



# **BIOSAFETY AND BIOSECURITY IN UGANDA**

National Health Laboratory & Diagnostic Services

***Joseph Nkodyo***

National Coordinator

Biosafety and Biosecurity Program



## Background – International Requirements

- The IHR (2005) require that States Parties develop, strengthen, and maintain their capacity to respond promptly and effectively to public health threats.
- They obligate States Parties to develop the eight (8) defined minimum core capacities to detect, assess, report, and respond to potential public health threats of international concern at the local, regional, and national levels.
- One of the cores **is laboratory capacity** and component under it is **biosafety and biosecurity**, requiring all States Parties to implement biosafety and biosecurity best practices.



# Background – International Requirements

- Establishment of GHSA in 2014, supported implementation of the IHR (2005) and other similar international frameworks.
- It was launched in response to the global health posed by infectious diseases to an increasingly interconnected world.

In order to encourage progress toward these goals, the “**Action Packages**” concept was developed to facilitate regional and global collaboration toward specific GHSA objectives and targets.

- At the launch of the GHSA, eleven (11) discrete GHSA Action Packages were identified, one being **Biosafety and Biosecurity Action Package**.

# Background – International Requirements

- Uganda has played a leading role in the implementation of some of the GHSA Action Packages, including the package on biosafety and biosecurity.
- In 2015, GHSA carried out a Pilot Assessment of Uganda to establish its existing capacity with regard to the GHSA Action Packages. Score was as follows;

| Technical Area            | Indicator   | Score | Capacity Level   |
|---------------------------|---|-------|------------------|
| Biosafety and Biosecurity | Whole-of-government biosafety and biosecurity system in place | 2     | Limited Capacity |
|                           | Biosafety and biosecurity training and practices              | 1     | No Capacity      |

## Background – National Response

- In response, the Ministry of Health established a well-structured Biorisk Management (BRM) programme.
- *National Biosafety and Biosecurity Coordination Office* under the *NHLDS* department has led the implementation of this program working with other MDAs like:
  - the Ministry of Agriculture, Animal Industry, and Fisheries;
  - the Ministry of Defence and Veterinary Affairs;
  - the Ministry of Water and Environment;
  - the Uganda Wildlife Authority
- The primary focus areas of the National coordination office **Bs** have been **BRM competence** and **BRM compliance**.

# Background – **BRM** Competence

Established the National training program in 2015 and B

Initially, this training programme focused on the laboratory workforce (technical staff).

In 2016, the office expanded scope of the training programme by developing BRM Curriculum to cover other cadres :

Basic Track ( support staff, nurses, doctors, maintenance);

Technical Track (for laboratory staff);

Management Track (for top and mid-level managers).

A glaring gap in implementation remained due to limited knowledge and buy-in from top management which allocates resources.

# Background – **BRM Competence**

The office so far 67 certified IFBA (BRM- 47, Bio security- 10,, Bio safety cabinet installation and certification- 6 & waste management- 4

National Trainers- 35, National BRM Auditors- 25

Cascaded these trainings across different levels of service delivery & MDA targeting cadres from different Agencies under one health framework.

# Background – **BRM Compliance**

In order to foster continuous improvement, the office set up a national audit programme to evaluate the national BRM performance.

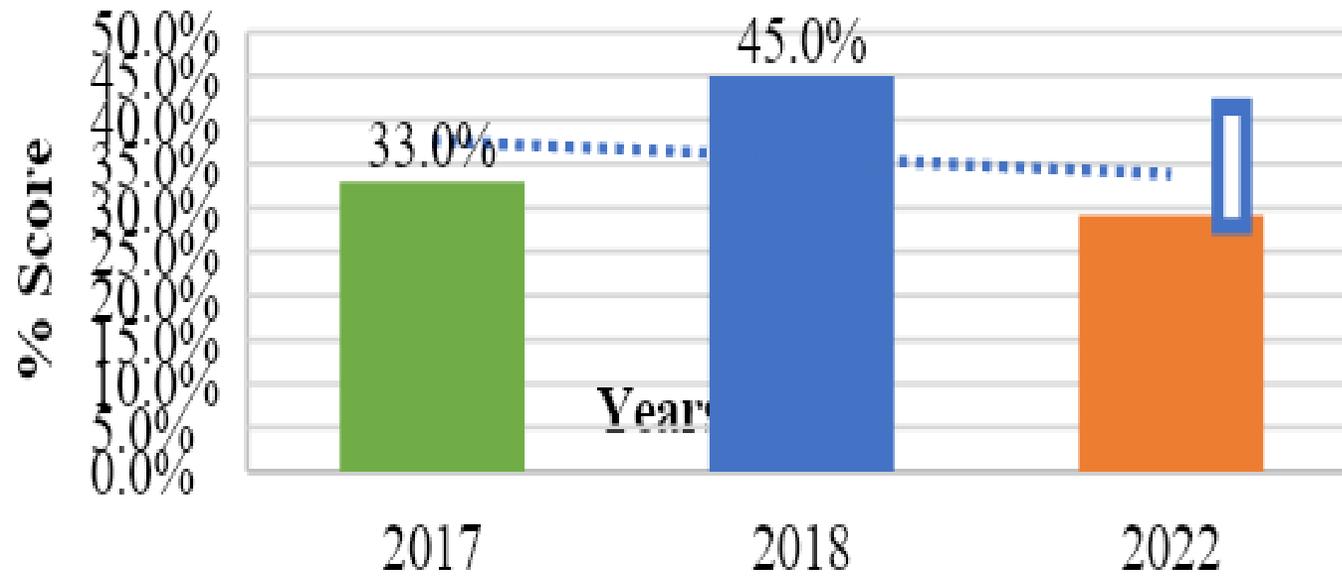
In 2017, the first version of the safety assessment checklist was developed.

Conducted the first national BRM audit and the average national score was **33%** .

In 2018, the office conducted another national BRM audit and the average national score was **45%**.

Prior to 2022, these are the documented national BRM audits that the office had conducted.

## Overall BRM Performance for 2017, 2018 & 2022



Generally, there has been a decline in BRM Performance following the release of the two international standards

# Background – JEE: Measuring Progress

- In 2017, JEE assessment on Biosafety and Biosecurity area, Uganda performed as follows:

| Technical Area            | Indicator   | Score | Capacity Level     |
|---------------------------|---|-------|--------------------|
| Biosafety and Biosecurity | P.6.1 Whole-of-government biosafety and biosecurity system in place for human, animal, and agriculture facilities | 3     | Developed Capacity |
|                           | P.6.2 Biosafety and biosecurity training and practices  | 3     | Developed Capacity |

## Background – New Standards; New Horizons

- **New developments with regard to BRM.**
- In 2019, *International Organisation for Standardisation* released the very first ISO standard exclusively focusing on BRM,  
**ISO 35001: 2019 - Biorisk Management for laboratories and other related Organisations.**
- In 2020, ISO released an updated standard for safety in medical laboratories, the **ISO 15190: 2020 – Medical Laboratories: Requirements for safety.**
- In 2020, *WHO* also released the **4<sup>th</sup> Edition Laboratory Biosafety Manual** (WHO LBM 4).
- These superseded previous BRM guidance and reinforced IHR (2005), GHSA and JEE, hence review of key national BRM documents and tools.

A blue ribbon graphic with a 3D effect, featuring a darker blue shadow on the left side. The ribbon is horizontal and contains white text at the bottom.

**Progress: July 2021 – June 2022**

# Measuring Progress 3

- During 2021, Uganda carried out an internal multi-sectoral self-assessment of its GHS capacities. The performance was as shown below:

| Technical Area            | Indicator   | Score | Capacity Level     |
|---------------------------|---|-------|--------------------|
| Biosafety and Biosecurity | P.6.1 Whole-of-government biosafety and biosecurity system in place for human, animal, and agriculture facilities | 3     | Developed Capacity |
|                           | P.6.2 Biosafety and biosecurity training and practices  | 3     | Developed Capacity |

## Progress – BRM Competence

- Reviewed the National Biosafety Manual and National BRM curriculum and training materials to:
  - To comply ISO 35001:2019, the ISO 15190:2020, and the WHO LBM 4;
  - align with the One Health Approach.
- National BRM Mentorship Handbook for BRM mentors.

# Progress – BRM Compliance

- Review of National BRM Audit Checklist to comply with the ISO 35001:2019, the ISO 15190:2020, and the WHO LBM 4.
- Carried out the 2022 National BRM Audit.
- Development of the National Healthcare Waste Management Guidelines.

A blue ribbon graphic with a 3D effect, featuring a dark blue shadow on the left side. The ribbon is horizontal and contains white text.

**Deep dive – 2022 National BRM Audit**

# NHLDS BRM RISK GRADING FOR INSTITUTIONS

| ACCEPTABILITY | Unacceptable Level of Risk      |                            | Acceptable Level of Risk          |                           |                                     |
|---------------|---------------------------------|----------------------------|-----------------------------------|---------------------------|-------------------------------------|
| BIORISK LEVEL | <b>Very High Risk</b><br>(Poor) | <b>High Risk</b><br>(Fair) | <b>Moderate Risk</b><br>(Average) | <b>Low Risk</b><br>(Good) | <b>Very Low Risk</b><br>(Very good) |
| SCORE         | $\leq 30\%$                     | 31%-49%                    | 50%-59%                           | 60%-79%                   | $\geq 80\%$                         |

# BIORISK LEVEL FOR THE AUDITED FACILITIES

| <b>Biorisk level</b>      | <b>Number of facilities</b> | <b>Proportion of facilities</b> | <b>Average Scores</b> |
|---------------------------|-----------------------------|---------------------------------|-----------------------|
| Very Low Risk (Very Good) | 0                           | 0.0%                            | 0%                    |
| Low Risk (Good)           | 3                           | 5.8%                            | 66%                   |
| Moderate Risk (Average)   | 4                           | 7.7%                            | 54%                   |
| High Risk (Fair)          | 15                          | 28.8%                           | 38%                   |
| Very High Risk (Poor)     | 30                          | 57.7%                           | 18%                   |

## Risk level by level of facility

| Level of health service delivery        | Number of facilities | Proportion of facilities | Average score | Biorisk Level         |
|---|----------------------|--------------------------|---------------|-----------------------|
| National Reference Laboratories         | 1                    | 2.1%                     | 44.0%         | High Risk (Fair)      |
| National Referral Hospital Laboratory   | 1                    | 2.1%                     | 24.6%         | Very High Risk (Poor) |
| Regional Referral Hospital Laboratories | 10                   | 20.8%                    | 45.8%         | High Risk (Fair)      |
| General Hospital Laboratories           | 14                   | 29.2%                    | 35.1%         | High Risk (Fair)      |
| Health Center IV Laboratories           | 15                   | 31.3%                    | 21.3%         | Very High Risk (Poor) |
| Health Center III Laboratories          | 7                    | 14.6%                    | 12.4%         | Very High Risk (Poor) |

Average  
national  
performance  
across all  
audited  
sections

Audit section



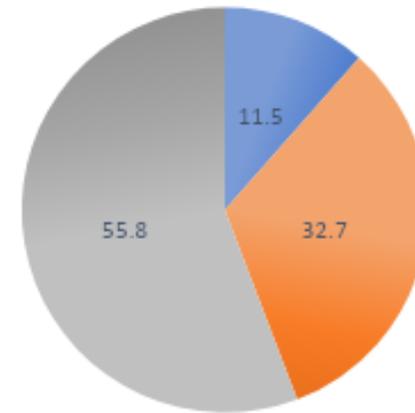
# Average BRM performance by ownership

| Ownership  | Number of facilities | Proportion of facilities | Average Score | Biorisk Level  |
|------------|----------------------|--------------------------|---------------|----------------|
| Government | 44                   | 91.7%                    | 28.8%         | Very High Risk |
| Private    | 4                    | 8.3%                     | 42.2%         | High Risk      |

Averagely private owned facilities performed better than government owned facilities

Performance of facilities on establishment of functional OSH

Performance of site-specific Occupational Health and Safety Program



■ Established OSH Program ■ Partially compliant ■ Lacking OSH Program

# AFRICA CDC PRIORITIES



## INITIATIVE GOAL

To strengthen the biosecurity and biosafety systems of African Union Member States to comply with international regulations including the International Health Regulations (IHR 2005), Biological Weapons Convention (BWC), and United Nations Security Council Resolution (UNSCR) 1540 and the GHSA action packages (APP3)



### PRIORITY 1

Develop a Biosafety and Biosecurity Legal Framework for the Africa Region

### PRIORITY 2

Establish Regional and Continental Biosafety and Biosecurity TWG to coordinate and monitor implementation

### PRIORITY 3

Establish a Regional Training and Certification Program for Biosafety and Biosecurity Experts

### PRIORITY 4

Establish a regulatory and certification framework for institutions handling high risk pathogens

### PRIORITY 5

Strengthen NPFI and NRL capacities to prevent, detect and respond to Events of public health concern in each MS

## Way forward

Results indicate an urgent need for the country to develop robust biorisk management implementation strategies.

The deliberate efforts will proactively identify all the potential Biosafety and Biosecurity risks in the continuum of the BRM program and set appropriate mitigation measures to detect, avert, respond to hazards and threats.

Management commitment to support these interventions should take center stage.

# Recommendations & Challenges

- Legal frame work
- Training and certification program
- Limited funding
- Pathogen Economy
- National repositories

# Acknowledgement.

- CDC
- FAO
- WHO
- IDI
- JCRC
- NADDEC
- MOH, MWE, UWA, MAAIF, USAID