

Processing of health care products-Quality management systems for processing in health care facilities

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The ANSI/AAMI ST90 standard specifies the requirements for an organization to develop a Quality Management System (QMS) for processed medical devices and loaned instruments, as well as to prevent adverse patient events. To maintain the effectiveness of the QMS, the health care organization shall establish, document and implement actions where necessary to achieve the planned results of those processes. There are three separate qualifications that the customer uses or does each day. The Installation qualification (IQ) is the process for obtaining and documenting that the equipment has been installed properly. Second, Operational qualification is the process for obtaining and documenting that the installed equipment operates in accordance with its operational procedures. Third, Performance qualification process is for obtaining and documenting the equipment consistently performs in accordance and yields product meeting its specification. Healthmark offers a variety of products that will allow the customer to accomplish performance qualification.

Quality Management System

There are several documentation requirements to include in the QMS for the health care organization. Section 4.2.1 Document requirements states, “a quality manual documents procedures required by this standard and other industry regulations, guidelines, standards and recommended practices, documents needed by the organization for the effective planning, operation, and control of its processes”.¹ The QMS documentation can differ from one organization to another depending on size of the organization and complexity of interactions. Documents shall be controlled by reviewing, making changes to current revisions of documents and are identified to prevent use of obsolete documents.

Annex D outlines the six major steps in creating a QMS which illustrate how the existing processes, procedures, documents, and records will feed into the QMS. Section D.2 QMS structure states, “Quality manual- High-level guidance that defines the scope of the quality

management system, the footprint for the quality management system”² Operating procedures and work instructions- Detailed information on specific procedures and process, “Shall be documented” = required procedure, Reference documents, which may include manufacturer’s instruction for use, ANSI/AAMI ST79, and other relevant standards;³ Records, data and checklists- Documented evidence that procedures and work instructions were followed, “Shall be recorded” = required record”. Section D3 QMS inputs states, “The quality management system is a living system and requires continuous review and oversight. New requirements could be needed at any time”. There four requirements are:

- **Regulations**- legal requirements that must be followed and are both generic and industry-specific. This could also include the Centers for Disease Control and Prevention, FDA, OSHA and state departments of transportation.
- **Validated processes**- Sources provide manufacturer’s instruction for use, user manuals, and clinical information.
- **Standards**- Reflects best practices, are developed according to a specified set of rules and procedures providing consensus amongst multiple parties, are published by a neutral party. Examples are ANSI/AAMI ST58, ANSI/AAMI ST79, ANSI/AAMI ST91.
- **Safety Concerns**- Organizations develop guidelines, recommendations, and requirements based on concerns for safety or as a result of a health or safety incident. Examples are the Joint Commission, the Association of perioperative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the International Association of Healthcare Central Service Materiel Management (IAHCSMM), and the Society of Gastroenterology Nurses and Associates (SGNA).”

Section D.4 QMS outputs states, “Quality outputs are when quality systems incorporate inputs from sources and then turn them into requirements or outputs of the quality management system.” Section D.5 Creating a quality management system states the six steps to create a Quality Management System, “**PLAN**- 1. Identify critical business functions- Clarifying cross-department functions and responsibilities focuses the applicability of the quality management

system on processes rather than on personnel. 2. Identify and document procedures for each business function- Required quality system document and procedures are identified through multiple input sources, including regulations, standards, and manufacturers' information. 3. Identify and document records showing compliance to procedures- Required records are ones identified in standards, are legal requirements, or are specific to each organization's procedures. They can be in many different forms and provides evidence of compliance to procedures. **DO** 4. Communicate, train and implement procedures, and record requirements- Management is responsible for communicating of the QMS and for training and retraining on procedures and when revised. Training must be conducted prior to implementation of procedures and documented in personnel training records. **CHECK** 5. Monitor accuracy and efficacy of procedures through quality inspections and review- QMS is maintained for accuracy and random inspections. Quality checks should be incorporated into all procedures to ensure that they can be measured and reviewed against these performance objectives. **ACT** 6. Review and revise procedures and documents to ensure applicability- Documented procedures need to be continuously reviewed to ensure that they are applicable and reflect "real world" practice".

Records shall be maintained to provide evidence of conformity to department processes. Section 4.2.4 Control of records states, "A procedure shall be established to define the controls needed to review and revise forms used to record conformity evidence, records are clearly identifiable and remain legible and retrievable, and define and follow a record retention program that meets the health care organization's policies and local and national regulations".

Management Responsibility

Management responsibility is for all levels of management identified by the quality management system to provide evidence of their commitment to the overall awareness and maintaining its effectiveness. Section 5.1 Management commitment states, "communicating to the health care organization the importance of patient safety, meeting statutory and regulatory requirements, establishing the quality policy, conducting management reviews, ensuring the availability of resources, ensuring that patient safety, infection prevention, and medical professional equipment requirements are determined and met". The management shall ensure that the quality policy for

the department and organization is appropriate. The policy is communicated, understood, implemented and reviewed for applicability.

Quality objectives are established by management for relevant functions and levels within the organization. The objectives shall be consistent with the quality policy, specific, actionable, and realistic. Planning the QMS to ensure the requirements are met and implemented to maintain the integrity of the system. Management shall ensure that requirements are met, and ensure that responsibilities are defined, assigned and that personnel have authority necessary to perform these tasks. Section 5.4.2 Management representative states, “Management shall also appoint a quality management representative is assigned responsibility and authority to report to the management team on the performance and health of the QMS and any need for improvement and also act as liaison with external parties on QMS matters”.

At least once a year management shall review the effectiveness of the QMS. This includes personnel from department within the healthcare organization that are involved or influenced on the QMS. Section 5.5.2 Review input (agenda items) states, “review shall include at a minimum both positive and negative feedback for stakeholders, the results of internal and external audits and supplier assessment, follow up action for previous management reviews, the status of corrective and preventive actions and opportunities for improvement”. Section 5.5.3 Review output (meeting minutes) states, “review shall include any decisions and actions related to improvements needed to maintain the effectiveness of the QMS and its processes, improvement of instrument and medical device processing, supplies, and equipment, resource needs, and follow-up action items to be addressed in the next management review”.

Risk management is a daily factor in sterile processing departments, with personnel, and equipment entering and leaving the department. This process is for identifying areas of potential risks and evaluating the probability of the risk occurring. Annex B.2 Risk management states, “a risk management program should be established, defined and documented within the department or facility’s quality management system, be evaluated on a regular basis but at least annually”. Risk cannot be managed but can be identified, reviewed and assessed. This consist of risk management, the root cause of risk, assessment of risk by measurement and evaluation, risk mitigation, residual risks and risk monitoring. Section B.3.5 Risk monitoring states, “The

purpose of the risk assessment is to control risk; the purpose of monitoring is to measure the effectiveness of the controls”.

Competency and Training

Required competencies shall be maintained through training and education, skills and experience by personnel. The employee shall obtain and maintain if applicable certification and verified once a year by employer. Education shall be provided to the new personnel through orientation and performing required job duties on the job. QMS shall be included in the training and training shall ensure understanding of the quality policy and objectives. Section 6.2.2 Competency, education, and training states, “New employees shall be provided a structured training program designed to ensure the development of their competencies to successfully execute established processes and achieve safe, quality product”. Healthmark offers education to the CSPD department with all day programs that help staff with continuing education and in-services to educate on products we offer. Healthmark also offers “Crazy4Clean Games” which are online games with CE credits for each game completed.

The work environment in all departments where processing activities are performed shall meet the requirements of accrediting agencies and policies and procedures shall be developed to provide a safe environment for all personnel. Establish and maintain the requirements for health cleanliness and dress code compliance for personnel. Section 6.4 Work environment states, “the work area facilitates effective medical device processing, the sterility for packaged items is maintained, lighting is sufficient for personnel to complete the task, specified utilities are available, climate controls comply with the processing standards, necessary engineering controls, emergency equipment, and personal protective equipment (PPE) are accessible at the point of use”.

Healthmark offers several different options of headwear to protect the technician’s hair. One size fits all, 100% cotton fabric custom imprinted reusable scrub hats and disposable bouffant and scrub hats are available.

- **Custom-Printed Cotton Scrub Hats (PRSC-WT)**



- **Custom-Printed Disposable Headwear (PSC-WT, PBC-WT)**



Healthmark offers several different type of decontamination gloves to help protect against contaminating the skin:

- **The Sleeve Glove** that reaches 12 inches in length and overall 28 inches reaching to the upper arm.



- **Wide Drape Face Shield- (1800W-100, 18000-100)**



- **Disposable Bootlegs- (BOOTLEG)**



- **Gowns with Thumb Loops- (42500)**



- **Decontamination Gown- (MN110 SMMD, MN110 LGXL, MN110 2X3X, MN110 4X)**



Healthmark also offers compression socks to help battle muscle fatigue and increase circulation in the lower legs and feet.

- **Compression Socks**



- **Swanky Athletic Socks- (94737-M, 94699-M)**



Healthmark also has other products to offer:

- **Dura Sponges- (ESD905201, ESD904101)**
- **Lint Free Wipes- (CC555, CC1212, CC1212B)**
- **Clamps and Spreaders- (20411, 20408, 20406)-** For effective cleaning of bone forceps
- **Adjustable Stringer- (AJS 8, AJS 13, AJS 17)**
- **Easy Stringer Base- (ES-100, ES-109, ES-112)**

Addition of New Equipment

A plan shall be put into place by the healthcare organization that is necessary for effectively and safely processing of new medical devices, equipment and materials. This plan shall be communicated with the other departments as necessary. Section 7.1 Planning for new devices, equipment, and materials states the organization shall specify the following, “Quality controls, quality assurance checks, and safety objectives for the device, equipment or material, processes, documents, inspection requirements, and test activities and necessary resources, Criteria for acceptance and rejection in accordance with device, material, or equipment manufacturer recommendations and records needed to provide evidence that the planning processes and new device, equipment, or material meet the predetermined requirements”. Throughout the planning process, risk concepts and the output shall be applied in suitable form for the organization’s operations.

Before the healthcare organization accepts the device or equipment into the facility, the organization shall identify and determine the requirements for turnaround time and device availability specified by the customer, if any regulatory requirements related to the device, equipment or material. Section 7.2.2 Review of requirements related to the device, equipment, or material states, “ The health care organization shall conduct a review of the requirements related to the device, equipment, or material prior to acceptance of the device, equipment, or material and shall ensure that device, equipment, and material requirements are defined and documented, the organization had obtained and reviewed the manufacturer’s recommendations or IFU, with records of the review and resulting actions are maintained”. The health care organization shall determine the customer requirements if a documented statement of requirements was not provided by the customer. Additionally, the organization shall ensure that documents are amended and are communicated to the proper personnel if the device, equipment, or material requirements have been changed.

Healthmark has a variety of labels to accommodate specific items that state contaminated or sterile. The 7 Day Hangtime Label indicates the length of time the endoscope was last processed. Self-Looping label shows the necessary information of when the scope was processed and by whom. Hangtime Labels track the day and month when scope was reprocessed and come in a variety of colors.

- **7 Day Hangtime Label- (HTK-7D2)**



- **Hangtime Labels- (403225 HTK)**



- **12 Day Indicator Hangtime Label- (HTK-12D)**



- **One Hour Indicator Label (HTK-1H)**



- **Self-Looping Information Label- (404225-351-GI)**



- **Green Mesh Valve Bag (VB604-GN, VB604-WT)**



- **Secure Mesh Bag- (VB604 WT)**



Healthmark also has other products to offer:

- **SST Tray Stands- (2136-STND, 2136-STND-2)**
- **Flex Endo Tray- (2220 Trolley)**
- **Sealed Transport Carts- (113-20,113-1220, 113-30, 113-40)**
- **Humipak®- (HPSS2035, HPSS4243, HPSS4267, HPSS6577)**

The development and design of surgical sets and other medical devices by documenting procedures shall be established by the health care organization. Section 7.3.1 Planning for design and development of surgical sets and other medical devices states, “the health care organization shall determine the processes to be followed when creating a new or updating an existing surgical set or other medical devices, the authorities needed to ensure that each step of the design and development process is followed and completed. The design and development process shall also include an assessment of the tools and equipment needed, identification of training needs or requirement and verification of processes used”. The organization shall also communicate with the surgeons and OR staff, sterile processing management and technicians.

The inputs for the design and development of surgical sets and other medical devices shall be determined with records maintained. Section 7.3.2 Design and development inputs for surgical set and other medical devices states, “the manufacturer’s written IFU related to disassembly/reassembly, cleaning, decontamination, inspection, packaging, and disinfection/sterilization, applicable regulatory requirements and national standards that apply to the processing of the surgical instrument set or other medical device”. This shall be documented and reviewed for adequacy and approved for the design and development process prior the finished product. The outputs shall be provided and approved prior to release in a form that

enables the verification against the design and development of the input. Section 7.3.3 Design and development outputs for surgical sets and other medical devices states, “outputs shall meet the inputs requirements for design and development, provide appropriate information for purchasing, production, and service provisions, including identification of supplier and catalog number, images individual instruments or devices, and drawing or pictures of tray configurations, include instructions for inspection of the set or device from cleaning to sterilization, instructions for applicable disinfection processes, and procedures for cleaning verification, instructions for sterilization packaging and cycle(s)”. The design and development outputs shall maintain all records which can include all cleaning, disinfection and sterilization specifications.

Healthmark offers options for testing the instruments quality and labeling them to identify whether they need repairing or sharpening.

- **Scissor Tests- (LT-130) Latex Free, (RT608, YT606) Latex**



- **Instrument Repair Tags- (994-G, 994-R, 994-S, 5030 WT CLN)**



Healthmark also has other products to offer:

- **Tip Protectors-**
 - **Transparent, vented- (10001, 10002, 10003....)**
 - **Duo-Vented- (09-3-031, 09-3-032, 09-3-033...)**
 - **Cylindrical Style Instrument Guards- (09-7-011, 09-7-012, 09-7-013...)**
 - **Mesh Style Tip Protectors- (CSW-03-2.0, CSW-04-4.0)**
- **Medical Grade Packaging- (PB1-PB10, PBTO, PBR-15)-** This complies with AAMI Guidelines by Using the Medical Grade Paper Bags to separate and protect small items.
- **Sterimarker Non-toxic Marker- (MAR1, MAR2, MAR3)**
- **Peel Pouches -**
 - **Tyvek Heat and Self Seal Pouches and Roll- (LTS7520 NI, LTS 0125, LTSS1, LTSS2, LTR43, LTR43 NI)**
 - **Pouch Sterilization Rack- (SR-048, SR-010, SR-040...)**

To ensure that the design and development outputs have met the input requirements, verification shall be performed in accordance with planned arrangements. Clinical and performance evaluations shall be performed by the health care organization as part of the design and development product quality assurance testing of the surgical sets or other medical devices as required by national standards. The design and development process shall review the changes identified, subjected to PQA testing when applicable, as well as records of the results shall be maintained. Section 7.3.7 Control of design and development changes for surgical set and other medical devices states, “The review or design and development changes shall include evaluation of the effect of the changes on existing set configurations and product already delivered. This might require the involvement of specialists such as infection prevention and control, risk management, or administration personnel”.

The purchasing process for the health care organization shall establish document procedures and evaluate and select suppliers on their ability to supply product in accordance with the organization’s requirements along with the criteria, evaluation and re-evaluation of suppliers. Section 7.4.2 Purchasing information states, “shall describe the product to be purchased, requirements for approval of the device, equipment, and materials, information required from the

manufacturer, including sterilization parameters, cleaning and sterilization processes, and approved equipment, requirements for qualification of personnel, including any necessary training, quality management system requirements”. Prior to the organization’s communication to the supplier, they shall ensure the adequacy of specified purchase requirements and shall maintain relevant purchasing information such as documents, records unique device identifiers. Incoming inspection shall be conducted to ensure the purchased product does meet the purchase requirements.

Reprocessing and Traceability

Section 7.5.1.1 Control of processing and serving states, “The healthcare organization shall plan and carry out processing and servicing under controlled conditions:

- a) include availability of information describing the characteristics of the product;
- b) availability of documented procedures, documented requirements processing instructions (IFU), reference materials, reference measurement procedures (national standards recommended practices and the guidelines) and reference measurement procedures, as necessary;
- c) use the suitable equipment for cleaning, decontamination, disinfection, and sterilization;
- d) availability and use of monitoring and measuring devices such as (sterilizer temperature and pressure recording devices);
- e) implementation of monitoring and measurement (use of chemical biological indicators and physical monitors on sterilization equipment, cleaning verification)

Healthmark offers Chemical Indicators for Ethylene Oxide (EO) and Biological Indicators for EO for monitoring ethylene oxide sterilization.

- **CROSS CHECKS EO Ethylene Oxide Sterilization Monitor- (CI-106)**



f) implementation of release, delivery, and post-delivery activities,

g) defined operations for labeling and packaging”.

Documented requirements for cleanliness of product shall be established by the health care organization. The requirements are products cleaned by the organization before sterilization, cleanliness of the product is required for safe handling by staff, cleaning is critical of further processing such as sterilization, disinfection. Testing the sterilizers are performed on the first load of the day prior to sterilizing surgical instruments.

Healthmark offer:

- **STERI-PAK Disposable Bowie-Dick Test Pack- (BD 111)**



- **ProFormance™ QA-** Is a secure online database that allows you to record key statistics for the performance of your decontamination procedures, including the test results from Healthmark’s Proformance™ line of monitoring products.

- **SonoCheck™- (TI108)** - which tests the presence of cavitation with a simple to interpret color change to indicate the ultrasonic unit is running correctly. If there is insufficient energy, overloading, or incorrect water level the SonoCheck™ will not achieve the proper color change.



- Testing the mechanical washer on a daily basis before the first load of the day will ensure spray arms are functioning properly.
- Mechanical washers can be tested with the **TOSI™ Instrument Washer Test by Healthmark- (WT101, WT-111)** - This test will show if there is any blood soil left behind on the test coupon after washing cycle is complete, with the stainless-steel test coupon simulating a soiled instrument.



- **AquaTest™- (AT101)**
- **TempaChek™**
- **Temp™-90 and Temp™-170**
- **LumCheck™- (WC-101, WLC-102)**
- **FlexiCheck™- (FLEXCHK-101, FLEXCHK-102)**
- **TempaChek™-LC**
- **Cart Wash Check™ (CW-101)**
 - Challenge the mechanical efficiency of the cart washer.
 - Easily adhered to any metal surface.
 - Place test furthest from the washer jets or in areas where you suspect coverage is most difficult.

- Will change color only if moistened by water.
- The test also reports a minimum temperature level reached, 120°F.



Healthmark offers several optical inspection devices to improve post cleaning inspection.

- **Interchangeable Magnifier- (MAG0225, MAG-LENS, MAG-L5D, MAG-L8D, MAG-L12D, MAG-L15D)**



- **Table-Top Lighted Magnifiers- (26501-DSG, 26505-SIV, 82400-4BL, 42400-4RD)**



- **Flexible Inspection Scope- (FIS-005)**



- **Flexible Inspection Scope- (FIS-006SK)**- Designed to inspect internal channels of 1.3mm in diameter or larger. The FIS-006SK is the ideal tool to visually see potentially soiled or damaged items.



- **Loup Set with Smartphone Adapter- (LUP-004)** • **LED 4x Magnifier- (MAG-002)**



Healthmark offers LBK Weighing Scale for quick and easy weighing.

- **LBK Weighing Scale- (LBX 30)**



Healthmark also has other products to offer:

- **Shark Tooth Heat MITTs- (SLG-001, SLG-002)**
- **Silicone Heat Glove- (09484, 09368)**
- **Tube Brushes- (4030, 4031, 52003-35, 4032...)**
- **Elevator Mechanism Brush- (EMB-002)**
- **Arthroscopic Shaver Brushes- (86-0340-1206, 86-021201234....)**
- **Flexistem Brushes- (FLEX001, FLEX002, FLEX003...)**
- **Brush Storage Rack- (BRO001, BRS03, BSK05)**

Annex C section C.2 Use of normal production cycles states, “Enough samples should be run to ensure that if consistent results are achieved, there is a high probability that these results will occur each time that particular product is subjected to the sterilization cycle. At least three replicate consecutive cycles are needed to provide a high level of probability that the results will be consistent”. Before a load is put into the sterilizer, all the sets must be able to be sterilized on the same cycle for temperature and length of time for sterilization and dry time. Section C.3 Identification of product families and master products states, “The products being sterilized in the health care facility must be analyzed and placed into product families: Design, weight, material, sterile packaging system, and reprocessing instructions provided by the manufacturer”.

The placement of the chemical integrator (CIs) are placed in the most challenging part of the instrument tray the corners, in between layers of the sets, and heavy instruments. The biological

indicator (BI) is placed between placed in the densest portion of the pack and over the chamber drain of the sterilizer which is the coldest spot.

- Several types of chemical integrator for steam sterilization and Eto sterilization integrators



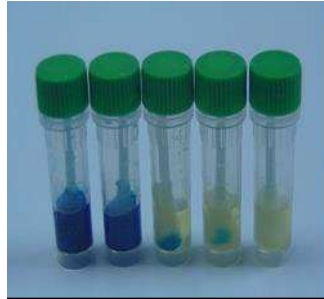
After the sterilizer has run its cycle, drying time is about 30 minutes that is recommended after the load is complete before removing it from the sterilizer. The biological indicator should then be put into the incubator and read at the appropriate time. Section C.8 Test results states, “All test BIs must be negative and all test Cis must reach their endpoint. Any results to the contrary must investigated”. Record all load information with all sterilization parameters met including cool down time, BI results must be negative with a control BI that is positive, and CI results reach designated endpoint.

- **EZTest® Biological Indicators- (EZG-6)- For Eto**



Healthmark Cleaning Verification Methods that help in aiding the detection of residual blood, protein, and carbohydrate and optical inspection devices help with visual inspection to improve post cleaning inspection.

- **HemoCheck™- (HC-101)**- Checking for blood (hemoglobin)



- **ProCheck™- (PT-202)**- For detecting protein on instruments or medical devices



- **EndoDolly™- (110405-SP)**- To hold endoscopes and allow them to hang properly while conducting active drying, quality assurance testing, and transportation procedures.



- **ChannelCheck™- (UCC-222)**- For testing of blood, protein and carbohydrates



- **Scope Sleeve- (SSLV-003, SSLV-004, SSLV-005)**- Manufactured of material comprised of 80% cellulose and 20% polypropylene, the single use Scope Sleeve are designed to cover and protect insertion tubes after reprocessing, during transportation and storage.



For installation services by an organization may be contracted to an outside service provider which specializes in these services. According to section 7.5.1.3 Installation activities states “The health care organization shall document the requirements for the medical device installation and acceptance criteria”. A written protocol for the installation and verification shall be provided by the service providers. Servicing activities such as calibration, repair, and routine maintenance may be performed by the facility’s employees or an outside service provider. Records of maintenance or servicing activities shall be maintained. The process parameters for the sterilization process for each cycle that is used to sterilize surgical sets or other medical devices shall have records maintained by the health care organization.

Healthmark offers products for Signage for walls and floors and labeling:

- Floor Signs



- Transportation Identification Tag (AV-52481, AV-52481-RL, VA-52482...)



- Quick Turnover 2-Part Clean-Dirty Label (HM-52489)



The health care organization shall have verification testing to demonstrate the ability of these processing procedures for which the resulting output cannot be objectively verified against the requirements by subsequent monitoring or measurement. The arrangements for the verification shall be established by the organization. Section 7.5.2.1 Verification of processes states, “defined criteria for review approval of the processes, approval of the equipment and the qualifications of personnel performing the verification, use of specific methods and procedures, such as installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) and re-

verification testing.” Documented procedures for execution of PQA testing shall be established by the health care organization on all product families sterilized by the facility. An evaluation shall be done for new surgical set and other medical devices to determine if the current PQA testing is applicable. Section 7.5.2.2 Particular requirements for sterile surgical instrumentation and other medical devices states, “ If current testing applies to the new set or device, it shall be added to the appropriate product family, if current testing is not applicable to the new set or device, the set/device shall be evaluated to determine if it is a new master product for an existing product family or if a new product family must be created, if a new set or device is designated as a new master product for an existing product family, the PQA testing shall be executed on the new master product, if it is determined that a new set or device does not fit into an existing product family, a new product family shall be created and PQA testing executed”.

There are numerous methods of identification which may be selected by the health care organization to fit the requirements they need. This includes barcodes, direct marking and color coding of surgical sets, individual instruments and medical devices that the organization shall make for product identification. Section 7.5.3.1 Identification states, “The health care organization shall ensure that all devices are identified, including implantable and active implantable medical devices, devices, equipment, and materials used in high-risk cases (e.g., patients with diagnosed or suspected Creutzfeldt-Jakob disease and loaned/vendor sets”. The traceability of surgical instrumentation and other medical devices through the cleaning, inspection, decontamination, disinfection sterilization and distribution process shall be considered by the health care organization.

For implantable devices and active implantable medical devices, the health care organization shall define and document procedures for traceability from cleaning through delivery to the patient. All implantable and active implantable devices shall have traceability records maintained that will include materials, and work environment conditions that could cause failure to the medical device. For high-risk procedures with patients that have a high-risk infectious diagnosis such as CJD, the health care organization shall document the procedures for the traceability of all the medical devices used in those procedures. Section 7.5.3.4 Traceability: Particular requirements for devices, equipment, and materials used in high-risk cases states, “Traceability of high-risk devices shall be maintained for the entire processing and use lifecycle

of the device from the point of cleaning and decontamination through delivery to the patient and back to the cleaning and decontamination area”.

Healthmark offers Transportation Labels designed for compliance with OSHA standard CFR 1910.1030. This is produced precisely for transporting material considered a biohazard, while acting as an essential communication tool.

- **High-Level Disinfected Labels- (HM-52483)**



- **HLD Labels- (DC-100214-71-BL) VB604-WT)**



Loaner/vendor instrument set or medical devices shall have documented procedures for traceability from the health care organization as well as the traceability of these sets shall also be maintained throughout the entire process from receipt from the vendor to cleaning and sterilization, back to the patient and then back to cleaning and decontamination to the delivery and back to the vendor. The status of the surgical sets and medical device shall be maintained by the health care organization throughout the processing of cleaning, decontamination, sterilization, storage, installation and servicing that have passed inspections are dispatched, used, installed, or returned to service. Procedures and responsibilities for tracking the useful life of health care products and accessory equipment shall be developed by the organization and shall also address scheduled maintenance, removal of equipment for use when needed. Section 7.5.3.5

Traceability: Particular requirements for loaned/vendor sets states, “Traceability of these sets or devices shall be maintained from the point of receipt from the vendor to cleaning and decontamination, sterilization, delivery to the patient, back to the cleaning and decontamination area, and delivery back to vendor”. The care for vendor/loaned equipment while it is being used by the organization shall be done with care. If any lost or damaged equipment that is vendor/loaner property shall be reported to the customer with records maintained of the incident. Section 7.5.4 Customer-owned and loaned/vendor property states, “Customer-owned property can include physician-owned surgical instruments or sets”. The department shall maintain the records of the processing of loaner sets.

Healthmark offers several options for loaner/vendor tray identification tags to help identify which are loaner sets.

- **Self-Tie Container TAGS-** are compatible with various tracking and tracing systems. The container tag serves to identify contaminated container when self-adhesive labels cannot be utilized.



- **Tray Identification Tags**



- **Clip-On Basket Tags**



Preservation of the product shall be established by the healthcare organization that will include training instructions for personnel for the control of the product, preserving and the conformity

during internal processing. Special storage conditions for products that have a limited shelf life shall also be established by the organization. This will also include the “identification, handling and packaging, shelf-life designation, storage and protection”, section 7.5.5 Preservation of product.

Healthmark offers several options for tray identification such as Laser C.A.A.T’s to customize your own basket trays to identify tray, containers and loaner trays. Available in round and rectangular shape in various colors.

- **Laser C.A.A.T’s TAGS**

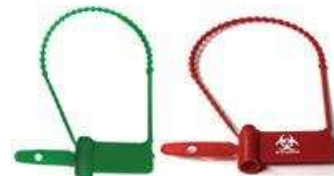


Tamper Evident Seals- For use with closed sterilization containers. Easily seals and breaks by hand. Can be ordered with the optional sterilization indicator dot.

- **Closed Container Locks**



- **Clean and Dirty Seal Pack**



Healthmark Products that Comply with Clean Transport

- **Round Soaker and Transport Trolley- (2220, 2220 Trolley)-** Round soaker bin has a 20” diameter and is perfectly sized to allow a flexible endoscope to coil naturally and safely for transport or soaking. A lift off lid completely covers the tray. The Trolley can accommodate up to 5 round soaker trays simultaneously.
- **Clean/Dirty Scope Seal Kit- (2220 LOK)-** Seals have clean/dirty tamper evident seals.

2 Part Clean/Dirty Label- (HM-52483-HLD): This sticker is used to communicate whether the endoscope contained within a bin is clean (HLD) or dirty.

- **Clean Label- (CLN4X4)**- Label is used to communicate whether the instruments contained within a bin or cart are clean
- **Liners- (SST-CCD-LNR)**- Eliminate confusion between reprocessed and soiled medical devices with color-coded SST Liners. The single-use liners assist with identification, temporary storage and transportation of medical equipment by providing an enclosed environment for instruments.



Monitoring of Equipment

The monitoring and measurement procedures are required throughout the processing cycle which shall be established by the health care organization for evidence of conformity of surgical sets and medical devices. Section 7.6 Control of monitoring and measuring equipment states, “measuring equipment shall be calibrated or verified at specified intervals, or prior to use according to the equipment manufacturer’s recommendations or written instructions for use or against measurement standards traceable to the primary standards of the National Institute for

Standards and Technology, identified the calibration status to be determined, safeguard from adjustments that would invalidate the measurement result, and protected from damage and deterioration during handling, maintenance, and storage”. If the equipment is found not to conform to requirements, the health care organization shall assess the validity of the previous measuring results and take the appropriate action affected by the nonconformance.

A plan for the monitoring, measurement, analysis shall be developed by the health care organization. A documented feedback system to provide an early warning of quality problems shall be implemented by the health care organization as one of the measurements of the performance of the GMS. The results will be reviewed by management and shall be shared with members of the organization. An internal audit shall be conducted at planned intervals with acceptance criteria, a scope and a predetermined method. Section 8.2.2 Internal audit states, “Management responsible for the audited area shall ensure that nonconformities are investigated, root causes identified, and any necessary corrections and corrective actions taken. Internal audits shall have a planned, systematic, and ongoing process for verifying compliance with procedures”. The methods and measurement of the quality management system processes shall be applied by the health care organization which shall demonstrate the processes to achieve the planned results. Corrective action shall be taken if the planned results were not achieved. The characteristics of the medical devices or equipment for cleanliness and functionality according to the manufacturer’s instructions shall be monitored by the organization. A procedure for the control of nonconforming products shall be established by the organization for responsibility of identification, documentation and disposition of the nonconforming product. Section 8.3 Control of nonconforming processes, medical devices, and equipment states, “When nonconforming product is discovered after delivery or after use has started, the health care organization shall take action appropriate to the effects, or potential effects, of the nonconformity”.

According to section 8.4 Analysis of data, “documented procedures shall be established by the health care organization to identify, collect and analyze data to demonstrate the suitability and effectiveness of the QMS and to evaluate whether the quality management system can be improved”. The data shall provide feedback, conformity to product requirements and suppliers with records that are maintained for performance improvement. The ProFormance™ QA 2.1 which is a secure online database offered by Healthmark, allows you to record key statistics for

the performance of your decontamination procedures and test results. This is a cloud-based database where you can record data and use the data to generate reports and track the performance of the departments cleaning equipment.

With continued maintenance and the effectiveness of the quality management system through quality policy and objectives, analysis data and management review shall be identified and implement changes by the health care organization. Customer complaint records shall be maintained by following corrective or preventive action. If the preventive action is not followed, the reason shall then be documented and authorized. Adverse events require notification by national or regional regulations, procedures for notification to regulatory authorities shall be established by the organization. Continuous quality improvement program is a “means of improving the performance of any process such as the process of decontamination, prep and pack, sterilization, quality control, sterile storage and product distribution”, as stated in section 8.5.1 Continuous improvement. To eliminate causes of nonconformities to prevent recurrence, a corrective action shall be implanted by the health care organization where procedures shall be established with requirements for “reviewing nonconformities and determining the cause, evaluating, planning and implanting the need for action, recording the results and reviewing the effectiveness of the corrective action”, section 8.5.2 Corrective action. Lastly, when a potential cause has identified, action is taken to eliminate the root cause which shall be applied with preventive action. To define the requirements, the health care organization shall determine the action needed which is stated in section 8.5.3 Preventive action, “determining potential nonconformities and their causes, evaluating the need for action to prevent occurrences, determining any action needed and recording results of action taken, reviewing the preventive action taken”.

Maintaining quality management system documentation for the sterile processing department comes different forms such as, written documents- which are stored in a way that the paper remains in good condition and is legible; second, electronic form- are backed up to ensure there is a usable document incase the original is not. Make sure to periodically check the electronic document to see if it has not become corrupted and can be retrieved. Annex A section A.3.2 Control of documents and records states, “only current documents are used. Revision numbers and dates are incorporated into the format for all documents. Obsolete documents are marked so

that it is obvious that they are not longer to be used. Obsolete document revisions are archived so that they are available for referral if needed”. When disposing obsolete documents, a designated person has the authority to shred the paper documents and delete from the computer and erase from the hard drive. The records of the processes performed in sterile processing department a system should be maintained and have a designated time to retain records before disposing of. Section A.4.1 Documents and records to be maintained by the sterile processing department states, “Many types of documents need to be maintained as part of the quality system for the sterile processing department: Quality policy manual, department procedure manual, and work instructions”.

References

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