract air in the workplace are to be filtered using HEPA filters or likewise</i>	No	<i>Yes, or extract air and safe discharge of air</i>	<i>Yes, on input and extract air and safe discharge of air.</i>
3. Access is to be restricted to authorised persons only.	Recommended	Yes	Yes, via air lock.
4. <i>The workplace should be sealable in order to permit disinfection.</i>	No	<i>Recommended</i>	<i>Yes</i>



Containment Measures

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
6. <i>The workplace is to be maintained at an air pressure negative to atmosphere.</i>	No	Recommended	Yes
7. <i>Efficient vector control, e.g. rodents and insects</i>	Recommended	Yes	Yes
8. <i>Surfaces impervious to water and easy to clean.</i>	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. <i>Surfaces resistant to acids, alkalis, disinfectants, solvents</i>	Recommended	Yes	Yes
10. <i>Safe storage of a biological agent.</i>	Yes	Yes	Yes, secure storage.
11. <i>An observation window or alternative is to be present so that occupants can be seen.</i>	Recommended	Recommended	Yes
12. <i>A laboratory is to be contain own equipment</i>	No	Recommended	Yes
13. <i>Infected material, including any animal, is to be handled in a safety cabinet or isolator or other suitable container.</i>	Where applicable	Yes, where infection is by airborne route	Yes
14. <i>Incinerator for disposal of animal carcasses</i>	Recommended	Yes	Yes, on site.

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Regulation 10



- Step 5 – Audit the Facility’s Controls, in terms of General Requirements, in terms of Regulation 10 – Control of Exposure to HBA, covering aspects such as (as deemed appropriately):
 - Limiting the amount of HBA used which might contaminate the working environment,
 - limiting the number of employees who will be exposed or might be exposed,
 - engineering control measures for the control of exposure
 - separate workplaces for different processes;
 - proper access control to prevent unauthorised access; and
 - immediate personal or environmental disinfection.
 - Appropriate, written work procedures to ensure:
 - the safe handling, use and disposal of HBA;
 - the proper use and maintenance of process machinery, installations, equipment, tools and local extraction and general ventilation systems;
 - the regular cleaning of machinery and work areas by vacuum cleaners fitted with a suitable filter that prevents contamination of the environment, and
 - emissions to the atmosphere comply with the provisions of the Atmospheric Pollution Prevention Act, 1965 (Act No. 45 of 1965);
 - displaying the biohazard sign shown in Annexure D to these Regulation and other relevant warning signs; and
 - specifying procedures for taking, handling and processing samples that might contain HBAs

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Regulations 11 and 12 (11 to 17)



- Step 6 – Audit the Facility’s general Controls, in terms of PPE and maintenance of Control facilities and equipment (as deemed appropriately):
 - PPE Suitability and Adequacy
 - Suitability and adequacy of Facilities.
 - Testing integrity of Engineering Control Measures at intervals not exceeding 24 months (or less)
- This Regulation reads the same as for in the HCS Regulations (just substitute HCS with HBA)
 - » Just note that the “surgical masks” commonly found at such facilities offers no respiratory protection (these are intended to prevent the “doctor” from breathing germs onto an open wound).
 - » Proper RPE must therefore be at a FFP2 rating or higher.

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Annexure C



- Step 7 – Audit the Facility’s compliance to “standard precautions” (as deemed appropriately):
 - **HAND WASHING**
 - **GLOVES**
 - **MASK, EYE PROTECTION, FACE SHIELD**
 - **PROTECTIVE CLOTHING**
 - **EQUIPMENT**
 - **ENVIRONMENTAL CONTROL**
 - **LINEN**
 - **OCCUPATIONAL HEALTH /Injuries**

Risk Assessment – Choice 1 (Labs, Animal Rooms and Industrial Processes) – Also See Annexure C



- Step 8 – Assess:
 - One can (if you like) award ratings to your audit findings, as a means to prioritize actions, as follow:
 - Any non-conformance regarding a Class 2 HBA = **Low Risk**
 - Any non-conformance regarding a Class 3 HBA = **Moderate Risk**
 - Any non-conformance regarding a Class 4 HBA = **High Risk**
 - Ultimately, all of these non-conformances are legal non-conformances, and need to be addressed, irrespective of the Risk/Priority rating.

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- These Areas/Conditions include:
 - Food Production Plant.
 - Where there is contact with animals or products of animal origin
 - Health Care Facilities, including isolation and post mortem units
 - In clinical, veterinary and diagnostic laboratories
 - Sewage purification installations, and
 - The general workplace.

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- For these areas, conducting a Risk Assessment in the common sense is impossible.
 - The potential for exposure to Class 4 HBAs always exist;
 - We are mostly dealing with communicable diseases (contact with, or merely being in the vicinity of a infected person can result in infection)
 - The risk of contracting a disease from a Class 4 HBA is dose independent (only zero exposure is safe)

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- The following terms and principles must be clearly understood, as it is critical to conducting an “Assessment”:

– **Contact:**

- Direct
- Indirect

– **Droplet Transmission:**

- coughing, sneezing, talking

– **Airborne Transmission:**

- Small particles (droplet nuclei) that remain suspended for hours (TB)

– **Common Vehicle Transmission:**

- food, water, devices and equipment

– **Vector-Borne Transmission:**

- mosquitoes, flies, fleas, etc.

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- Consider an example (do a detailed task analysis, as you would in a normal Risk Assessment – and try and identify all possible routes of exposure):
 - A worker reports to the Clinic, with a laceration that needs stitches – try and consider all potential routes of exposure (remember there is no telling what diseases this person is a carrier of):
 - He greets the doctor by a customary handshake
 - He talks to the Doctor, explaining the problem
 - From the shock he starts to hyperventilate, which triggers a cough
 - With his hands, the Doctor examines the wound from close by
 - The Doctor wipes off excess blood and cleans the wound
 - He administers local anesthetic with a syringe, which afterwards drops from the table, to the floor (the Cleaner later found this re-usable syringe, and put it back in its usual place).
 - During stitching up, the Doctor punctures a vesicle and blood squirts into his face
 - What is the Risk/s under these seemingly “normal” circumstances?

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- Therefore – again, instead of trying to assess (as we have already, by default) confirmed that it is a High Risk task, audit compliance to the statutory guidelines/standards for preventing contact, transmission and Exposure:
 - Audit Against General Requirements – Regs. 10 to 17.
 - Audit against “Standard Precautions” – Annexure C; Sections A1&2 and B1
 - Audit against Additional Precautions, regarding every identified route of exposure; Annexure C; Sections B2 to B5

Risk Assessment – Choice 2 (Areas of Incidental Exposure) – Also See Annexure C and Tables I and II



- Conclusion
 - Treat every non-conformance as a High Risk
 - Treat every High Risk as High Priority Action
 - Deserving urgent implementation

CONCLUSION



- Remember:
 - With HBAs, even more than with HCSs, “Prevention is better than cure”
 - Don’t focus on trying to proof that exposure occurs, focus on trying to come up with as many possible ways of:
 - Preventing exposure, and
 - Spreading of contamination
 - Inoculate/Vaccinate, Train/inform, prevent/remove, protect, contain and dispose safely.

**Thank You (for those of you
that are still awake)**

GijimaAst
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