FOOD AND DRUGS AUTHORITY

GUIDELINE FOR LICENSING OF PREMISES FOR THE STORAGE AND DISTRIBUTION OF MEDICAL DEVICES

Document No. : FDA/MCH/MID/GL-MD-GDP 2019/03
Date of First Adoption : 1st September 2020
Effective Date : 1st September 2020
Version No. : 01

ACKNOWLEDGEMENT

It is acknowledged that, in the development of this Guideline, reference was made to the following sources:

- ISO 13485: 2016 (Medical Devices – Quality Management Systems – Requirements for regulatory purposes).
- Global Harmonization Task Force (GHTF) Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers (GHTF/SG4/N30:2010)
- Health Sciences Authority's Medical Device Technical Specification on Good Distribution Practice for Medical Devices Requirements (TS-01)
- Health Products Regulatory Authority (HPRA) Guide to Distribution of Medical Devices, including in vitro diagnostic Medical Devices
- Public Health Act, 2012 (Act 851)
- US Food and Drug Administration (US FDA) Quality System Regulation – 21 CFR 820

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1.0 INTRODUCTION

In pursuance of Sections 122(1), 130, 131 and 148 of the Public Health Act, 2012 (Act 851), this Guideline is hereby made to provide information on the requirements for the registration and licensing of premises or facilities for the storage and distribution of medical devices in Ghana and also for the upkeep of already licensed storage facilities. This includes information on Good Storage Practice/Good Distribution Practice (GSP/GDP) requirements for medical devices

This Guideline applies to all person(s) that engage in the importation, exportation, storage, transportation, wholesale and distribution of medical devices in Ghana. In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), these person(s) shall not offer for sale, sell, supply or store medical devices except in premises registered and licensed by the Food and Drugs Authority (FDA) for that purpose. In addition, in accordance with Section 118(1), medical devices imported, exported, sold, supplied, exhibited for sale and distributed by these person(s) are required to be registered with the Authority.

Premises for the storage, wholesale and distribution of medical devices shall be subjected to pre-licensing and post-licensing GSP/GDP inspection in accordance with the requirements of this Guideline. The inspection will be risk-based, and will be informed by factors such as product and process risk, compliance history, risk associated with the use of the product, and relevant recalls carried out.

Improper storage and distribution of medical devices along the supply chain may lead to undesirable, and in some cases extremely serious consequences.

The purpose of the GSP/GDP inspection therefore is to verify that medical devices imported, exported, stored, transported, wholesaled and distributed consistently meet applicable regulatory requirements. The GSP/GDP inspection observations, if found to be satisfactory, will guide the Authority in its decision to issue a new licence or renew an existing licence in accordance with Section 131 of the Act.

Applicants are advised to observe the provisions of this Guideline before submitting an application for registration and subsequent licensing of its premises for the storage and distribution of medical devices.

This Guideline is hereby promulgated for information, guidance and strict adherence by all concerned.

2.0 GLOSSARY

In this Guideline, unless the context otherwise requires, the following terms have the assigned meanings:

2.1 **Authority:** Food and Drugs Authority (FDA).

2.2 **Authorized officer:** A Regulatory Officer of the Authority.

2.3 **Adverse Event:** Any event or other occurrence, that reveals a defect in any medical device or that concerns any adverse effect arising from the use thereof.

2.4 **Contamination:** The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a finished product during production, sampling, packaging or repackaging, storage or transport.

2.5 **Counterfeit product:** A product which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeit products may include products with the correct ingredients, with the wrong ingredients, with an incorrect quantity of ingredients or with fake packaging.

2.6 **Customer Complaint:** Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

2.7 **Distribution:** The release, delivery and post-delivery activities conducted by an entity.

2.8 **Distributor:** Legal person in the supply chain who makes a product available on the market up until the point of putting into trade.

2.9 **Entity:** Any legal person, engaging in the importation, exportation, storage, transportation and wholesale distribution of medical devices.

2.10 **Expiry date:** The date given on the individual container (usually on the label) of product up to and including the period within which the product is expected to remain within specifications, if stored correctly.

2.11 **Export:** To take or cause to be taken out of the Republic.

2.12 **Field Safety Corrective Action (FSCA):** Any action taken to reduce the risk of death or serious deterioration in the state of health of a person associated with the use of a medical device, including

(a) The return of the medical device to its product owner;
(b) The replacement or destruction of the medical device;

(c) Any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
(d) The clinical management of any patient who has used the medical device;
(e) The modification of the medical device;
(f) The retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;
(g) The making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
(h) Any upgrade to any software used with the medical device, including any such upgrade carried out by remote access;

2.13 **Field Safety Notice (FSN):** a communication sent out by a product owner or its representative to the device users in relation to a FSCA.

2.14 **First expiry/First out (FEFO):** A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date.

2.15 **Good Distribution Practice (GDP):** That part of quality assurance that ensures that the quality of a product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, substandard, falsified or misbranded products.

2.16 **Good Storage Practices (GSP):** That part of quality assurance that ensures that the quality of a product is maintained by means of adequate control throughout the storage thereof.

2.17 **Import:** To bring or cause to be brought into the Republic.

2.18 **Importer:** A person who brings into the Republic a medical device.

2.19 **Labelling:** The action involving the selection of the correct label, with the required information, followed by line clearance and application of the label.

2.20 **Manufacture:** Manufacture may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or refurbishing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

2.21 **Manufacturer**: any person who manufactures.

2.22 **Medical Device or Devices:** An instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is recognized

in the Official National Formulary, or Pharmacopoeia or any supplement to them;

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
- Intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

2.23 **Premises:** Any location that is used for activities dealing with medical devices, including manufacture, storage and distribution.

2.24 **Recall:** A process for withdrawing or removing a product from the distribution chain because of defects in the product, consumer complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

2.25 **Storage:** The storing of products up to their point of use.

2.26 **Supplier:** An entity providing medical devices on request. Suppliers may be agents, brokers, distributors, manufacturers or traders. Where possible, suppliers should be authorized by a competent authority.

2.27 **Wholesale:** Supplying medical devices to a person or entity who obtains the product for the purposes of supplying it further to another person or entity.

3.0 REQUIREMENTS

3.1 APPLICATION REQUIREMENTS

3.1.1 New Applications

3.1.1.1 An application to register and license a new facility for the storage and distribution of medical devices shall be made in writing by submitting a completed application form with a cover letter addressed to:

The Chief Executive Officer
Food and Drugs Authority
GA-237-7316
Accra

3.1.1.2 The completed application form (FDA/MCH/MID/APS-LMD/2019/03) shall be dated, signed and stamped by the applicant and shall provide the following minimum information as part of the licence acquisition:

(a) The name, full business address, location/site address and telephone numbers (including mobile telephone numbers) of the applicant.

(b) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of medical devices. If the storage facility is owned by a third party, other than the owner of the business, the details of the third party, should also be provided.

(c) The type of ownership of the premise (i.e. whether applicant-owned or third-party owned) and the name(s) of owner(s)

(d) The type of business operation (i.e., partnership, corporation, or sole proprietorship); and the name(s) of the partner(s)/director(s)/proprietor(s) of the applicant.

3.1.1.3 The completed application form shall be accompanied by:

(a) Non-refundable application fee as specified in the Authority's Fee Schedule.

(b) Certified true copies of Certificate of Incorporation and Certificate to Commence Business from Registrar General's Department.

3.1.1.4 In situations where the storage facility is more than one, a separate application is required for each premise, except where a group of buildings on one or more sites are engaged in storing and distributing the same kind of product under the same direct storage and distribution management.

3.1.1.5 The Authority shall consider, as a minimum, the following factors in reviewing the qualifications of applicants:

(a) Any convictions of the applicant relating to FDA-regulated products.

(b) The applicant's history of regulatory compliance in the storage and distribution of FDA-regulated products.

(c) The applicant has provided the Authority with false or fraudulent information or material in respect of its application for FDA-regulated products.
(d) The applicant's licence has been suspended or revoked by the Authority for violation of any FDA law.
(e) Any other requirements the Authority may from time to time prescribe.

3.1.1.6 The Authority may approve, defer or refuse an application following assessment including GSP/GDP inspection findings which shall be duly communicated to the applicant.

3.1.1.7 A licence issued under this Guideline shall be valid for one year and shall be renewable.

3.1.1.8 The Authority shall exercise the right to cancel or suspend a licence in accordance with Section 119(1) of the Act.

3.1.1.9 An applicant shall submit any and all changes in their application information to
the Authority prior to amending or changing its existing records or information.

3.1.2 Renewal Applications

3.1.2.1 The registration and licensing of the premises shall be renewed annually.

3.1.2.2 An application for renewal of registration of premises shall be made at least 3 months before the expiry of the existing licence by submitting with a cover letter the following:
(a) Duly completed application form ((FDA/MCH/MID/APS-LMD/2019/03)
(b) Non-refundable application fee in accordance with the FDA fee schedule

3.1.2.3 The applicant's compliance with GSP/GDP shall be a key determinant to the renewal of the registration and licensing of the premises.

3.2 GSP/GDP REQUIREMENTS

Aspects of quality systems for storage, transportation, documentation and record-keeping practices that are observed in the manufacturing environment shall be applied to the storage and distribution of medical devices. Entities engaged in the importation, storage, wholesale, distribution, transportation, exportation of medical devices shall therefore establish, implement and maintain the requirement of ISO 13485 applicable to the storage and distribution of medical devices. The key requirements are as listed below:

(1) Quality system
(2) Management and Personnel
(3) Premises and Storage Areas
(4) Management of Products
(5) Distribution, Dispatch and Transport

(6) Installation and Servicing
(7) After-sales Obligations
(8) Documentation and Records
(9) Disposal of Products

3.2.1 Quality System

3.2.1.1 *Quality management system*: The entity is required to put in place an effective quality system that provides assurance that:

(a) Only medical devices which comply with applicable regulatory and customer requirements are distributed
(b) Non-compliant, defective or unsuitable medical devices can be detected
(c) A traceability system is established, implemented and maintained
(d) Non-conformances and the introduction of changes are controlled.

The entity is therefore required to document and implement a quality management system and maintain its effectiveness in accordance with the requirements of the current ISO 13485 as applicable to the specific medical device(s) being stored and distributed. Furthermore, the entity shall apply a risk-based approach to the control of the appropriate processes needed for the quality management system

3.2.1.2 *Outsourced activities:* Where an entity outsources any activity that may affect the quality of medical devices being stored and distributed, the entity shall ensure control over such processes to ensure that the outsourced activities conform to specified requirements. Technical agreements should be in place for all outsourced activities relating to storage and distribution. The technical agreements should at least describe the roles and responsibilities of both parties including details on transportation arrangements, receipt of goods, batch release arrangements, customer approval, documentation, recalls, returns, customer complaints, suspected falsified medical devices, and management of deviations and changes.

3.2.1.3 *Rental of storage premise*: Where an entity rents a premise for the purposes of storage and distribution, the entity shall ensure that the activities in the rented premises conform to specified requirements contained in this Guideline.

3.2.2 Management and Personnel

3.2.2.1 *Management Commitment*: Top management shall provide evidence of its commitment to the development, implementation and maintenance of the quality system for the storage and distribution of medical devices. Top management is therefore required to establish a quality policy, quality objectives and quality plan and should ensure resource availability for implementation of the quality system. In addition, top management must also communicate to the organization the importance of meeting applicable regulatory requirements for customer satisfaction.

3.2.2.2 *Organizational chart (reporting structures and role profiles):* The organizational structure should be defined such that the organization and functioning of the staff of the entity is understood. It should be appropriate for the size of the entity and the diversity of products stored and distributed. The responsibilities and authorities within the entity should be defined, documented and communicated. Additionally, the entity shall establish the interrelation between all personnel who manage, perform and verify work that affects storage and distribution of medical devices and should ensure the independence and authority to perform these tasks.

3.2.2.3 *Personnel Adequacy, Competency and Training:* There should be sufficient competent personnel on the basis of appropriate training, skills and experience to carry out all necessary tasks with respect to the storage and distribution of medical devices. Training should include but not be limited to the following:

(a) Defined responsibilities and roles
(b) Product storage requirements
(c) Labelling
(d) Reporting of non-compliances
(e) Segregation of storage areas to minimize the risk of mix-ups
(f) Recall/withdrawal procedures
(g) Complaints procedures
(h) Product security
(i) Product identification
(j) Detection of counterfeits and the prevention of counterfeits entering the supply chain.

The effectiveness of trainings or other actions taken should be evaluated and appropriate records on education, training, skills and experience should be kept.

3.2.2.4 *Personnel Hygiene and Health:* The entity shall document and implement requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance.

3.2.2.5 *Management Representative:* The entity shall appoint a member of the management who, irrespective of other responsibilities, shall have the ultimate responsibility of:

(a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
(b) Reporting to top management on the performance of the quality management system and any need for improvement, and
(c) Ensuring the promotion of awareness of regulatory requirements and customer satisfaction in the entity.

The responsibility of a management representative can include liaising with external parties on matters relating to the quality management system.

3.2.2.6 *Internal Audits:* The entity shall conduct internal audits at planned intervals to monitor the implementation of and compliance to the requirements of its quality system and related regulatory requirements with respect to good storage and distribution practice and whether it is effectively maintained. The entity shall therefore define in a documented procedure, the responsibilities and requirements for planning internal audits (a risk based internal audit plan), conducting and reporting of audit results and maintenance of the audit records. Actions to eliminate detected nonconformities and their causes shall be taken without undue delay. Verification of the actions taken and the reporting of verification results shall be recorded.

3.2.2.7 *Management Review:* The entity shall review its quality management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system. The input to management review should be defined and the output should be recorded. Records from management reviews shall be maintained.

3.2.3 Premises and Storage Areas (Infrastructure/work environment)

3.2.3.1 *Receiving and Dispatch Bay:* The receiving and dispatch bays should protect medical devices from the weather and possible objectionable effects on product quality. The receiving and dispatch bay should also facilitate cleaning of incoming products, if necessary, before storage.

3.2.3.2 *Accessibility to Storage Area*: Precautions must be taken to prevent unauthorized persons from entering storage areas, particularly, if contact between such persons and the product or storage area could affect medical device safety and performance.

3.2.3.3 *Size and Capacity of Storage Areas*: Storage areas should generally permit organized storage. It should therefore be of sufficient capacity to allow for orderly arrangement of all category of products under storage (i.e. products in good condition, returned or recalled products as well as quarantined products). The storage areas for the various categories of products should be clearly defined and demarcated.

3.2.3.4 *Ventilation and Illumination:* Storage areas should provide adequate ventilation and lighting to enable all operations to be carried out accurately and safely.

3.2.3.5 *Cleaning and Sanitation:* Storage areas should be clean, and free from accumulated waste and vermin. The entity shall establish documented requirements for cleaning of premises, including frequency and methods. Records of cleaning shall be maintained. There should be procedures for the

clean-up of any spillage to ensure complete removal of any risk of contamination. Wastes should be disposed of in a timely and sanitary manner. As appropriate, the entity shall plan and document arrangement for the control of contaminated or potentially contaminated product in order to prevent contamination of the storage area, personnel or product.

3.2.3.6 *Pest Control:* Premises should be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin. There should be a pest control programme appropriate for the premises to identify and prevent pest infestation and measures should be taken to control the exterior of the premises to prevent attracting or harbouring pests. Any pest-control agents used should be safe, and there should be no risk of contamination of the products. A bait map should show the locations of all pest control monitoring stations and should be approved by the distributor. Any recommendations made by a pest control service provider should be implemented and recorded. If recommendations are not implemented, an explanation should be recorded. All pest control records should be approved by the entity and maintained.

3.2.4 Management of Products

3.2.4.1 *Receipt of products:* The entity shall establish and implement inspection or other activities necessary to ensure that medical devices received meet specified requirements. It is recommended that deliveries are examined at receipt to include checking for damage (including any breaches to sterile packaging) and appropriate remaining shelf life. A written SOP should be in place to enable any non-conforming or defective product to be detected and quarantined. Records of the verification shall be maintained.

3.2.4.2 *Product Segregation:* Where an entity's storage facility has capacity to hold different regulated products, the owner shall ensure that markedly distinct, separate or defined areas are provided for the different regulated products.

3.2.4.3 *Packing and Arrangements of Products:* Generally, products should be handled and stored in such a manner as to prevent contamination and mix-ups. Products received should be suitably packed on pallets, racks, shelves and other packing aid which should be kept in a good state of cleanliness and repair. Products should be stored off the floor and suitably spaced (preferably not against the wall) to permit cleaning and inspection. Containers of products should be closed.

3.2.4.4 *Storage of products and monitoring of storage conditions:* Medical devices under storage or in transport are required to comply with the storage conditions set by the manufacturer. Generally, medical devices shall be stored under specified conditions to prevent deterioration by light, moisture, temperature or other conditions. Medical devices subject to specific storage measures shall be immediately identified and stored in accordance with the specified storage condition. Storage conditions shall be monitored and

recorded where appropriate and records of the storage conditions shall be maintained. Equipment such as thermometers used to measure and monitor the storage conditions of the storage area to ensure proper conservation of medical devices (during storage and distribution) shall be calibrated or verified at specific intervals, or prior to use against measurement standards traceable to international or national standards and corresponding records kept.

3.2.4.5 *Stock Rotation:* The entity shall establish a system to ensure stock rotation. The "first expired/first out" (FEFO) principle should be followed. Except in special circumstances such as expiry, stock rotation should ensure that the oldest released stock is used first (FIFO-first-in/First-out). Medical devices beyond their expiry date or shelf life shall be segregated from usable stock and should be clearly identified as such. All stock should be checked regularly for obsolete and outdated products. All due precautions should be observed to prevent the issue of outdated products.

3.2.4.6 *Stock Reconciliation*: Periodic stock reconciliation should be performed by comparing the actual and recorded stock. All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue and corrective action taken.

3.2.4.7 *Damaged Containers:* Products with damaged packages should not be issued unless the quality of the product has been shown to be unaffected. Where possible, this should be brought to the attention of the person responsible for quality control. Any action taken should be documented. Broken or damaged items should be withdraw from usable stock and separated.

3.2.4.8 *Returned Medical devices:* The entity shall establish documented procedures for handling of returned medical devices.

All returned medical devices shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal. There should be a register or log of returns in place which should include all medical device details and reasons for their return.

The criteria for re-evaluation of the returned medical devices and the assessment performed should be documented and should include the final disposition (i.e. approved for sale, quarantined, rejected or intended for destruction).

Special care must be exercised with the return of any medical devices requiring storage at low temperatures and sterile medical devices. Should an organization decide to accept returns of medical devices requiring storage at low temperatures, the criteria for accepting these (including evidence that the medical device was maintained within the cold chain for the period during which it was outside of its control) should be adhered to.

Sterile medical device stock should only be returned to saleable stock where there is no reasonable possibility that sterility has been compromised (i.e. broken seals, damaged packaging or suspected of possible contamination, etc.).

3.2.4.9 *Substandard/Falsified Medical Devices:* The entity shall take steps to prevent substandard, falsified or counterfeit medical devices from being traded with other distributors, placed on the market or returned to the company. The entity therefore must:

(a) Have a procedure in place detailing the processes to be followed in the event of identifying a suspected falsified medical device or of being notified that a suspected falsified medical device has been received. It should include keeping them apart from other products to avoid any confusion and clearly labelling them as “not for sale”.
(b) Be aware of the possibility of falsified medical devices being supplied inadvertently through legitimate sources.
(c) Have robust systems for ensuring the legitimacy of their suppliers and ensure that this is regularly reviewed.
(d) Maintain a list of approved suppliers and ensure that medical devices are only sourced directly from these approved suppliers.
(e) Be familiar with the supply chain history of the medical devices received and question previous stages in the supply chain, if deemed necessary.
(f) Train staff to be aware of falsified medical devices and what to look out for.
(g) Ensure that the goods-in procedure involves a detailed inspection of medical devices received and is capable of identifying changes or unusual aspects to the appearance and packaging of medical devices.
(h) Be vigilant and do not allow themselves to be used by counterfeiters to ‘launder’ falsified medical device.
(i) Be aware of the possibility of falsified medical device entering the supply chain through returns.
(j) Be knowledgeable of medical devices at risk of counterfeiting. Purchasers for the distributor should also be made aware of these medical devices.

An entity in possession of a medical device that is found to be (or suspected of being) falsified is responsible for the removal and quarantine of the medical device from saleable stock. If the entity is suspicious that a medical device which is being offered or has been received is not genuine then the Authority should be informed immediately.

3.2.4.10 *Rejected products:* When products are quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance.

3.2.5 Distribution, Dispatch and Transport

3.2.5.1 *Handling:* The entity shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer. The entity shall therefore establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other objectionable effect to product do not occur during handling for dispatch and distribution.

3.2.5.2 *Distribution*: The entity shall establish and maintain procedures for the control and distribution of the device to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. This should include the first expiry/first out (FEFO) distribution procedure. Where a device's fitness for use or quality deteriorate over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

3.2.5.3 *Transportation*: Medical devices must be transported appropriately and in accordance with labelled storage conditions (including sterile conditions if applicable) and written procedures. The entity shall therefore establish adequate methods of transportation to achieve safe and secured delivery of all medical devices from their point of collection to their point of delivery. Medical devices shall be transported in such a way that:

(a) Their identification is not lost;
(b) They do not contaminate, and are not contaminated by other medical devices or materials/substances;
(c) Adequate precautions are taken against spillage, breakage or theft;
(d) They are secured and not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence, or to attack by microorganisms and pests.
(e) Records on dispatch and transport should be retained, readily accessible and available on request stating at least, the date of dispatch, the customer's name and address, the product description, batch/serial number and quantity as well as the transport and storage conditions.

3.2.6 Installation and Servicing

3.2.6.1 *Installation*: Where the installation of a medical device is a specified requirement, the entity shall establish and maintain adequate installation and inspection instructions, and where appropriate, test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the medical device will perform as intended after installation. Installation, inspection and any required testing are to be performed in accordance with the instructions and procedures. The records of inspection and any test results to demonstrate proper installation shall be maintained.

3.2.6.2 *Servicing*: Where servicing is a specified requirement, the entity shall establish and maintain instructions and procedures for performing and

verifying that the servicing meets the specified requirements. Records of servicing shall be maintained.

3.2.7 After-sales obligations

3.2.7.1 *Distribution records/ Device Traceability*: Devices shall be appropriately identified and the entity shall keep and maintain records on the distribution of the devices to allow for traceability. These records should include amongst others batch/serial number, manufacturing date, expiry date, name and address of the consignee, date of issue and any other records to facilitate traceability.

3.2.7.2 *Complaint handling*: All complaints to the entity should be reviewed, investigated and followed-up on, as appropriate. The entity shall therefore establish a documented procedure for handling of customer complaints. Records of the complaint, investigation and any subsequent actions taken shall be maintained.

3.2.7.3 *Adverse Event reporting*: Any complaint or reports of adverse event that meets the regulatory reporting criteria received by the organization shall be reported to the regulatory authority as well as the manufacturer.

3.2.7.4 *Recall*: The entity shall establish documented procedures for the recall of medical devices that do not meet regulatory requirements. The recall procedure in place should be robust enough to enable the swift and effective recall from the marketplace of defective and/or potentially harmful medical devices. When a product recall decision is made, appropriate steps should be taken to complete the recall as required and to implement corrective action. All recalled medical devices shall be segregated apart from saleable stock to prevent redistribution until a decision has been reached regarding their disposal or otherwise.

3.2.7.5 *Field Safety Corrective Action (FSCA)*: The entity shall establish documented procedures for handling FSCA.The responsibilities for planning, conducting, reporting of the corrective action shall be defined in the documented procedure and should include Field Safety Notices (FSN). The regulatory authority shall be informed prior to execution of the FSCA. If the medical devices are exported, the overseas counterparts shall be informed of the FSCA. Records of all actions taken in connection with the FSCA and their approval by the entity and regulatory authority shall be maintained.

3.2.7.6 *User training*: The entity shall determine any user training needed to ensure specified performance and safe use of the medical device.

3.2.7.7 *Advertising (Representation)*: Unapproved advertisement of product is prohibited. The entity shall therefore take steps to ensure that any products to be advertised are duly registered with the Authority and the advertisement is vetted and approved by the Authority.

3.2.8 Documentation and Records

3.2.8.1 *QMS Documentation*: The entity shall establish and maintain documentation and records for the quality management system which shall include:

(a) Documented statements of a quality policy and quality objective;
(b) A quality manual;
(c) Documented procedures;
(d) Work instructions where necessary;
(e) Records (to provide evidence of activities performed or results achieved)
(f) Any other documentation specified by the regulatory authorities.

3.2.8.2 *Procedures and Records:* Written instructions, procedures and corresponding records should be available to support activities carriedout in the facility. This should include but not limited to the following:

(a) Training
(b) Documentation control
(c) Approval of suppliers and customers
(d) Order processing and deliveries
(e) Waste management
(f) Internal audit
(g) Change control
(h) Management review
(i) Quality risk management
(j) Deviation management
(k) Corrective and preventive actions

3.2.8.3 Some other records required:

Other records to be maintained by the entity should include:

(a) copies of invoices relating to the receipt and supply of a medical device
(b) copies of orders relating to the receipt and supply of a medical device
(c) a list of approved medical device suppliers and details of the relevant medical devices
(d) customer list to include contact details of all customers to whom medical devices were supplied
(e) records of checks carried out at receipt (for example labelling checks) and the approval of medical device into saleable stock

3.2.8.4 *Control of Documents and Records*: All documents shall be prepared, approved, signed and dated by an appropriate authorized person(s) and any change in person(s) permitted to carry out this task requires authorization. Documents and records shall be legible, readily identifiable and retrievable. Documents shall be reviewed regularly and kept up-to-date. When a document has been revised, a control system shall be established to prevent the unintended use of the superseded version.

3.2.8.5 *Records retention*: Records should be retained for a period equal to the shelf-life of the incoming products, where applicable, plus 1 year. Where the

records are generated and kept in electronic form, back-ups should be maintained to prevent any accidental data loss.

3.2.9 Disposal of Products

3.2.7.1 All medical devices that are rejected in-house, rejected when received as a return from a customer, expired, unwanted or recalled stock should, if instructed accordingly, be destroyed in an appropriate and timely manner and in accordance with waste legislation.

3.2.7.2 A documented procedure for safe disposal should therefore be developed. The decision to dispose of products and inventory of such products should be documented.

3.2.7.3 In accordance with Section 132(2) & (3), the Authority shall supervise the safe disposal process at a fee. Accordingly, a person shall not dispose of an unwholesome regulated product without the supervision of the Authority.

3.2.7.4 If the unwanted products have not been immediately sent for disposal, they shall be kept in a clearly segregated area and identified so that they will not be sold inadvertently or contaminate other products. Records of the disposal including certificates shall be maintained.

3.3 CLASSIFICATION OF INSPECTION FINDINGS / NON-COMFORMITIES

3.3.1 Non-conformities

Non-conformities identified, following an inspection may be classified as major or minor and they have to be corrected. These shall be communicated to the entity and a corrective and preventive action to address them would be required of the company inspected.

3.3.1.1 *Major non-conformity:* A major non-conformity is a serious deficiency that could adversely affect product quality (i.e. specification). It could also be a single infraction that by itself constitutes evidence of persistent failure. A number of observations that individually are of small importance whose frequency indicates a serious deficiency can also be classified as a major non-conformity.

3.3.1.2 *Minor non*-conformity: A minor non-conformity is an isolated instance of failure to conform with a specified requirement that does not have an effect on product quality.

3.3.2 Other Observations

Inspection observations that are not non-conformities per se but worth noting may be expressed as “Opportunity for improvement” or “Concern”.

3.3.2.1 *Opportunity for Improvement:* Inspection findings that appear to be undesirable but cannot be cited as a non-conformity are described as “Opportunity for improvement”. Corrective action is not required.

3.3.2.2 *Concern:* An inspection or audit finding is said to be of “Concern” in situations in which there is no information at the time of the inspection to determine if a non-conformity exists. The concern shall be noted in the inspection report for further regulatory action.

3.4 STAKEHOLDER TRAINING

The Authority will periodically conduct appropriate stakeholder training for importers and distributors to enhance their level of compliance.

4.0 TIMELINES

4.1 Conducting the inspection

Barring unforeseen circumstances, inspection of the storage facility will be carried out within 90 days upon receipt of application.

4.2 Unannounced Inspections

Despite existing protocols with respect to planned inspections, the Authority shall, when it deems it necessary, conduct unannounced inspections for the purposes of ensuring that the importer/distributor's operations conform to applicable law.

4.3 Communication of Inspection findings

The inspection findings shall initially be communicated to the importer/distributor during the closing meeting of the inspection and an observation form shall be issued. This will be followed by a formal inspection observation letter within 21 days after the inspection.

4.4 Response to nonconformities

The importer/distributor is required to formally respond to the deficiencies/nonconformities identified in the inspection report as officially communicated within a specified timeframe (15 working days on receipt of the formal inspection findings letter)

4.5 Issuing of licences

4.5.1 After all corrections and corrective actions have been submitted to the Authority, evaluated and found to be satisfactory, a licence would be issued to the inspected company to close out the inspection.

4.5.2 The licence will only be valid for the period stated on the licence, provided there will be no quality and safety issues on the product or product category stored and distributed at the site inspected.

4.5.3 For a previously inspected existing importer/distributor applying for a licence, the licence will be issued within 30 days upon payment of the required application fee and satisfactory evaluation of the importer's/distributor's previous inspection Corrective and Preventive Action (CAPA).

5.0 ADDITIONAL NOTE

The manufacturing facility from where medical devices are produced and subsequently marketed in Ghana shall be subjected to QMS /GMP audit/inspection in accordance with the requirements of the current iso 13485. Applicants should refer to the guideline for licensing of premises for manufacturing medical devices **(FDA/MCH/MID/GL-MD-GMP 2019/01).**