

SEAM Tanzania

Quality Assurance: Establishing Standard Operating Procedures

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Objective

Under the Tanzania Food and Drugs Authority (TFDA) Act of 2003, the TFDA inspectors have the authority to enter any premises to verify that pharmaceutical regulations are being followed. Qualified, experienced pharmaceutical inspectors are central to the TFDA's efforts and serve as key law enforcement officials. Effective training of inspectors requires the development of standard procedures.

The TFDA compliance decision tree, developed in collaboration with the Ministry of Health (MOH) and SEAM Tanzania, provided the structure to create standard operating procedures (SOPs), which outline steps for conducting and recording inspections of products and premises for compliance with regulations. These SOPs are set out in the *Inspectors' Handbook*, which also serves as a reference for manufacturers, importers, wholesalers, and retail distributors.

Implementation

- Each inspectional function was defined and reviewed by a group of key managers and experienced field investigators.
- Step-by-step procedures on what actions are required at each decision point were discussed and documented.
- These procedures were adapted to SOP format, and checklists were prepared to guide inspectors through the process.

SOP Inventory

- ✓ POE Inspection, Screening, and Testing SOP
- ✓ POE Reporting Form
- ✓ Physical Examination of Pharmaceutical Products SOP
- ✓ Physical Examination Reporting Form
- ✓ Antimalarial Drug Surveillance Program Phase 1 SOP
- ✓ Suspicious Sample Surveillance Program SOP
- ✓ Dispensing Outlet Inspection SOP
- ✓ Dispensing Outlet Report Form
- ✓ Postmarketing Surveillance Program SOP
- ✓ Chain-of-Custody, Packing, and Shipping SOP

Sample SOP: Premises

Dispensing outlets subject to inspection—

- Pharmaceutical warehouses
- Wholesalers
- Medical Stores Department
- Part I drug shops—pharmacies
- Part II drug shops—*duka la dawa baridi*/over-the-counter+ outlets
- Hospitals
- Health centers
- Dispensaries



Premises scope of inspection—

- Personnel qualifications
- General condition of the premises
- Security
- Storage conditions
- Availability of ancillary items
- Record keeping and documentation
- Product labeling
- Sample collection for further testing
- Availability of reference materials
- General observations



Sample SOP Element

Record Keeping and Documentation

Directed audits

- ✓ Prescription book
- ✓ Poison book
- ✓ Controlled drugs book
- ✓ Written procedures for maintenance of cold-chain products
- ✓ Import permits
- ✓ Ledger book or other appropriate inventory control system

- ✓ TFDA–endorsed Pro forma Invoices
- ✓ Receipts and invoices
- ✓ Copies of delivery notes
- ✓ Accuracy of record keeping
- ✓ Endorsement of entries by authorized persons
- ✓ Legality of origin of supplies
- ✓ Written procedures for handling returned, recalled, and/or expired drugs
- ✓ Written procedures for dealing with complaints and/or adverse reaction reports