**BIORISK MANAGEMENT AUDITORS’ TRAINING REPORT AT NILE HOTEL –JINJA; 7th – 11th MAY 2018**



*Participants and facilitators in a group photo in Nile Hotel building from 7th -11th May 2018.*

*REPORT COMPILED BY****; Ms. Atwijuka Diana***

***Mr. Ojaku Alex***

***Executive summary***

ISO standards emphasize the importance of audits as a management tool and for verifying the effective implementation of the organization’s quality and or environmental policy. Audits are essential part of conformity assessment activities such as external certifications and accreditation.

In line with the ISO requirements, the Infectious Diseases Institute’s (IDI) Global Health Security Partner Engagement (GHSP) Project grant, IDI in collaboration with Ministry of health / Uganda National Health Services (UNHLS) conducted training on Biorisk Management Audit to Health workers from Uganda.

This report therefore gives a summary of what transpired during the BRM Audit training conducted in Nile Hotel Jinja from 7th -11th May 2018 for five days.

A total of 21 health workers from public facilities from both private health facilities, public health facilities and veterinary facilities from Ministry of Agriculture Animal Industries and Fisheries were trained by a team of national certified Auditor trainers under the guidance of Project Coordinator-IDI and the National Biosafety and Biosecurity Coordinator from UNHLS.

***Background to the training***

Biorisk Management (BRM) programs are key components of laboratory quality management systems. They are put in place for prevention, control and protection from unintended and intended exposure to biological agents and toxins, during work in laboratories. The nature of work in health diagnostic laboratories involves handling and processing biological materials and toxins that often expose personnel and community to risk of infections, injuries and other harms. The magnitude of the infections, injuries and contamination originating from health laboratories may vary from mild to fatal. These biosafety biosecurity threats are evidenced by inadequate emerging and re-emergency of infectious agents such as Ebola, Anthrax and Marburg leading to an eminent threat of bioterrorism a growing global public health concern.

Over the years, CPHL- MOH in partnership with implementing and development partners have undertaken several initiatives to strengthen BRM at all facility levels in the country. For instance, development of national BRM policy, national Harmonized BRM training curriculum, development of quality improvement documents and not excluding the targeted laboratory support supervisions.

However, the performance of all the previous implemented interventions to check the gaps and improve the system were qualitatively assessed and thus the program was unable to specifically measure the improvements despite the intense implementation activities by the different stake holders. Despite, the assessors were just laboratory personnel that were not specifically equipped with auditing skills.

The ministry of health through CPHL has selected a group of 40 technical personnel who have undergone written interviews and have been assessed for their presentation skills at the Uganda National Laboratory Services complex in Butabika. The desire to strengthen the capacity of the BRM program informed the 5 days training for the selected personnel who shall be ultimately be trained as National BRM auditors.

***Objectives of the training***

The objectives of the training were to:

* Equip trainees with adequate knowledge and skills for internal monitoring and verification of the effective implementation of quality management systems in medical laboratories.
* Ensure that conformity assessment activities meet the requirements of the selected management body through audit practice
* Provide skills in identifying non conformities, root cause analysis and conducting corrective and preventive action

***Training methods and approaches***

A wide range of teaching methods were used including class room based lectures, demonstrations, role plays, group discussions and practical sessions. During the practical sessions, trainees practiced how to conduct an audit using the BRM checklist in Nalufenya Children’s Hospital, Jinja Regional Referral Hospital and Jinja Central Health Centre III

***Facilitators for the course***

The course was facilitated by experienced and certified ASLM and National SANAS auditors as shown in the table below:

**List of Trainers**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Tittle** | **Workstation** | **Phone Contact** | **Email** |
| Ojaku Alex | National Trainer | MOH/Mulago NRH | 0779-600216 | aojaku@gmail.com |
| Nandala Michael | National Trainer | MOH/UNHLS | 0773-087501 | nandalawm@yahoo.com |
| Akello Patricia | National Trainer | MOH/UNHLS |  | aapatrish@gmail.com |
| Diana Atwijuka | National Trainer | MOH/UNHLS | 0776-349464 | atwijukadiana@gmail.com |
| Atek Kagirita | BRM Coordinator | MOH/UNHLS | 0782-909153 | akagirita@gmail.com |

***Trainees’ leadership and training norms***

The following were the representatives of the trainees during the training.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Name*** | ***Responsibility*** | ***Contact*** | ***Email*** |
| Baguma Andrew | Chairperson | 0752-202068 | [abaguma@idi.co.ug](mailto:abaguma@idi.co.ug) |
| Varentina Kababiito | Welfare | 0779-092389 | kab.biito@gmail.com |
| Kadhumbula Sylvester | Spiritual Leader | 0774-292577 | kadhumbula@gmail.com |
| Innocent Tibagambirwa | Time Keeper | 0777-409094 | tinno11@gmail.com |

The following were the norms of the training.

* Phones on silence mode
* Speak one at a time
* Avoid unnecessary movements
* Active participation
* Time management

***Trainees***

A total of 21/ 24 targeted health workers were trained, 3 participants did not turn up for the training. In terms of gender, there were 8 females and 13 males. The distribution of trainees according to their cadre is as shown in appendix 1.

***Training evaluation method (Post Test evaluation)***

In order to assess the effect of the course on trainees’ knowledge and skills a post tests using short answer questions and multiple choice questions (MCQ) were administered at the end of the course respectively. The minimum mark improved from 32% to 60% in the post test while the maximum mark improved from 72% in the pre-test to 98% in the post- test. There was a significant change in knowledge gain after the training as the mean mark improved from 57% in pre-test to 80% in post-test. The average knowledge gain was 23.0%.The average performance at the post test may be due to new concepts that require more time to internalize and practice in order to obtain mastery. For individual health worker scores see appendix 1 attached and Graph 1 below

***Table 1: summary results of pre and post assessments***

|  |  |  |  |
| --- | --- | --- | --- |
| **Scores** | **Pre-test (%)** | **Post-test (%)** | **Average gain in knowledge** |
| **Average** | 57.0 | 80.0 | 23.0 |
| **Maximum** | 72 | 98 |  |
| **Minimum** | 32 | 60 |  |

Graph 1: Pre and post test results BRM Audit Training

***End of course evaluation***

End-of-course evaluation was administered to determine participants’ overall thoughts on the strengths and weaknesses of the course. For more details refer to appendix 4.

Major points from the evaluation included:

* The trainees appreciated more understanding of tools, ISO standards and guidelines to be used in BRM audits
* Understanding the roles and responsibilities of a BRM Auditor
* How to plan, conduct and manage an audit
* Principles of auditing
* Skills on non-conformity identification and correlating the NCs with the ISO standards.
* Practical exposure in Jinja RRH helped us to put theories learnt into context.

***Lessons learnt***

It was greatly observed that there is need to build the capacity of the trainees to understand the different clauses in the ISO 15189:2012; CWA 15793:2011; ISO 15190:2003 and ISO 19011 to help them better conduct BRM audits in their respective districts or regions.

***Challenges***

* There was miscommunication to participants where three participants did not turn up for the training.
* Late arrival of participants was noticed on most days of the training.

***Recommendations***

* Immediate follow up and mentorship of trainee auditors should be carried out to reinforce the knowledge and skills learnt during the BRM audit training.
* In order to consolidate the progress so far made, there is need for each trainee auditor to conduct audits in at least two health facilities with support of certified auditors.
* There is need to support the trainee auditors to reinforce their skills in BRM auditing with several auditing opportunities either within their facilities or other health facilities within the country.

***Closure***

The closing ceremony was presided over by the Lead Trainer, Mr. Nandala Michael who represented UNHLS/CPHL and MOH. He emphasized that establishment of BRM Audit program by trained auditors contributes to the improvement of the effectiveness of the BRM system. He encouraged the trainee auditors to apply the principles of auditing to help make audits an effective and reliable tool by providing information on which each facility can act in order to improve its performance.

***Acknowledgement***

The Ministry of Health/UNHLS acknowledges and appreciates the GHSP Project of IDI for funding the training, the course facilitators for their time and commitment to impart new skills to participants as well as the trainees for the commitment exhibited.

Special thanks go to staff of Jinja Regional Referral Hospital, Children’s Hospital Nalufenya and Central Division HCIII who provided support during the practical audit assessment.

***Appendices:***

***Table 1: List of the trainees***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PIN** | **Names** | **Telephone contact** | **Facility** | **Pre-Test** | **Post-Test** |
| 1 | Baguma Andrew | 0752202068 | IDI | 32 | 86 |
| 2 | Eriaku David | 0775585829 | Bukedea HC III | 66 | 96 |
| 3 | Okek Erick | 0776207089 | Apac Hospital | 54 | 73 |
| 4 | Mpaka Peter | 0756569977 | KIU -Ishaka | 46 | 74 |
| 5 | Atim Stella | 0782449337 | MAAIF/ NADDEC | 50 | 60 |
| 6 | Agoriat Brenda | 0777800775 | Atutur Hospital | 60 | 92 |
| 7 | Prisca Atwinirembabazi | 0772907555 | Mulago NRH | 70 | 83 |
| 8 | Ongole Francis | 0782312802 | UNHLS/CPHL | 68 | 69 |
| 9 | Nabaigwa Barbra Irean | 0755939991 | Jinja Central HC III | 44 | 84 |
| 10 | Kadhumbula Sylvester | 0757182515 | Uganda Cancer Institute | 58 | 73 |
| 11 | Ainunu Lillian Katambi | 0781562810 | UNHLS/CPHL | 60 | 65 |
| 12 | Katalaga Ramlah | 0702-615535 | UNHLS/CPHL | 48 | 60 |
| 13 | Wambele N Richard | 0772404750 | Tororo Hospital | 60 | 98 |
| 14 | Aluko Daniel | 0783450600 |  | 58 | 87 |
| 15 | Tomusange Joseph | 0782339183 | Kakumiro HC IV | 60 | 82 |
| 16 | Tibagambirwa Innocent | 0777409094 | Kiryadongo Hospital | 62 | 79 |
| 17 | Oguma Geoffrey | 0701395783 | MOH/NMCP | 64 | 85 |
| 18 | Kata Kassim | 0772675203 | IDI | 60 | 77 |
| 19 | Achol Emmanuel | 0702913433 | URC | 72 | 78 |
| 20 | Kantume Ronah | 0780286858 | Case Hospital | 46 | 78 |
| 21 | Varentina Kababiito | 0779092389 | Mayanja Hospital | 58 | 88 |
| **Average Mark** | | | | **57** | **80** |

***2. Audit -Non conformity Matrix Jinja RRH BRM Practicum Audit***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NC No.** | **Clear Description of the identified NC** | **ISO Clause No.** | **Proposed CA** | **Proposed closing Date** |
| 1 | Absence of a lightening conductor & broken main Hospital gate | ISO 15190: 2003, 6 | Acquire and fix lightening conductor and broken main hospital gate |  |
| 2 | Laboratory stools in poor condition | ISO 15190: 2002, 6.3.1;  ISO 15189: 2012, 5.2 | Acquire standard stools/ chairs for use in the laboratory |  |
| 3 | Sink taps not elbow / peddle operated | ISO 15190; 6.2 | Acquire and fix elbow/peddle operated taps |  |
| 4 | No response plan in place to assess acceptable risks & response planning parameter | CWA 15793; 4.4.8.4 | Conduct risk assessments and put in place preventive actions for potential risks |  |
| 5 | No records of regular testing of the Fire alarm | ISO 15190; 19.7 | Develop a schedule for testing fire alarm and implement it |  |
| 6 | Emergency exit door bolted at the time of the audit | ISO 15190; 20 | Ensure emergency exit door is left un bolted all the time |  |
| 7 | Available MDSD sheets not reviewed | ISO 15190; 17 | Review all MSDS sheets |  |
| 8 | Electric sockets located close to water sinks, Cables connected to multiple equipment. | ISO 15190; 21 | Remove sockets away from water sinks and ensure few equipment connected to one cable |  |
| 9 | No evidence of RCA in the CA forms | ISO 1793: 2011, 4.1.2 | Perform and document RCA on CA forms |  |
| 10 | No records BRM QIP implemented | ISO 1793: 2011, 4.1.2 | Initiate, implement and document BRM QIPs |  |
| 11 | No access control in the laboratory | CWA 15793: 2011, 4.4.4.8.4; CWA 15793: 2011, 4.4.4.2 | Acquire biometric access control system and relevant signages |  |
| 12 | Hub rider did not use PPE (gloves & Lab coats) at the time of the visit | CWA 15793: 2011; 4.4.4.5.4 | Provide PPE to hub rider |  |
| 13 | No policy for reporting (to HF mgt, district & National level) in the event of laboratory accidents | CWA 15793: 2011; 4.4.4.6 | Develop a policy for reporting lab accidents to HF mgt, district level and National level |  |
| 14 | No SOP for BSC at the time of the visit | CWA 15793: 2011; 4.4.4.8.3 | Develop SOP for care , use and maintenance of BSC |  |
| 15 | No equipment decontamination SOP | CWA 15793: 2011; 4.4.4.8.3 | Develop SOP for equipment decontamination |  |
| 16 | No protocol for reporting missing biological specimen | CWA 15793: 2011; 4.4.2.4 | Develop a protocol/SOP for reporting missing biological specimen |  |
| 17 | No records of ongoing BRM CQI projects | CWA 15793: 2011; 4.4.2.4, ISO 15189:2012; 4.12; 4.15 | Initiate and implement BRM CQI projects |  |
| 18 | No evidence of root cause analysis (RCA) in the CA forms |  | Perform RCA and document on appropriate CA forms |  |

***3. BRM Auditors’ Training Schedule***

|  |  |  |  |
| --- | --- | --- | --- |
| **BRM AUDITORS TRAINING FOR MEDICAL LABORATORIES**  **ISO 15189:2012 BASED ON ISO 19011:2011** | | | |
| ***DAY ONE: Arrival Sunday*** | | | |
| ***DAY TWO: Monday*** | | | |
| DAY 2 | 8:00am - 08:30am | Arrival & Registration | Jackie N |
|  | 08:30am - 9:00am | Welcome Remarks & Introduction, | Atek K |
|  | 9:05am– 19:15am | Opening remarks | Bakunda K |
|  | 9:15am– 10:25am | Objectives of the BRM Auditor’s Training | Michael N |
|  | 9:25am– 9:35am | Expectations and Ground Rules | Alex O |
|  | 9:35am– 10:35am | Pre-test assessment | Diana A |
|  | **10:35am– 11:00am** | **Break** |  |
|  | 11:00am– 12:30pm | Introduction to BRM Auditing | Alex O |
|  | 12:30am–1:00 pm | ISO 15189:2012 clause 5.2 Requirements related to BRM | Michael N |
|  | **1:00pm–2:00pm** | **Lunch** |  |
|  | 2:00pm– 3:30pm | Overview of CWA 15793: 2011 | Michael N |
|  | 3.30pm-5.00pm | ISO 15190:2003 Requirements related to BRM | Alex O |
|  | **5:00pm** | **Close of Day 2** |  |
| ***DAY THREE: Tuesday*** | | | |
| DAY 3 | 8:00am -08:30am | Registration & Recap of the Previous Day Activities |  |
|  | 8:30am - 9:30am | Principles of Auditing (Module 2)  ISO 19011:2011 Clause 4, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6 | Diana A |
|  | 9:30am - 10:30am | Managing an Audit Programme (Module 3)  ISO 19011: 2011 Clauses 5.1, 5.2, 5.3, 5.4, 5.5, 5.6. | Patricia A |
|  | **10:30am-11:00am** | **Break** |  |
|  | 11:00am-1:00pm | Audit Planning (Module 4)  ISO 19011:2011 Clauses 6.2.1, 6.2.2, 6.2.3, 6.3.1, 6.3.2, 6.3.3, 6.3.4 | Michael N |
|  | **1:00pm-02:00 pm** | **Lunch** |  |
|  | 2:00pm-3:30pm | Conducting an Audit  ISO 19011: Clauses 6.4.1, 6.4.2, 6.4.3, 6.4.4, 6.4.5, 6.4.6 | Alex O |
|  | 3:30pm-5:00pm | Audit Reporting  ISO 19011:2011 Clauses 6.5, 6.6 | Michael N |
|  | **5.00pm** | **Close of Day 2** |  |
| ***DAY 4: Wednesday*** | | | |
|  | 8:00am-08:30am | Registration/ Recap of the Previous Day Activities |  |
|  | 8:30am-10:00am | Audit follow up/ Tools for RCA | Alex O |
|  | **10:00-10:30am** | **Break** |  |
|  | 10:30am-11:30am | BRM checklist-Understanding and Scoring | Patricia A |
|  | 11:30am-1:00pm |  |  |
|  | **1:00pm-02:00pm** | **Lunch** |  |
|  | 2:00pm-3:30pm | BRM checklist-Understanding and Scoring | Diana A |
|  | 3:30pm-4:30pm | BRM checklist-Understanding and Scoring | Patricia A |
|  | **4:30:00-5:00pm** | BRM checklist-Understanding and Scoring | Diana A |
|  | **5.00pm** | **Close of Day 3** |  |
| ***DAY FIVE :Thursday*** | | | |
| DAY 5 | 08:00am–08:30am | Registration/Recap of the Previous Day Activities |  |
|  | 08:30am–10:30am | Mock Audit –Jinja RRH, Nalufenya Children’s hospital and Central Division HC III | All facilitators |
|  | **10:30-11:00am** | **Break** |  |
|  | 11:00am–1:00pm | Mock Audit –Jinja RRH, Nalufenya Children’s hospital and Central Division HC III | All facilitators |
|  | **1:00pm- 02:00pm** | **Lunch** |  |
|  | 02:00pm–04:30pm | Mock Audit Report writing | All facilitators |
|  | **05:00pm** | **Closure of Day 4** |  |
| ***Day 6 Friday*** | | | |
| DAY 6 | 08:00am– 08:30am | Registration/Recap of the Previous Day Activities |  |
|  | 08:30am– 09:00am | Post test | All facilitators |
|  | 09;00am - 10:00am | Presentation of group work | All facilitators |
|  | **10:00am– 10:30am** | **Break** |  |
|  | 10:30am– 11:40am | Training Evaluation | All facilitators |
|  | 11:40am–12:50 am | Closing of Training Program | All facilitators |
|  | **01:00pm–02:00pm** | **Lunch** |  |
|  | **02:00pm– 03:30pm** | **Closure and Departure of participants** |  |

***4. End of Course Evaluation***

**Tell us 3 most significant outcomes this training has achieved in terms of your personal development, improvement in BRM, or any other changes as a result of this training.**

* Practical hands on experience and competence on BRM auditing//////
* Principles of auditing /////
* Audit report writing///
* Given a more understanding of tools, ISO standards and guidelines to be used in BRM audit//////////
* More knowledge as regards to BRM auditing//
* Understanding the roles and responsibilities of a BRM Auditor
* Planning, conducting and management of an audit
* Enrichment with knowledge and skills on BRM///
* Career growth and network with experts
* Associate with BBAU Association//
* Interacted and made many friends

**What are the three things you learned from this training that had the biggest impact on you?**

* Presentation skills//
* Auditing skills/////
* Reporting skills////
* Audit programming
* Principles of auditing///////
* Skills on non-conformity identification and correlating the NCs with the standard///
* Team work during auditing
* How to perform BRM auditing////
* Preparation for an audit//
* Learning the whole Audit process////
* Knowing clauses for ISO15189:2012;ISO 15190:2003 ISO 19011:2011 and CWA 15793:2011/////
* In future to be prepared for a pre- test. It was my first experience
* Significance of documented evidence in an audit.
* Practical exposure in Jinja RRH helped us to put theories learnt into context.//

**What is your plan for applying your learning in the future?**

* To expound more on BRM//
* I will routinely conduct BRM audits for my facility to aid in improvement//////////
* After identifying NCs, perform root cause analysis and perform corrective actions.
* Conduct CME at my workplace///
* Train other auditors when given the chance//
* Review existing Biorisk measures in my facility and propose / initiate programs for internal audit.
* Carry out required audits country wide and internationally///
* Improve the quality of BRM and entire LQMS in the facilities.
* Conduct internal audits
* If given an opportunity to go to the field and audit, I will help the facilities to identify gaps in BR and suggest corrective actions.

**Personal testimonies about the program**

* BRM is critical in ensuring the safety of everyone.//
* I learnt a lot. Sessions were engaging and the facilitators were very knowledgeable.
* The training was interactive and participatory which enabled us to learn and understand the concepts///
* With this training and the use of the checklist, I believe great improvement audits in service delivery in regard to BRM.
* The program has opened my mind as regards auditing by giving me both knowledge and hands on experience
* Personally, this program has opened my eyes to Biorisk management gaps that exist in our laboratories.//
* I have fully learnt auditing and am to apply the knowledge to the place of work to bring changes in BRM.
* This is an eye opener, because most of the laboratories may not score highly if audited. So this is a timely training and I pray that the implementation of the audit rolls on.
* BRM audit program has opened up many future personal opportunities. This will definitely have impact on my economic, academic, social status.
* I have sincerely learnt a lot of things and I feel my competence in the area of BRM is energized and re-energized.
* I was very glad when I got invited to the training and I hope my future has started.
* So educative especially for me who really wants to be an auditor

**What changes do you suggest for future trainings?**

* Training period could be increased to 2 weeks to provide opportunity for a second mock audit after reviews of performance in the first mock audit///
* More time given for trainee presentations and practical’s///
* Maintain what’s in place
* Increase per-diem rates
* Reviews of the checklist; expand the areas covered to have a comprehensive coverage.
* More facilities should be mock audited and fewer trainees should be sent to each facility.
* Adequate transport refund for auditors
* Learning material can be shared prior to the training//
* More practical days than class days

**Do you have any other comments?**

* Information as regards accommodation and facilitation should be sent a week before the activities so that people are informed and get prepared//
* I appreciate the efforts of the trainers in covering the course contents within the time schedule.
* Generally the training was well delivered and good.
* The training for National Auditors for BRM has been fulfilling.
* The trainers’ were knowledgeable in the subject matter and exhibited professionalism.
* Very engaging though intense
* The program was handled according to planned schedule.
* I just want to thank my facilitators for the good work.
* Everybody was friendly including the trainers and hotel staff

*Trainees during the BRM Auditors’ training session in May 2018*