Market vigilance procedure

Intended use: This SOP describes how complaints expressed by the end-user are handled and how corrective measures are taken. It also describes the different parties and persons involved

End-user: Any person or representative of an institute, a national control programme, an NGO etc. that has purchased or otherwise received mAECT columns from INRB.

Principal contact: In the instruction leaflet that comes with the mAECT kit, the coordinates of the person to contact in case of complaints are mentioned (actually D. Mumba).

Parties involved in follow-up:

INRB (Director: J.J. Muyembe)
ITM (Project Leader: P. Büscher)
FIND (Quality Manager: B. Porstmann, Program Manager: J. Ndung'u)

Persons involved in corrective measures

INRB: Head Production Unit: D. Mumba
Principal Technician: S. Fumie
Sterilisation Unit: Z. Mossoko
Functional QC responsable: P. Pyana
ITM: Project Leader: P. Büscher

Procedure (see also flowchart)

1. Any complaint by the end-user about technical failure, ordering, purchase, delivery of the mAECT kit observed at different level (field station, laboratory, hospital, central dispatching etc.) should be expressed by email, fax, letter, telephone to the central contact point at INRB, Kinshasa as indicated in the instruction leaflet. The person currently acting as the central contact point is the actual Head of the Production Unit.

2. The Head of the Production Unit (D. Mumba) keeps record of the complaints with copy to the Director at INRB (JJ Muyembe), the Quality Manager (B. Porstmann) and the Program Manager (J. Ndung'u) at FIND, and the Project Leader at ITM (P. Büscher).

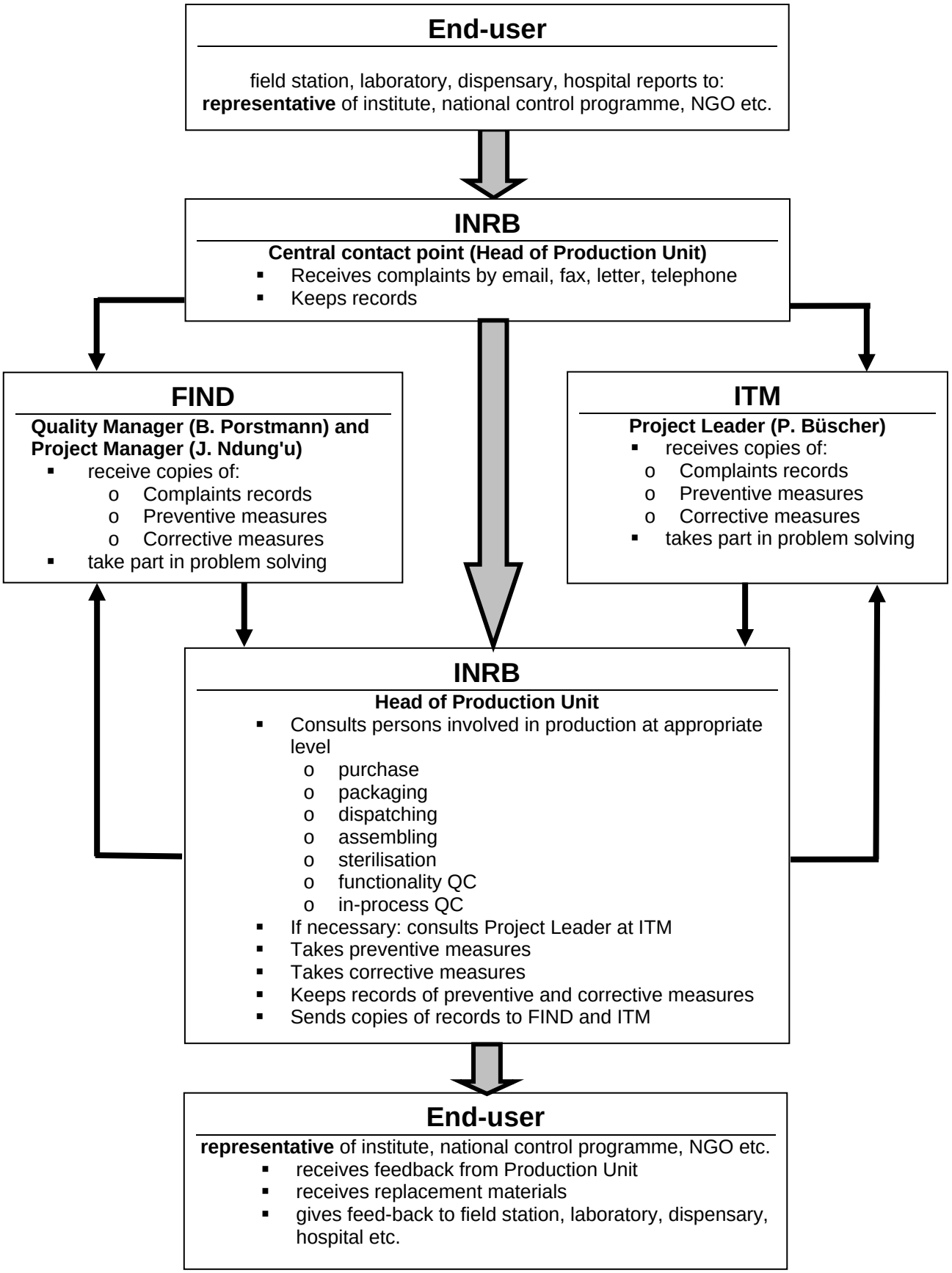
3. Depending on the type of complaint, the Head of the Production Unit consults the persons involved in the mAECT production process (purchase, packaging, dispatching, assembling, sterilisation, functionality QC, in-process QC) to identify the problem and to find a solution to the problem. If necessary, the Project Leader at ITM assists in this process.

4. Preventive measures are taken at the appropriate level (purchase, packaging, dispatching, assembling, sterilisation, functionality QC, in-process QC) by adapting materials, reagents etc. or by adapting the relevant SOPs. The Head of the Production Unit keeps record of the preventive measures taken, with copy to the Quality Manager and Project Manager at FIND, the Project Leader at ITM and the Director at INRB.

5. Corrective measures are taken at the appropriate level and, if necessary, materials or whole kits are dispatched to the end-user to replace failing materials. The Head of the Production Unit keeps record of any corrective measure taken, with copy to the Quality Manager and Project Manager at FIND, the Project Leader at ITM and the Director at INRB.

6. If root cause analysis of product failures shows systematic failures of specific lots, INRB will inform all sites having been provided with kits from this lot about failures, and call back remaining kits from the affected lot.

Market Vigilance Flowchart



Dispatching of mAECT tests and accessories

Intended use The SOP M/32 describes how mAECT tests and accessory materials are prepared and dispatched to the end-user

Material
Computer
MS-Excel
File "Logbook dispatching.xls"
File "Production and stock monitor.xls"

Procedure

1. Note each step in the file "Logbook dispatching.xls" with the different sheets: mAECT kit, tube rack, viewing chamber, collector tubes, costumer, carrier.

2. Note the number per batch of mAECT kits dispatched in the file "Production and stock monitor.xls".

3. Prepare the colli with packing list and send it by DHL, World Courrier or other carrier or person

4. Prepare the invoice with transport costs included and to be paid by the end-user

5. Communicate the Airway Bill (AWB) to the end-user and follow the colli through the website of the carrier

6. Check arrival of colli at end-user.

7. Check payment of invoice by end-user.

Temperature check of fridges, freezers and production room

Intended use The SOP M/33 describes how temperature of fridges, freezers and the production room are monitored to guarantee correct storage and working conditions and to take corrective measures if needed.

Materiel Computer with printer
Software MS-Excel
File "logbook temperature.xls"

Procedure

1. Identify the apparatus that should be monitored for temperature (all fridges and freezers for storage of reagents and mAECT columns.

2. Install thermometers with a sensor within the fridges and the freezers.

3. Print the different temperature monitoring sheets from the file "logbook temperature.xls" and make sufficient copies.

4. Stick a sheet on every apparatus and on the wall of the production room.

5. Record the temperature every morning and evening, except on sundays.

6. Pay attention that the temperature for each apparatus falls within the tolerated minimum and maximum. If not correct, adjust the temperature control of the apparatus or the air conditioning.

7. If the apparatus or the air conditioning is broken, have them repaired or replaced. In the meantime, store the reagents or columns in another apparatus.

8. After each month, replace the temperature control sheets and keep them in the filer "Temperature monitoring".

TEMPERATURE SHEET

MONTH		MINIMUM TEMPERATURE: 4 °C.
FRIDGE NR		MAXIMUM TEMPERATURE: 10 °C

DATE	T° 8.00 A.M.	T° 4.00 P.M.	SIGN.	REMARKS AND CORRECTVE MEASURES
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TEMPERATURE SHEET

MONTH		MINIMUM TEMPERATURE: -20 °C.
FREEZER NR		MAXIMUM TEMPERATURE: -10 °C

DATE	T° 8.00 A.M.	T° 4.00 P.M.	SIGN.	REMARKS AND CORRECTIVE MEASURES
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TEMPERATURE SHEET

MONTH			MINIMUM TEMPERATURE: n.a.	
FREEZER NR			MAXIMUM TEMPERATURE: n.a.	
DATE	T° 8.00 A.M.	T° 4.00 P.M.	SIGN.	REMARKS AND CORRECTIVE MEASURES
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Daily cleaning of the production laboratory

Intended use This SOP M/34 describes how the mAECT production laboratory is cleaned daily and how the cleaning is checked and registred

Materiel
Computer with printer
Software MS-Excel
File "Logbook nettoyage atelier.xls"
Cleaning material and disinfectants

Procedure

1. Identify the person who will daily clean the production room, with exception of the days that there is no production.

2. Print a sheet of the file "logbook nettoyage atelier.xls" and stick it .each week to the wall of the production room. *Note: this sheet is represented here after.*

3. Have the production room cleaned by the responsible person and instruct this person how to register the cleaning steps on the sheet "logbook nettoyage atelier"

4. Check every week if the production room is cleaned properly and if the checklist is filled.

5. Replace the sheet "logbook" with a new sheet and keep it in the file "Nettoyage".

6. If the production room is not cleaned properly, take measures to correct the situation.

CHECK LIST CLEANING OF THE PRODUCTION LABORATORY

MONTH: **WEEK N°**

CLEANING PERSONNEL: **SUPERVISOR:**

		MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATERDAY
1	EMPTY THE BIN						
2	BRUSH THE FLOOR						
3	CLEAN THE CUPBOARDS						
4	WASH THE WALLS (TILES)						
5	WIPE THE DOORS						
6	WIIPE THE WINDOWS						
7	CLEAN TABLES						
8	WIPE THE CHAIRS						
9	CLEAN THE FLOOR WITH LIQUID SOAP						
10	CLEAN THE BIN WITH LIQUID SOAP						
11	CLEAN THE SINK WITH LIQUID SOAP						
12	POUR DESINFECTANT LIQUID IN THE WATER EFFLUX IN THE FLOOR						
13	CLEAN BEHIND CUPBOARDS (1 x per week)						
14	VAPORISE INSECTICIDE EVERY EVENING						
	SIGNATURE CLEANING PERSONNEL						
	SIGNATURE SUPERVISOR						