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DNV·GL

STERILE PROCESSING PROGRAM CERTIFICATION (SPPC) REQUIREMENTS

Version 18-0

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Use of DNV GL Healthcare Sterile Processing Program Certification Requirements

Effective Date

DNV GL Healthcare Sterile Processing Program Certification Requirements, Version 18-0

Effective Date: 10/22/18

National Professional Organizations- Standards of Practice

Guidelines, recommendations, and standards of practice of the national professional organizations referenced in this program certification requirements document are consultative and considered in the certification decision.

Federal Laws, Rules and Regulations

The most current version of Federal law and the Code of Federal Regulations referenced in this program certification requirements document are incorporated herein by reference and constitute program certification requirements. The applicant organization is expected to be in compliance with the CMS requirements relative to its scope of operations (e.g., Conditions of Participation, Conditions for Coverage) or in compliance with another entity applying related standards or requirements to be met as demonstrated by the organization and is deemed acceptable by DNV GL Healthcare (e.g., the State Agency, other certifying organization).

The Sterile Processing Department (SPD), through its association with the host organization participating in the Medicare and Medicaid Program, is expected to comply with current CMS requirements. When new or revised requirements are published, the SPD is expected to demonstrate compliance in a time frame consistent with the effective date as published by CMS in the Federal Register and/or as required by DNV GL Healthcare.

INTRODUCTION

DNV- GL Healthcare Sterile Processing Program Certification is designed to recognize excellence in an organization's sterile processing department within the scope of infection prevention and control, surgical services, endoscopic services and related departments, inclusive of policies, procedures and related practices involving the sterile processing department.

The certification verifies that an organization has demonstrated compliance with the DNV GL Healthcare Sterile Processing Program Certification Requirements.

GLOSSARY

AAMI	Association for the Advancement of Medical Instrumentation
AORN	Association of Perioperative Registered Nurses
APIC	Association for Professionals in Infection Control and Epidemiology
CDC	Centers for Disease Control
CMS	Centers for Medicare and Medicaid Services
CoP	Conditions of Participation
IFU	Instructions for Use
IUSS	Immediate Use Steam Sterilization
QMS	Quality Management System
SPD	Sterile Processing Department
SPPC	Sterile Processing Program Certification

QUALITY MANAGEMENT SYSTEM (QM)

QM.1 QUALITY MANAGEMENT SYSTEM

The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the SPD), medical staff, and administrative officials is responsible and accountable for ensuring that the SPD implements and is included in the host organization's quality management system (QMS). The host organization shall assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the SPD's performance and reducing risk to patients.

CR.1 The SPD must be involved in and implement the host organizations method for maintaining an ongoing system for managing quality and patient safety.

CR.2 The SPD must implement quality assessment (QA) and performance improvement (PI) efforts to address priorities for improved quality of care and patient safety and ensure that corrective and preventive actions are implemented and evaluated for effectiveness.

CR.3 The SPD has established measurable quality objectives; the results are analyzed and addressed; and,

CR.3a Appropriate information from the SPD has been submitted to the host organization oversight group for quality management.

CR.4 The SPD must have a formal documentation process for all policies, procedures, protocols, and forms.

CR.4a All policies, procedures, protocols and forms are reviewed at least annually with date of the review/revision documented.

CR.4b All previous policies, procedures, protocols, and forms are removed from any manuals, references or patient care areas to ensure that only the most current versions are available for use.

CR.5 Control of Records: The SPD ensures that suitable records are maintained.

QM.2 QUALITY OUTLINE/PLAN

CR.1 The SPD shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

QM.3 QUALITY OBJECTIVES

CR.1 The governing body shall ensure that SPD quality objectives, including those needed to meet requirements for the Sterile Processing Program Certification (SPPC), are established. The quality objectives shall be measurable and consistent with the requirements of the SPPC.

QM.4 STERILE PROCESSING DEPARTMENT QUALITY MANAGEMENT REPRESENTATIVE

CR.1 A quality management representative shall be designated and shall have the responsibility and authority for ensuring requirements of the QMS are implemented and maintained for the SPD.

QM.5 DOCUMENTATION AND PROGRAM REVIEW

CR.1 Any variation, deficiency or non-conformity identified by the SPD shall be addressed by the appropriate committee (or, appropriate department or individual). Appropriate actions will be determined, applied, and documented.

CR.2 Program review shall be performed at regular intervals, at a minimum of once a quarter, with an annual evaluation of the effectiveness of the SPD components and metrics.

Note: Documentation of actions may take the form of a Failure, Mode and Effect Analysis, Root Cause Analysis, Performance Report, Non-Conformity Report, specific project improvement analysis, etc.

QM.6 SYSTEM REQUIREMENTS

The SPD will participate in and follow the system requirements of the host organization in establishing a QMS. The SPD shall be required to have the following as a part of this system:

CR.1 Interdisciplinary group to oversee the SPD specific quality data that includes the SPD Manager, Director of surgical services; an infection control practitioner or infection control nurse with APIC certification and a quality management representative. Other discipline representatives and practitioners are at the discretion of the organization. The interdisciplinary group shall conduct Quality and Program reviews;

CR.2 Written document defining the SPD QMS, to include all clinical and nonclinical services;

CR.3 Measurable quality objectives; and,

CR.4 Goal Measurement / Prioritization of activities to include:

- CR.4a Focus on problem-prone areas, processes, or functions;
- CR.4b Consideration of the incidence, prevalence and severity of problems in these areas, processes or functions; and,
- CR.4c Consideration of efforts to affect health outcomes, improve patient safety and quality of care.

QM.7 MEASUREMENT, MONITORING, ANALYSIS

The SPD shall strive to optimize the effectiveness of program processes and systems. This goal shall be accomplished by identifying both process and outcome measures for key functions and for the program as a whole.

CR.1 Evaluations of the SPD shall encompass overall department outcomes, linkages among key components of the SPD and potential problems that could affect the services provided by the SPD, including contract services.

CR.2 Documentation of quality improvement initiatives, performance measures and/or clinical indicators are presented and discussed at least quarterly.

CR.3 The SPD shall develop performance measures and strategies for measuring, refining and reassessing the following key system components including but not limited to:

- CR.3a Surgical Site Infection Rate to include 90 days following a patient’s surgery, not just the hospitalization period;
- CR.3b Immediate Use Steam Sterilization (IUSS) and implantable devices utilizing IUSS.

CR.3c Tracking of damaged trays to include, but not limited to:

CR.3c (i) Trays with holes in wraps and filters;

CR.3c(ii) Wet trays; and,

CR.3(iii) Trays where chemical or biologic indicators failed.

CR.3d Preventative maintenance strategy and compliance;

CR.3e Incomplete or inaccurate instrument trays;

CR.3f Instrument and tray management system effectiveness as defined by the organization; and,

CR.3g Periodic microbiological sampling and testing of instruments and environment.

QM.8 PATIENT SAFETY SYSTEM

CR.1 The SPD shall follow and participate in the host organizations' Patient Safety System, establishing clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety.

CR.2 The host organization's Patient Safety System shall be documented and shall address the following:

CR.2a Detection;

CR.2b Preventative and corrective action;

CR.2c Defined processes to reduce risk;

CR.2d Implementation of action plans;

CR.2e On-going measurement to ensure action effectiveness;

CR.2f Management review of response and resource allocation to the results of the patient adverse event and other analyses; and,

CR.2g Policy and practice of informing patients and/or families about unexpected adverse events.

PROGRAM MANAGEMENT (PM)

PM.1 TOP MANAGEMENT

CR.1 The host organization top management is responsible and accountable for ensuring the following:

CR.1a The host organization must be accredited by an organization approved by CMS, certified by the state agency acting on behalf of CMS or in compliance with another entity applying related standards or requirements to be met as demonstrated by the organization and is deemed acceptable by DNV GL Healthcare.

CR.1b The SPD is in compliance with all applicable Federal and State laws regarding the health and safety of its patients;

CR.1c Criteria that include aspects of individual character, competence, training, experience and judgment is established for the selection of individuals working for the SPD, directly or under contract;

CR.1d The personnel working in the SPD are properly trained or otherwise meet all applicable Federal, State and local laws;

CR.1e Responsibilities and authorities are defined and communicated within the SPD; and,

CR.1f Qualifications for the management of the SPD.

CR.1f(i) The management of the SPD shall be either a Registered Nurse with sterile processing training, or an individual with certification in sterile processing or surgical technology by a nationally recognized certification program.

CR.1f(ii) SPD Management will have documented infection prevention and control training as defined by the organization.

PM.2 MANAGEMENT COMMITMENT

CR.1 Host organization top management shall provide evidence of its commitment to the development and implementation of the SPD and continually improving its effectiveness by:

CR.1a Communicating to the SPD the importance of meeting customer as well as statutory and regulatory requirements;

CR.1b Establishing and assisting in meeting the SPD mission, goals and objectives; and,

CR.1c Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes.

PM.3 DEPARTMENT LEADERSHIP

The SPD leadership shall:

CR.1 Define in writing the program mission and scope of service which describes the design, implementation and evaluation of the processes needed for the SPD service delivery;

CR.2 Determine SPD goals and objectives and the criteria and methods needed to ensure consistent, effective processes and delivery;

CR.3 Conduct department reviews to determine achievement towards goals, objectives and outcomes;

CR.4 Monitor, measure, and analyze department processes; and,

CR.5 Implement actions necessary to achieve planned results and continual improvement of these processes.

STAFFING MANAGEMENT (SM)

SM.1 PERSONNEL (GENERAL)

Personnel performing work affecting conformity to the SPPC requirements shall be competent based on appropriate education, training, skills and experience.

CR.1 The host organization shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license or certification or training as required by the SPD and Federal and State laws. This written policy shall be strictly enforced, and compliance data reported to top management.

SM.2 COMPETENCE, TRAINING AND AWARENESS

The SPD shall:

CR.1 Determine the necessary competence for personnel performing work affecting conformity to the SPPC requirements;

CR.2 Have evidence to demonstrate initial and ongoing training in all aspects of the SPD;

CR.3 Where applicable, provide training or take other actions to achieve the necessary competence;

CR.4 Evaluate the effectiveness of the actions taken;

CR.5 Provide continuing education or other equivalent educational activity no less than annually to staff members assigned to the SPD, as determined appropriate by the SPD QMS and as appropriate to the individuals' level of responsibility related specifically to SPD services;

CR.6 Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and,

CR.7 Maintain appropriate records of education, training, skills and experience.

CR.7a The SPD shall determine the appropriate number of hours of education to be provided initially and on-going to maintain the appropriate competencies.

CR.7b Staff not directly assigned to the SPD shall receive education, training and direction for managing items processed through the SPD.

Note: This requirement may be met in a variety of ways, including online continuing credits, attendance at staff development meetings, regional and national meetings and various educational courses.

SM.3 DETERMINING AND MODIFYING STAFFING

CR.1 The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with process outcomes, including any untoward patient events or process failures.

CR.2 This validation shall be completed and reported to quality management oversight at least annually.

SM.4 JOB DESCRIPTION

CR.1 All SPD personnel, including contract staff, shall have available a current job description that contains the experience, educational and physical requirements, and performance expectations for that position.

SM.5 ORIENTATION

CR.1 All SPD personnel, including contract staff, shall receive an orientation to specific job duties and responsibilities, and their work environment, as required by Federal and State law and regulation and the SPPC requirements. The SPD shall determine orientation content that must take place prior to the individual functioning independently in their job.

SM.6 STAFF EVALUATIONS

CR.1 The performance/competency evaluation shall contain indicators that objectively measure the ability of SPD staff to perform all job duties as outlined in the job description.

CR.2 The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement that are identified through the following, as applicable:

CR.2a Variations and problem processes identified through the analysis of outcomes measurement as required by the SPD;

CR.2b New technology/equipment/processes;

CR.2c Customer satisfaction/Interested Party feedback; (e.g. vendor feedback)

CR.2d Scheduled training session outcomes;

CR.2e Staff learning needs assessments that include variations identified through prior staff performance measurement;

CR.2f Staff feedback;

CR.2g Medical staff feedback; and,

CR.2h Requirements of Federal and State law (as applicable).

CR.3 Indicator measurement for contract staff may be modified based on SPD outcomes and frequency of service of the individual. Modification of this measurement must take place no less than annually and shall be justified by data analysis.

CR.4 The SPD shall aggregate objective performance data for individual staff, and within each job classification, to identify variations for further training, coaching and mentoring.

CR.4a Reassessment of objective data shall follow any intervention.

CR.4b The outcomes of this aggregated data will be reported to Quality Management Oversight to monitor staff performance improvement.

CR.5 The host organization shall define a timeframe, not less than annually, and a policy and practice for sharing the indicators measurement of individual staff member with

those staff members that allows for staff feedback.

CR.6 The host organization shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, law or regulation, or SPD policy. Compliance with this standard shall be reported to Quality Management Oversight.

PATIENT RIGHTS (PR)

PR.1 PATIENT RIGHTS

CR.1 The host organization shall protect and promote each patient's rights.

PR.2 GRIEVANCE PROCEDURE

The SPD shall participate in and follow the host organization's formal grievance procedure for submission of a patient's written or verbal grievance that provides for the following:

CR.1 A list of whom to contact to file a grievance;

CR.2 Grievance resolutions must be in writing and directed to the patient. The grievance resolution shall include the following:

CR.2a Organization's contact person;

CR.2b Steps taken to investigate;

CR.2c Results of the grievance process; and,

CR.2d Date of completion.

CR.3 The organization has the responsibility for effective operation of the grievance process. The organization must implement and follow policies on:

CR.3a Review and resolution of grievances;

CR.3b Specification of reasonable timeframes for review and response to grievances; and,

CR.3c Measuring, monitoring, and analysis of grievance data for process improvement.

INFECTION PREVENTION AND CONTROL (IC)

IC.1 INFECTION PREVENTION AND CONTROL SYSTEM

CR.1 The SPD shall participate in the host organization's Infection Prevention and Control Program (IPCP) to maintain a sanitary environment for patients, staff, and others.

CR.2 The SPD shall have a representative attend the host organization's Infection Prevention and Control (IPC) meetings.

CR.3 The SPD shall report data, as determined by the SPD department, to the IPC meeting.

CR.4 The SPD in coordination with the IPCP shall periodically, at least quarterly, test instruments and equipment to validate sterilization and disinfection processes.

PHYSICAL ENVIRONMENT (PE)

The SPD shall abide by the host organization's management system for maintaining the physical environment including applicable CMS CoP and accreditation organization requirements or in compliance with another entity applying related standards or requirements to be met as demonstrated by the organization and is deemed acceptable by DNV GL Healthcare.

PE.1 INFRASTRUCTURE

The host organization shall determine, provide, and maintain the infrastructure needed to achieve conformity to the SPPC requirements. Infrastructure includes, as applicable:

CR.1 Buildings, workspace and associated utilities;

CR.2 Facilities for appropriate storage of products;

CR.2a The host organization shall ensure appropriate temperature and humidity controls in all sterile storage areas as defined by nationally recognized standards.

CR.3 Process equipment (both hardware and software);

CR.3a The host organization shall provide all necessary equipment for the decontamination, testing, disinfection and sterilization of the equipment as specified by manufacturers' Instructions for Use (IFU) for all instruments and equipment processed by the SPD.

PE.2 SAFETY MANAGEMENT SYSTEM

The host organization shall provide a Safety Management System that maintains safe and adequate facilities for its services.

CR.1 The host organization shall provide and maintain safe and adequate facilities for the SPD.

CR.2 The facilities for the SPD shall be maintained to ensure the safety of patients, visitors, and staff.

CR.3 The host organization shall require that facilities, supplies, and equipment are properly maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered under the SPD.

CR.4 The host organization shall require that the SPD maintains an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.

CR.5 The host organization shall address safety recalls and alerts involving the SPD.

CR.5a The SPD shall have a defined process for management and notification of the recall process for internally and externally processed items. The process shall include surgeon/practitioner notification and patient notification as appropriate.

CR.6 Supporting services (e.g., transport, communication, or information systems) shall be adequate to meet the needs of the SPD.

CR.6a The SPD shall ensure all transportation of instruments occurs in a controlled manner within the organization or between the SPD and point of use.

CR.7 The host organization shall ensure the availability and appropriate use of personal

protective equipment (PPE) at the point of use for all staff.

PE.3 SECURITY MANAGEMENT SYSTEM

CR.1 The host organization shall develop a system that provides for a secure environment.

CR.2 The host organization shall provide for identification of patients, employees, and others.

CR.3 The host organization shall require a process for reporting and investigating security related issues.

PE.4 MEDICAL EQUIPMENT MANAGEMENT SYSTEM

The host organization shall ensure:

CR.1 The SPD has effective processes in place for the acquisition, safe use, storage, and the appropriate selection of equipment used within the SPD.

CR.2 That the SPD addresses issues related to initial service inspections, orientation, and the use of physician owned, rental, loaned or demonstration equipment.

CR.3 The SPD has policies and procedures in place for the appropriate maintenance of all SPD equipment.

PE.5 UTILITY MANAGEMENT SYSTEM

CR.1 The host organization shall ensure maintenance, testing, and inspection processes for critical utilities used in the operation of the SPD.

CR.1a The SPD shall identify equipment that is critical to the operation of the SPD and test the equipment at least biannually.

CR.2 The host organization shall ensure emergency processes for utility system failures or disruptions.

CR.3 The host organization shall ensure that all relevant utility systems are maintained, inspected and tested.

STERILE PROCESSING DEPARTMENT SERVICE DELIVERY (SD)

SD.1 PLANNING FOR SERVICE DELIVERY

The SPD shall plan and develop the processes needed for SPD service delivery. The SPD service delivery processes shall be consistent with the DNV GL Healthcare SPPC requirements. The host organization shall ensure that the SPD is inclusive of all items reprocessed in the organization and utilized for patient use inclusive of instruments and medical equipment processed utilizing steam, dry heat, ethylene oxide, chemical and high-level disinfection methods.

In planning SPD service delivery, the SPD shall determine:

CR.1 Quality objectives and requirements for the SPD;

CR.2 Required processes and documents, and necessary resources specific to the SPD;

CR.3 Required verification, validation, monitoring, and measurement, specific to the SPD; and,

CR.4 Records needed to provide evidence that the processes meet requirements. The output of this planning shall be in a form suitable for the SPD's method of operations.

SD.2 REVIEW AND DETERMINE REQUIREMENTS FOR PRODUCTS AND SERVICES

The SPD shall review requirements related to the SPD. This review shall be conducted prior to the SPD's commitment to provide services to patients and shall ensure:

CR.1 The SPD requirements are clearly defined;

CR.2 The SPD has the ability to meet the defined SPD requirements;

CR.3 Results of the review and actions arising from the review shall be maintained;

CR.4 If any SPPC Requirements are changed, the SPD shall ensure that all relevant documents are amended; and,

CR.5 Communication to all relevant personnel is made about any changes and the competence of all practitioners is reassessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the SPD.

SD.3 CUSTOMER FOCUS AND INTERESTED PARTIES

The SPD shall define the customers and interested parties who are the recipients of the departments services and/or products. The SPD shall ensure that satisfaction is measured and evaluated for continual improvement, (e.g. vendors, patients, departments, physicians, and staff).

CR.1 The SPD shall ensure that the customers/interested parties identified have a method to provide feedback to the SPD (e.g. provider; department; and vendor feedback).

SD.4 CONTROL OF SERVICE DELIVERY

The SPD shall plan and carry out services under controlled conditions. Controlled conditions shall include, but are not limited to:

CR.1 The availability of information that describes the characteristics of the SPD;

CR.2 Work instructions, for all equipment and products (e.g. Manufacturer's IFU, Safety Manuals, Material Safety Data Sheets) shall be readily available to all staff in the SPD;

CR.3 The use of suitable equipment as defined by Manufacturer's IFU and professionally recognized organizations (e.g. AAMI, APIC, AORN, CDC);

CR.4 The availability and use of monitoring and measuring equipment; and,

CR.5 The implementation of monitoring and measurement as recommended by professionally recognized organizations (e.g., AAMI, APIC, AORN, CDC). This shall include but not be limited to:

CR.5a Use of chemical and/or biological testing for all sterilization loads.

CR.5b Documentation ensuring physical parameters of sterilization and disinfection have been met.

CR.5c Daily testing of all critical equipment as defined by Manufacturer's IFU.

CR5d Use of external sterilization indicators.

SD.5 STERILE PROCESSING DEPARTMENT PROCESSES

CR.1 The SPD is responsible for the development, maintenance, and utilization of efficient and appropriate processes to ensure safe care of all patients where the SPD impacts patient care.

CR.1a All process guidelines are based on scientific data and recommendations of recognized professional organizations, (e.g. AAMI, AORN, APIC, CDC). The organization must evaluate and update any process guidelines when more data and information on the guideline topic becomes available.

CR.1b Appropriate participating surgeons, practitioners, and clinical staff are to be involved in the adoption of pathways, clinical protocols and clinical practice guidelines.

SD.6 ACQUISITION OF NEW PRODUCTS AND/OR SERVICES

CR.1 The SPD shall have an identified process for acquiring new medical devices, products or equipment in the department. This process shall include:

CR.1a Review of Manufacturer's IFU including requirements for appropriate cleaning, disinfection, sterilization and use;

CR.1b Identification of additional resources needed for new medical devices, products or equipment;

CR.1c Provision of training and service for new medical devices, products or equipment;

CR.1d Terms defining the expectations of SPD regarding new medical devices, products or equipment prior to acceptance; and,

CR.1e The organization shall retain documented information describing the results of the review and/or acquisition of new products and/or services.

SD.7 INSTRUMENT SETS

CR.1 The SPD shall have a documented process for the development and maintenance of instrument sets.

CR.1a The SPD shall have an identified process for requesting new or changing existing

instrument sets, review of requirements for new instrument sets, review of customer feedback for instrument sets, and appropriate education for all staff who have contact with the new or changed instrument sets.

SD.8 EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

The SPD shall:

CR.1 Define minimum expectations for all items provided by external resources including delivery and storage.

CR.2 Review all Manufacturers' IFUs for externally provided resources.

CR.3 Process all externally provided resources and equipment utilizing its processes that will impact patient care.

CR.4 Establish guidelines for externally provided resources in emergent situations impacting patient care.

CR.5 Establish a system to account for all externally provided resources prior to acceptance of the resources.

CR.6 Have a process in place for accounting for all externally provided resources while they are in the facility and when they are removed from the facility.

CR.7 Ensure that all externally provided resources are appropriately decontaminated prior to removal from the facility.

SD.9 PROCESS VALIDATION

The SPD shall audit key processes, internally and/or externally, at least quarterly. The audits shall incorporate guidelines and recommendations of recognized professional organizations, (e.g., AAMI, AORN, APIC, CDC). The processes audited shall include, but not be limited to:

CR.1 Point of use gross decontamination;

CR.2 Instrument and equipment preparation prior to transport to SPD;

CR.3 Transportation to SPD;

CR.4 Manual decontamination in SPD according to Manufacturers' IFU;

CR.5 Equipment facilitated decontamination in SPD according to Manufacturers' IFU;

CR.6 Automatic washer or disinfection processes as required by Manufacturers' IFU;

CR.7 Visual and manual inspection of equipment after disinfection processes;

CR.8 Inventory and accounting for all items and documentation of inventory;

CR.9 Use of appropriate and required packaging for the sterilization process;

CR.10 Appropriate use and selection of sterilization technique;

CR.11 Documentation for tracking and identification of processed items;

CR.12 Measuring and monitoring of post-sterilization/high level disinfection parameters;

CR.13 Quarantine processes for equipment waiting on validation results;

CR.14 Release processes for items deemed urgently or emergently needed;

CR.15 Appropriate storage; and,

CR.16 Controlled transportation to the point of use.

SD.10 IDENTIFICATION AND TRACKING

CR.1 The SPD shall ensure that all equipment and instruments intended for patient use can be identified and tracked through critical processes in the SPD and to the patient and procedure in which the equipment and instruments were utilized. At the time of certification, if the organization does not have the ability to trace equipment and instruments specific to the patient, a plan to achieve this requirement must be in place and approved by Top Management with an identified date of implementation within 24 months from the date of survey.

SD.11 PERFORMANCE EVALUATION

The SPD shall evaluate the performance and effectiveness of the program as a part of its QMS (see QM.7).

CR.1 The SPD shall collect and analyze data on at least the following performance measures:

CR.1a Surgical Site Infection Rate: (This rate will include 90 days following a patient's surgery, not just the hospitalization period);

CR.1a(i) The SPD shall have a process in place to determine if the root cause of the infection occurred is a result of SPD;

CR.1b Immediate Use Steam Sterilization Rates: (This rate will include reasons for IUSS, appropriate documentation of IUSS, implantable devices utilizing IUSS and appropriate measures to track and trend for performance improvement.);

CR.1c Tracking of damaged or defective trays (This includes: trays with holes in wraps and filters, wet trays, trays where chemical or biologic indicators failed);

CR.1d Preventative maintenance strategy and adherence for equipment and instruments;

CR.1e Incomplete trays;

CR.1f Instrument and tray management system effectiveness (tracking and identification);

CR.1g Periodic microbiological sampling and testing of instruments and equipment;

CR.1h Interested Party Feedback (This includes: Surgeon and practitioner feedback, surgical staff feedback, vendor feedback and/or anesthesia services feedback).

SD.12 PERFORMANCE IMPROVEMENT

CR.1 The SPD shall determine opportunities for improvement and take the necessary steps to evaluate, modify and reevaluate processes. This should include improving service provision, anticipating future needs, correcting and preventing undesired outcomes and improving performance;

CR.2 The SPD shall take appropriate corrective action when nonconforming products and services are identified;

CR.3 Documentation of corrective actions taken and steps taken to determine if similar

nonconformities exist in the SPD; and,

CR.4 The SPD shall continually improve the processes to enhance patient safety and efficacy of its processes.

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DNV GL is one of the world's leading certification bodies. We help businesses manage risk and assure the performance of their organizations, products, people, facilities and supply chains through certification, verification, assessment, and training services. We combine technical, digital and industry expertise to empower companies' decisions and actions.

Within healthcare we help our customers achieve excellence by improving quality and patient safety through hospital accreditation, managing infection risk, management system certification and training.

With origins stretching back to 1864 and operations in more than 100 countries, our experts are dedicated to helping customers make the world safer, smarter and greener.