The Physical Environment Survey: The Application of NFPA, NIAHO® and ISO 9001 in Barrier Wall Management

Randall Snelling, Chief Physical Environment Officer, DNV GL- Healthcare
DNV GL: We are a global classification, certification, technical assurance and advisory company

OUR PURPOSE

TO SAFEGUARD LIFE, PROPERTY AND THE ENVIRONMENT
Highly skilled people across the world

300+ offices

100 countries

16,500 employees
Position
A world-leading certification body for management systems, products, persons, supply chains and facilities.

People
2,000 highly skilled employees with a reason to get up in the morning.

6,000
Food and beverage companies partner with us to ensure safety and sustainability.

Partnership
Working with more than 70,000 customers in over 180 countries to help them build sustainable business performance and create stakeholder trust.

Innovation
Certification, verification, assessment, training and sustainability advisory services that help companies meet changing demands.

2,400
Healthcare organizations trust us to help them improve quality and patient safety.
Section One: A Brief Overview of the DNV GL-Healthcare PE Accreditation Process
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

## Feature of NIAHO®

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit to Hospital</th>
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<tr>
<td>Stable standards, infrequent change</td>
<td>Sustainable system</td>
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<td>Annual Surveys</td>
<td>Constant readiness</td>
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<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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<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
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:

A Discussion of the Regulations Addressing Barrier Wall Penetrations
NIAHO® PE.2 Life Safety Management System:
Most Common Findings

- Items hanging from sprinkler piping
- Fire extinguishers missing inspection, placement, and blocking
- Penetrations (and no penetration permit program)
- Doors: Fire door malfunctions, locked exit doors
- Exit signage
- Fire drill documentation (including off-sites)
- ALSM coordination with AHJ
- Hot work permits/LOTO Issues
CMS CoP 482.41(b)(2); 482.41(b)(3)  
Waivers and State Control

- **482.41(b)(2):** After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

- **482.41(b)(3)** The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.
Comparison: CMS CoP’s 482.41(b)(7) and 482.41(b)(8)

482.41(b)(7)
- The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

482.41(b)(8)
- The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.
NIAHO® PE.2 LIFE SAFETY MANAGEMENT SYSTEM


- **NIAHO® PE.2 SR.4** The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel, and guests; evacuation; and cooperation with firefighting authorities.

- **18.1.1.4.2** Communicating openings in dividing fire barriers required by 18.1.1.4.1 shall be permitted only in corridors and shall be protected by approved self-closing fire doors. *(See also Section 8.2.)*

- **19.1.1.4.2** Communicating openings in dividing fire barriers required by 19.1.1.4.1 shall be permitted only in corridors and shall be protected by approved self-closing fire doors. *(See also Section 8.2.)*

- **NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers.**

- **NFPA 101, 2000 8.2.3.2.4.1** Openings in fire barriers for air-handling ductwork or air movement shall be protected in accordance with 9.2.1.
NFPA 101, 2000 9.2.1 Air Conditioning, Heating, Ventilating Ductwork, and Related Equipment. Air conditioning, heating, ventilating ductwork, and related equipment shall be in accordance with NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems, or NFPA 90B, Standard for the Installation of Warm Air Heating and Air-Conditioning Systems, as applicable, unless existing installations, which shall be permitted to be continued in service, subject to approval by the authority having jurisdiction.

- **NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers**

- **NFPA 101, 2000 8.2.3.2.4.2*** Pipes, conduits, bus ducts, cables, wires, air ducts, pneumatic tubes and ducts, and similar building service equipment that pass through fire barriers shall be protected as follows:
NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers

NFPA 101, 2000 8.2.3.2.4.2

(1) The space between the penetrating item and the fire barrier shall meet one of the following conditions:

a. It shall be filled with a material that is capable of maintaining the fire resistance of the fire barrier.

b. It shall be protected by an approved device that is designed for the specific purpose.
NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers

NFPA 101, 2000 8.2.3.2.4.2

(2) Where the penetrating item uses a sleeve to penetrate the fire barrier, the sleeve shall be solidly set in the fire barrier, and the space between the item and the sleeve shall meet one of the following conditions:

a. It shall be filled with a material that is capable of maintaining the fire resistance of the fire barrier.

b. It shall be protected by an approved device that is designed for the specific purpose.

- NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers

- NFPA 101, 2000 8.2.3.2.4.2

(3) *Insulation and coverings for pipes and ducts shall not pass through the fire barrier unless one of the following conditions is met:

a. The material shall be capable of maintaining the fire resistance of the fire barrier.

b. The material shall be protected by an approved device that is designed for the specific purpose.
NFPA 101, 2000 8.2.3.2.4 Penetrations and Miscellaneous Openings in Fire Barriers

8.2.3.2.4.2
(4) Where designs take transmission of vibration into consideration, any vibration isolation shall meet one of the following conditions:
   a. It shall be made on either side of the fire barrier.
   b. It shall be made by an approved device that is designed for the specific purpose.
8.2.4.4 Penetrations and Miscellaneous Openings in Smoke Partitions

8.2.4.4.1 Pipes, conduits, bus ducts, cables, wires, air ducts, pneumatic tubes and ducts, and similar building service equipment that pass through smoke partitions shall be protected as follows:
8.2.4.4 Penetrations and Miscellaneous Openings in Smoke Partitions

8.2.4.4.1

(1) The space between the penetrating item and the smoke partition shall meet one of the following conditions:

a. It shall be filled with a material that is capable of limiting the transfer of smoke.

b. It shall be protected by an approved device that is designed for the specific purpose.
8.2.4.4 Penetrations and Miscellaneous Openings in Smoke Partitions

8.2.4.4.1
(2) Where the penetrating item uses a sleeve to penetrate the smoke partition, the sleeve shall be solidly set in the smoke partition, and the space between the item and the sleeve shall meet one of the following conditions:

a. It shall be filled with a material that is capable of limiting the transfer of smoke.

b. It shall be protected by an approved device that is designed for the specific purpose.
8.2.4.4 Penetrations and Miscellaneous Openings in Smoke Partitions

8.2.4.4.1 (3) Where designs take transmission of vibrations into consideration, any vibration isolation shall meet one of the following conditions:

a. It shall be made on either side of the smoke partitions.
b. It shall be made by an approved device that is designed for the specific purpose.

- **19.3.7.3** Any required smoke barrier shall be constructed in accordance with **Section 8.3** and shall have a fire resistance rating of not less than 1/2 hour.

- **8.3.6 Penetrations and Miscellaneous Openings in Floors and Smoke Barriers.**

- **8.3.6.1** Pipes, conduits, bus ducts, cables, wires, air ducts, pneumatic tubes and ducts, and similar building service equipment that pass through floors and smoke barriers shall be protected as follows:
**PE.2 LIFE SAFETY MANAGEMENT SYSTEM**

- NIAHO® PE.2 SR.4 The organization must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel, and guests; evacuation; and cooperation with firefighting authorities.

- The fire control plan shall provide for the following (NFPA 101-2000, 18.7.2.2 & 19.7.2.2):
  - SR.4a Use of alarms
  - SR.4b Transmission of alarm to fire department
  - SR.4c Response to alarms
  - **SR.4d Isolation of fire**
    - SR.4e Evacuation of immediate area
    - SR.4f Evacuation of smoke compartment
    - SR.4g Preparation of floors and building for evacuation
    - SR.4h Extinguishment of fire
CMS CoP 482.42 : Infection Control

- **Sec. 482.42 Condition of participation: Infection control**
  - The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.
Comparison CMS CoP
482.42(b)(1) and 482.42(b)(2): Infection control

– 482.42(b)(1)
  ▪ Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and

– 482.42(b)(2)
  ▪ Be responsible for the implementation of successful corrective action plans in affected problem areas
The Life Safety Management System shall include in the elements of **SR.4d** a written plan for the protection of the integrity of hospital smoke and fire barriers. The plan should include:

1. **Name(s) of Responsible hospital staff for barrier protection program**
2. **Requirement for written permission for anyone (including all hospital staff, contractors and vendors) to penetrate a smoke or fire barrier wall, ceiling or floor**
3. **Input from Infection Control and Prevention Practitioner on critical clinical areas prior to issuance of written permit for performing work on barriers**
4. **Establishment of monitoring process to ensure all work is completed correctly**
While you are above the ceiling ... low hanging Fruit

- **NFPA 13, Sprinklers, 1999 Edition**
- **6-1.1.5*** Sprinkler piping or hangers shall not be used to support nonsystem components.
Section Three:

A Discussion of the ISO 9001 Concepts that affect the Accreditation of the PE
NIAHO® PE.1 FACILITY
Key ISO 9001-related Requirements

- PE.1 SR.3 The organization shall have policies, procedures and **processes in place to manage staff activities**, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization’s patients, staff, and others.

- PE. 1 SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility’s infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are **prevented, controlled** investigated, and reported throughout the organization.

- PE.1 SR.5 The organization shall evaluate the facility’s physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
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.
ISO 9001 Top Management Responsibilities: Communication

- 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.
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**.
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.
OUR VISION

GLOBAL IMPACT FOR A SAFE AND SUSTAINABLE FUTURE

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Infrastructure and Accreditation

CMS (CoPs) (Accreditation Oversight)

NIAHO℠ Accreditation Requirements (Consistent with CMS CoPs - Requirement for ISO Compliance/Certification)

ISO 9001:2008 Quality Management System (Infrastructure of QMS)

Hospital Patient Care Processes and Supporting Operations

Improved patient care and safety
Comparison CMS CoP
482.41(c)(2) and 482.41(c)(4)

- 482.41(c)(2)
  - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. (Please note that changes to the interpretive guidelines per S&C:14-07 hospital were made but not in the standard itself)

- 482.41(c)(4)
  - There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
Comparison: CMS CoP 482.41 and 482.41(a)

482.41: Physical environment:
- The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

482.41(a) Standard: Buildings:
- The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.
Section Three:

Discussion of the specific application of ISO 9001 and CMS CoP in PE survey findings
NIAHO® PE.1 FACILITY
Key ISO 9001-related Requirements

- PE.1 SR.3 The organization shall have policies, procedures and processes in place to manage staff activities, as required and/or recommended by local, State, and national authorities or related professional organizations, to maintain a safe environment for the organization’s patients, staff, and others.

- PE. 1 SR.4 The organization shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility’s infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the organization.

- PE.1 SR.5 The organization shall evaluate the facility’s physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
SR.6 Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.

SR.7 The organization, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues.

SR.8 Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.
Infrastructure and Accreditation

Hospital Patient Care Processes and Supporting Operations

ISO 9001:2008 Quality Management System
(Infrastructure of QMS)

NIAHO® Accreditation Requirements
(Consistent with CMS CoPs - Requirement for ISO Compliance/Certification)

CMS (CoPs)
(Accreditation Oversight)

Improved patient care and safety
Example of common PE.7 finding:

“The Surveyor observed equipment in various areas of the hospital that was in use but was overdue for maintenance according to the equipment inventory.”
Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. (Please note that changes to the interpretive guidelines per S&C:14-07 hospital were made but not in the standard itself)
NIAHO® Accreditation Requirements

- **PE.7 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.

- **PE.7 SR.5** The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.

- **PE.7 SR.6** The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.
ISO 9001:2008 Quality Management System

8.3 Control of non-conforming product

- The organization shall ensure 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.
8.3 Control of on conforming product

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) **by taking action to eliminate the detected nonconformity**;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) **by taking action to preclude its original intended use or application**;

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.
Hospital-developed policy on controlling nonconforming (NC) equipment

- Staff education on recognizing NC equipment
- Enhanced inter-staff communications
- Equipment Inventory controls
- Tagging system
- Follow-up procedures to enhance finding efforts
- RFID system