Establishment and Implementation of a National Biological Safety Cabinets (BSCs) Certification Program in Kenya

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Beth Njaramba,
Bio Medical Engineering, MOH-NPHLS
Email:bethnjaramba@yahoo.com
Co-authors:Gabriel Okondo, George Otieno, Lucas Ngoroi, Victoria Ouma & Eunice Minabo

Introduction

What is a Biological Safety Cabinet?

- A BSC is a cabinet or enclosure that uses directional airflow and HEPA filters to provide personnel, environment and product protection
- BSCs are installed in the laboratories to ensure safe environment for the staff.
- A BSC has to be fully maintained and certified to achieve this safety.

When to certify a BSC

- During installation-New
- After repair or service
- If re-located
- Annually

Background

- BSCs certification involves an evaluation to determine whether the operations have the potential to protect the health care worker, the materials being manipulated and the environment.
- A faulty BSC poses high risk to health care workers
- Prior to the establishment of this program in Kenya, access to biological safety cabinet certification was reserved to few research laboratories
- The prohibitive cost associated with the activity, which required outsourcing experts from South Africa
- There was need to train personnel-CDC/MOH

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This program aimed at addressing three challenges:

- Supporting the increased number of BSCs being procured and installed in high volume HIV/TB treatment facility laboratories
- Lack of in-Country capacity to certify such equipment
- The high cost of certifying Biological Safety cabinets.

Method

- The National biological safety cabinet certification program was started in 2011 through a collaborative effort between Centers for Disease Control and Prevention (CDC) and the Kenya Ministry of Health (MOH)
- Local biomedical engineers who could certify the BSCs locally were selected and trained at the Eagleson Institute in Sanford, ME, USA
- The training is done in two sets: basic certification and advanced certification
- In-Country proficiency mentorship by the Eagleson Institute mentor

Results

- In 2011, 2 engineers were trained-KEMRI/CDC
- In 2012, 2 from MOH
- In 2014/2015, 2 more from MOH

In total, six engineers have been trained and equipped with four sets of certifying equipment (1 Water Reed)

Expectations

- The trained engineers carry out annual certification for BSCs and TB Hoods at the National level and counties in order to maintain competency and safety
- Carry out inventory of the installed BSCs and TB Hoods in the country-keep record
- Train the users on proper operation and maintenance of BSCs
- Create awareness

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- By 2011-2012, only 45 BSCs were serviced and certified
- By 2014-2015, the total number of BSCs as per stock taking is 237 and that of TB Hoods 86
- 121pcs (51%)BSCs Certified , 118 (97.5%) were safe for use and 3(2.5%) found unsafe for use
- 57pcs(66%) Certified , 48(84%) were safe for use and 9 (16%) found unsafe for use
- The output growth is recommendable (395%)
- For sustainability, a Calibration COE is set at NPHLS

5 Counties Sampled

No.	County	No. Of Facilities	Total BSCs /TB Hoods	BSCs Certified	Tb Hoods Certified	No. Of Lab Tec Trained	No Of BME Trained	State Of BSC	State Of TB Hood
1.	Nairobi	32	64/15	41	11	57	5	2 Failed	6 Failed
2.	Turkana	7	7	7	N/A	11	0	All passed	N/A
3.	Mombasa	31	25/27	22	27	67	2	All passed	3 Failed
4.	Makueni	6	7/3	6	None	23	4	All Passed	N/A
5.	Bomet	5	4/2	4	2	27	6	All Passed	All Passed

Contd’

The certifiers must ensure the safety of:

- Inflow Velocity Test
- Downflow Velocity Profile Test
- Airflow Smoke Pattern Tests
- HEPA Filter Leak Test
- Site installation Test

Contd’

- Guaranteed functionality and reliability
- Guaranteed safety for the personnel, product and environment
- More efficient and effective quality results in the laboratories
- Minimize corrective cost and maximize equipment lifespan

Cleaning BSC/ Scanning of HEPA Filters

Teamwork!!

Advocacy

The trained certifiers have presented BSCs certification at different forums-locally and Internationally

- BSCs sensitization workshop for BMEs-27-29 June 2012-Karatina
- WHO Global Forum on medical devices Conference 22-24 Nov 2013-Geneva Switzerland
- AMEK Conference 13-15 Nov 2013
- Biennial BMEs Conference 17-19 December 2014 Kigali Rwanda
- AMEK Conference 13-15 November Embu
- Trainings in Bio-safety/Bio-security workshops

WHO Conference-Geneva

Africa Representatives at Geneva

BMEs Workshop-Karatina

Conclusions

- Expanded from BSCs certification to the TB hoods
- Increased access to safe and functional BSCs and TB hoods
- Enhanced infection prevention at a reduced cost

Challenges in this Field:

- Many people not well informed about the certification needs
- No updated inventory of the BSCs and TB Hoods nationally- not all counties
- Most BMEs don’t understand or take safety serious
- Facility design

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Safety is everybody's responsibility and it starts with you, 'BE SAFE'
Every cadre needs capacity building


Thank You