BUSINESS ASSURANCE

The Integration and Application of ISO 9001 and the NIAHO® Requirements In Medical Equipment Management

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20 October 2017
DNV GL: We are a global classification, certification, technical assurance and advisory company

OUR PURPOSE

TO SAFEGUARD LIFE, PROPERTY AND THE ENVIRONMENT
Course Learning Objectives

▪ This session will enable the attendee to:

➢ Describe the DNV GL Physical Environment survey process, including unique methods specific to medical equipment management.

➢ Outline how integration of ISO 9001 concepts affects development of a hospital’s Medical Equipment Management System procedures.

➢ Discuss current issues and common findings related to the NIAHO® Medical Equipment Management accreditation survey.
Highly skilled people across the world

300+ offices

100 countries

16,500 employees
Healthcare

Our services:

➢ Hospital Accreditation to DNV GL standards
➢ Managing Infection Risk
➢ Disease-specific certifications
➢ Management systems certification
➢ Training

2,400

HEALTHCARE ORGANIZATIONS
ACCREDITED OR CERTIFIED

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Section ONE:

A Brief Overview of DNV GL Survey Processes
Survey Team Composition

- **Clinical Surveyor**
  - Patient Care Unit Visits (Clinical Settings)
  - Med/ Surg, ICU, CCU, Obstetrics, Emergency Department
  - High acuity units

- **Generalist Surveyor**
  - Quality Management Review
  - Medication Management
  - Medical Staff and Human Resources Review
  - Utilization Review Interview
  - Patient Grievance Interview
  - Med/Surg & Ancillary / Support Services Review (Lab, Medical Imaging, Rehab, etc.)

- **Physical Environment / Life Safety Surveyor**
  - All Physical Environment aspects and Management Plans
  - Physical Environment / Comprehensive Building Tour
  - Biomedical Engineering & Calibration of Equipment
**Key Features of the DNV GL HC Survey Process**

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<thead>
<tr>
<th>Characteristic of NIAHO®</th>
<th>Affect on Hospital</th>
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<tr>
<td>Stable standards, infrequent change</td>
<td>Sustainable system</td>
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<tr>
<td><strong>Annual Surveys</strong></td>
<td><strong>Constant readiness</strong></td>
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<tr>
<td>ISO 9001 Gradual Introduction @ no additional staff</td>
<td>More value, lower $</td>
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<td>Focus on sequence and interactions of processes throughout the hospital</td>
<td>Clear, traceable pathway to improve</td>
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<tr>
<td>Demeanor of the survey team</td>
<td>Collaboration, sharing of ideas</td>
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<td>No survey findings “tipping” point</td>
<td>Fear becomes confidence</td>
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NIAHO® Standard Requirement Chapters

- Quality Management System
- Governing Body
- Chief Executive Officer
- Medical Staff
- Nursing Services
- Staffing Management
- Rehabilitation Services
- Obstetric Services
- Emergency Department
- Outpatient Services
- Dietary Services
- Patient Rights
- Infection Control
- Medical Records Service
- Medication Management
- Surgical Services
- Anesthesia Services
- Laboratory Services
- Respiratory Care Services
- Medical Imaging
- Nuclear Medicine Services
- Discharge Planning
- Utilization Review
- **Physical Environment**
- Organ, Eye and Tissue Procurement

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NIAHO® Physical Environment (PE) Management Systems

- PE.1 Facility
- PE.2 Life Safety Management System
- PE.3 Safety Management System
- PE.4 Security Management System
- PE.5 Hazardous Material (Hazmat) Management System
- PE.6 Emergency Management System
- PE.7 Medical Equipment Management System
- PE.8 Utility Management System
Section Two:

Discussion of the NIAHO® Requirements that apply to Medical Equipment
SR.1 The organization shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.

SR.2 The Medical Equipment Management System shall address issues related to the organization’s initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.

SR.3 The Medical Equipment Management System shall address criteria for the selection of equipment.

SR.4 The Medical Equipment Management System shall address incidents related to serious injury or illness or death (See SMDA 1990).
SR.5 The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.

SR.6 The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.

SR.7 The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.
Section Four:
A Discussion of the ISO 9001 Concepts that affect the Accreditation of Medical equipment
**ISO 9001 General requirements: contractor control**

- Where an organization chooses to outsource any process that affects product conformity to requirements, the organization ensures control over such processes.

- Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.
Top management ensures that responsibilities and authorities are defined and communicated within the organization.

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.
ISO 9001 Resource management concepts

- Personnel performing work affecting conformity to product requirements shall be **competent** on the basis of appropriate education, training, skills and experience.

- The **organization determines the necessary competence** for personnel performing work affecting conformity to product requirements, provides training or take other actions to achieve the necessary competence, evaluates the effectiveness of the actions taken, ensures 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 maintains appropriate records of education, training, skills and experience.
ISO 9001 Infrastructure and work environment

- The organization determines, provides and maintains the **infrastructure needed to achieve conformity** to product requirements. Infrastructure includes, as applicable,
  - a) buildings, workspace and associated utilities,
  - b) process equipment (both hardware and software), and
  - c) supporting services (such as transport, communication or information systems).

- The organization determines and manages the work environment needed to achieve conformity to product requirements.
Where necessary to ensure valid results, measuring equipment shall

- be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards

- **traceable** to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded

- be adjusted or re-adjusted as necessary;

- **have identification** in order to determine its calibration status;

- be safeguarded from adjustments that would invalidate the measurement result;

- **be protected from damage and deterioration** during handling, maintenance and storage.
ISO 9001  Control of monitoring and measuring equipment

- The organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected.
ISO 9001  Purchasing Process Concepts

- The **organization ensures that purchased product conforms to specified purchase requirements**. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

- Purchasing information describes the product to be purchased
  - The organization establishes and implements the **inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements**.
  - Where the organization or its customer intends to **perform verification at the supplier’s premises**, the organization states the intended verification arrangements and method of product release in the purchasing information.
ISO 9001 Control of nonconforming product

- The organization **ensures that product which does not conform to product requirements is identified and controlled** to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

- Where applicable, the organization deals with nonconforming product by one or more of the following ways:
  - by taking action to **eliminate** the detected nonconformity
  - by taking action to **preclude** its original intended use or application.
ISO 9001 Corrective action concepts

- The organization takes action to **eliminate the causes of nonconformities** in order to prevent recurrence.
- Corrective actions **shall be appropriate** to the effects of the nonconformities encountered.
- A documented procedure is established to define requirements for
  - reviewing nonconformities (including customer complaints),
  - determining the causes of nonconformities,
  - evaluating the need for action to ensure that nonconformities do not recur,
  - determining and implementing action needed,
  - records of the results of action taken
  - reviewing the effectiveness of the corrective action taken.
Section Five: Common Survey Findings related to Medical Equipment Management
Common Survey Findings

- Traceability of calibrating equipment including corrective actions on OOT equipment
- Improper use of AEM and lack of OEM recommended checks
- Control of nonconforming equipment
- Separating clean from soiled equipment
- Training Documentation of bio-techs
- Procedure deficiencies regarding equipment suspected of patient harm
Common Survey Findings
PE.7 findings that are PE.1 (Senior Leadership controlled)

- Training of staff outside department (self alarming equipment)
- Control of all vendors/contractors
- Access to contractor inventory / Inventory Management
- Control of Equipment during emergency/disaster
- Control of Nonconforming Equipment (including unable to locate equipment, continual use, unavailable equipment)
- Cross-contamination warning to staff
- Recalls and alerts
OUR VISION

GLOBAL IMPACT FOR A SAFE AND SUSTAINABLE FUTURE

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