A New Choice for Hospitals: Achieving Both Medicare Accreditation and ISO 9001 Certification At The Same Time

Introduction to DNV Healthcare and NIAHO℠

Lab Quality Confab

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DNV

- Established in 1864
- Third Party Evaluator in many sectors
- Independent, self supporting Foundation
- Tax paying entity in every country it operates
- 300 Offices in 100 Countries – 15 offices in the United States
- 9000 Employees
- 50,000 clients worldwide; 85,000 Certificates world-wide
- Largest registrar in the US; third largest in the world
- Operating in the U.S. since 1898
- DNV received CMS deeming authority on September 26, 2008 (5 year exhaustive process)
The DNV Purpose

Safeguarding life, property and the environment

The DNV Vision

Global impact for a safe and sustainable future
DNV Values

- We build trust and confidence
- We never compromise on quality or integrity
- We are committed to teamwork and innovation
- We care for our customers and each other

DNV Healthcare Inc.

NIAHO℠ and ISO 9001 Quality Management System

Hospital Accreditation: Integration of NIAHO℠ Standards with ISO 9001 Quality Management System Standards
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)

Integrated Accreditation Model

- Integrates ISO 9001 and Medicare CoP compliance
  - ISO 9001 provides the framework for a sustainable CoP implementation
  - ISO 9001 allows hospitals to use its combined knowledge, wisdom, and innovation to improve quality and safety
  - ISO 9001 is the framework within which methodologies such as LEAN and Six Sigma are better understood and utilized
- The DNV Surveyors make the difference
  - Training and competence in ISO 9001 and NIAHO℠
  - Clinical, Administrative, and Physical Environment expertise
- Combined result drives quality transformation into the organization’s core processes
Advantages to DNV Healthcare Accreditation

- Meets and exceeds CoP requirements
- Includes ISO 9001 Quality Management System (proven basis for continual improvement)
- No additional staff required to implement NIAHO™
- Annual visits – added accountability
- Demeanor of the Survey Team
- Focus on sequence and interactions of processes throughout the hospital
- No survey findings “tipping” point
- Leads to improvement of patient safety and reduction in hospital’s internal cost of accreditation
- Accreditation as a strategic business asset

Terminology

**Quality Policy** = Mission, Vision  
**Quality Objectives** = Organization’s Quality Goals & Objectives  
**Corrective Action** = CQI/PI Process – RCAs  
**Preventive Action** = FMEA Process  
**Internal Audit** = Review of departmental & organization processes and outcomes; individual performing cannot come from area being audited  
**Document Control** = Sundown provision  
**Management Representative** = Quality Director  
**Management Review** = Enlarged Quality Council Function
Process Map Example

ABC Regional Hospital

Inpatient Treatment

Cross Functional Flowchart

Physician/ED

Registration

Inpatient Unit

Physician

Pharmacy

Physical Therapy

Respiratory Care

Laboratory

Radiology

Cardiology

Infection Control

Social Services

Environmental Service

Purchasing/Distribution

Medical Records

Pt registered

Diagnostic testing

Assessed.

Treatment initiated

Provides therapy

Reassesses.

Develops plan/orders

Transfer to another hospital

Transfer back to Nursing Home

Writers admit orders

Discharged home

Room cleaned

Supplies restocked

Assesses discharge needs

Medication orders processed & dispensed

Transcription. Chart assembly, coding

Assesses IC needs

NIAHOSM Standards - 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
4.0 Quality Management System

4.1 General
4.1.1 Continual Improvement*
4.2 Document requirements
4.2.2 Quality Manual Justification & process flow diagram*
4.2.3 Documentation
4.2.4 Records

5.0 Management responsibility
5.1 Management commitment (4.1)
5.2 Customer focus*
5.3 Quality Policy*
5.4 Planning (objectives)
5.5 Responsibility & authority
5.5.3 Internal Communication*
5.6 Management review

6.0 Resource management
6.1 Resources
6.2 Human Resources
6.3 Infrastructure
6.4 Work environment

7.0 Product realization
7.1 Planning and product realization
7.2 Customer related
7.2.1 Determine requirements*
7.2.2 Review requirements
7.2.3 Customer requirements*
7.3 Design & development
7.4 Purchasing
7.5 Production
7.6 Calibration

8.0 Measurement, analysis and improvement
8.1 General
8.2 Monitor & measure
8.2.1 Customer Satisfaction*
8.2.2 Internal audit
8.2.3 Processes*
8.2.4 Product
8.3 Nonconforming product
8.4 Analysis of data
8.5 Improvement
8.5.1 Continual*
8.5.2 Corrective
8.5.3 Preventive
The inherent requirements for **process improvement** result in good outcomes specified in the CMS Conditions of Participation.

Hospitals are held **accountable** through the mechanisms required in ISO 9001 for Internal Audits, Management Review and Corrective / Preventive Action.

Allows hospital innovation to determine HOW assures sustainable and safe **best practices** that support this approach.

**NIAHO℠ Surveyors & Survey Activities**
Surveyor Competency and Consistency

Clinical, Generalist, & Physical Environment Surveyors must successfully complete the following:

- The DNVHC NIAHO℠ Surveyor Training
- The DNV Quality Lead Auditor or an equivalent course accredited by IRCA or RAB-QSA
- The DNV Risk-Based Certification methodology training
- Orientation to DNVHC policies, procedures and software requirements
- Observation surveys
- Additionally, the Physical Environment / Life Safety Specialists must successfully complete the following:
  - Successful completion of a NFPA (National Fire Protection Association) Life Safety Code training with an additional focus on hospital requirements.
  - All must attend annual surveyor training & complete 45 hours CEUs every 3 years
  - Hospital staff OPTION as a contract surveyor

Survey Team

- **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 Specialist**
  - All Physical Environment aspects and Management Plans
  - Physical Environment / Comprehensive Building Tour
  - Biomedical Engineering & Calibration of Equipment
Conducting Survey Activities

Survey activities are carried out as follows:

- A comprehensive review includes observation of care/services provided to the patient in all patient care areas, both in and out, patient and/or family interview(s), staff interview(s), and medical record review.

- Using Tracer methodology, department/patient unit visits to include staff interviews and open medical record review as appropriate (both clinical and support departments)
  - identify performance issues
  - handoff between steps
  - Tracer methodology

- Visits to non-clinical support areas

- Comprehensive Building Tour (days, not hours)

Compliance and Corrective Action

- **Category 1 Nonconformities**
  - Submit Corrective Action Plan within 10 days from receipt of Final Report
  - The organization shall submit performance measure(s) data, findings, results of internal audits, or other supporting documentation, including timelines, to verify implementation of the corrective action measure(s).

- **Category 2 Nonconformities**
  - Submit Corrective Action Plan within 10 days from receipt of Final Report
  - Validation of effective implementation of the agreed Corrective Action Plan will take place at the next annual survey.

- **Category One Condition Level Finding – requires re-survey to clear – egregious findings**
| Survey Team | Day One | | | Physical Environment / Life Safety |
|-------------|---------|----------------|----------------|
| General     | Clinical|                           |               |
| 8:30 – 9:00a | Opening Meeting with Organization Leadership | 9:00a – 12:00p | Operational Activities Review – Key Processes (Inpatient Methodology) + Patient Care Unit Visits
|             | Participants: Director of Quality, Management Representative, and Other Administrative Staff (as organization's discretion) | 9:00a – 12:00p | Physical Environment (Document/Plan Review) + Begin Physical Environment / Life Safety Tour |
|             | 9:00a – 11:00a | Quality Management System Review + Quality Objectives + Process Improvement + Monitoring and Measurement (Data Analysis and Reporting) + Corrective and Preventive Action | 9:00a – 12:00p | Physical Environment (Document/Plan Review) + Begin Physical Environment / Life Safety Tour |
|             | 11:00a – 12:00p | Patient Coordination Process |               |
| 12:00p – 12:30p | Lunch (Cafeteria) |               |               |
| Survey Team Planning Session | 12:30p – 1:00p |               |               |
| 12:30p – 1:00p | Survey Team Planning Session | 1:00p – 2:30p | Operational Activities Review – Key Processes (Inpatient Methodology) + Patient Care Unit Visits |
|             | 1:00p – 2:30p | Care Management Utilization Review/Discharge Planning Process | 1:00p – 2:30p | Physical Environment (Continued) + Physical Environment / Life Safety Tour |
|             | 2:30p – 4:00p | Document Review Session (See Document Request List) |               |
|             | 4:00p – 4:30p | Survey Team Meeting with Quality Management Representatives (and other staff members, if requested) |               |

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| Survey Team | Day Two | | | Physical Environment / Life Safety |
|-------------|---------|----------------|----------------|
| General     | Clinical|                           |               |
| 8:30 – 8:00a | Planning Session (Session with Organization – Review Schedule and Plan for Audit Activities) | 9:00a – 11:00a | Medical Records (Record Review) + Cloud Medical Records + Include review of medication, narcotics, DOF patients, moderate sedation |
|             | Participants: Director of Quality (Management Representative) + Other Administrative Staff (as organization's discretion) | 9:00a – 12:00p | Physical Environment (Continued) + Physical Environment / Life Safety Tour |
|             | 8:00a – 10:00a | Ancillary / Support Services Review (Data Process Review) | 10:30a – 11:30a | Purchasing |
|             | (This will include such areas as Laboratory, Medical Imaging, Inpatient, Day Services and any other areas not reviewed as part of the Operational Activities Review) | 11:30a – 12:30a | Finance/Patient Accounting |
|             | 10:30a – 11:30a | Purchasing | 11:00a – 12:30p | Operational Activities Review – Key Processes (Inpatient Methodology + Inpatient Care Process) + Patient Care Unit Visits |
|             | 11:30a – 12:30a | Finance/Patient Accounting |           | Interview) Infection Control |
|             | 12:30p – 1:30p | Lunch (Cafeteria) |               |               |
|             | 1:30p – 2:30p | Human Resources (Competency Assessment and Training Evaluation) | 1:30p – 4:30p | Operational Activities Review – Key Processes (Inpatient Methodology + Inpatient Care Process) + Assessing Moderate/Conscious Sedation |
|             | 2:30p – 3:30p | Medication Management Review (Pharmacy) | 1:30p – 4:30p | Physical Environment (Continued) + Physical Environment / Life Safety Tour |
|             |           | - Include visits to ICUs (Infection Control) |               | Biomedical Engineering Review |
|             | 4:00p – 4:30p | Auditor Meeting with Administration, Quality Management Representatives (and other staff members, if requested) |               |               |
ISO 9001 and Lean

<table>
<thead>
<tr>
<th>ISO Clause</th>
<th>ISO 9001:2008</th>
<th>Relationship to Lean</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2</td>
<td>Customer Focus</td>
<td>Lean and ISO require a Customer focus</td>
</tr>
<tr>
<td>5.4.1</td>
<td>Quality Objectives</td>
<td>Lean metrics provide a means to measure Customer Satisfaction as part of the ISO Management System</td>
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<tr>
<td>8.1</td>
<td>Measurement, analysis and improvement</td>
<td></td>
</tr>
<tr>
<td>8.4</td>
<td>Data Analysis</td>
<td></td>
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<tr>
<td>7.5.2</td>
<td>Validation of processes for production and service provision</td>
<td>This reduces waste in the form of rejects from incapable processes or processes that are unstable</td>
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<tr>
<td>8.2.3</td>
<td>Monitoring and measurement of processes</td>
<td>Lean eliminates waste from processes as procedures are developed or reviewed.</td>
</tr>
<tr>
<td>8.5.1</td>
<td>Continual Improvement</td>
<td>Lean Principles can be the focal point of the Continual Improvement process</td>
</tr>
<tr>
<td>7.5.1</td>
<td>Control of production and service provision</td>
<td>Standard work, a Lean Concept, can provide the framework for developing standard work instructions.</td>
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ISO 9001 and Lean

- Leverage the ISO 9001 quality management system to implement Lean because Lean works best when it is built on the solid framework of stability, standardization and simplification.
- ISO 9001 provides a containment mechanism from which corrective and preventive action can take place and is an excellent means for standardizing work.
- ISO 9001 provides management a project management tool (audit, corrective action, effectiveness check).

ISO 9001 and Lean

- An ISO 9001 management system is ideally suited to effectively implement Lean programs. It provides for the success of such programs with provisions for:
  - Management vision, direction, authorization and involvement
  - Resource evaluation and application, inclusive of personnel qualification and training, processes, etc.
  - Planning functions
  - Qualification and control of designs, technologies, processes, materials, and services
  - Review and analysis of results, application of decision-making processes and initiation of needed changes
ISO 9001 and Lean

- ISO 9001 and LEAN links
  - [http://www.asqwindsor.ca/calendarFiles/2009Jan15AppendixB.pdf](http://www.asqwindsor.ca/calendarFiles/2009Jan15AppendixB.pdf) - this is a valuable appendix
  - [http://www.euroquest.net/qualitytools.shtml](http://www.euroquest.net/qualitytools.shtml)

Accreditation/Certification Cycles

- Initial Agreement/Contract
  - Year 1 - NIAHO Accreditation ONLY (ISO general education (informal) also will take place during this first survey)
  - Year 2 - NIAHO Accreditation and ISO Pre-Assessment
  - Year 3 - NIAHO Accreditation and ISO Stage One (basically where you are with ISO and what is left to be done to prove ISO Compliance/Certification)

- Second Agreement/Contract
  - Year 4 - NIAHO Accreditation and ISO Stage Two (ISO Compliance/Certification)
  - Year 5 - NIAHO Accreditation and ISO Periodic
  - Year 6 - NIAHO Accreditation and ISO Periodic
Accreditation/Certification Cycles cont.

- Third Agreement/Contract
  - Year 7 - NIAHO Accreditation and ISO Re-Certification/ Compliance
  - Year 8 - NIAHO Accreditation and ISO Periodic
  - Year 9 - NIAHO Accreditation and ISO Periodic

- All Subsequent Agreements/Contracts: same as Third Agreement/Contract
ACGME, Managed Care, and Bonds

Approvals

- **ACGME**
  - ACGME has approved DNV Healthcare in regard to accreditation under the Institutional Requirements

- **Managed Care Organizations and Other Third Party Payors**
  - To our knowledge no barriers have been encountered regarding contractual revisions to recognize DNV Healthcare as an approved accreditation organization since we are approved by CMS as an accreditation organization with deeming authority for hospitals in accordance with Section 1865 of the Social Security Act.

- **Bond Covenants**
  - To our knowledge no barriers have been encountered regarding bond covenants as a result of hospitals changing accreditation organizations.
Innovative Approach

- Annual on-site surveys
- Collaborative
- Less prescriptive
- Allows organization innovation
  - More than one way to accomplish a goal
  - Encourages best practices
  - ISO Tenets
    - Document what you do
    - Do what you document
    - Prove it
    - Improve it
Infrastructure and Accreditation

- Improved patient care and safety
- CMS (CoPs) (Accreditation Oversight)
- NIAHO℠ Accreditation Requirements (Consistent with CMS CoPs - Requirement for ISO Compliance/Certification)
- Hospital Patient Care Processes and Supporting Operations

DNV HEALTHCARE INC.
CERTIFICATE OF ACCREDITATION

Certificate No. 1234-ABC-USA-MARO
This is to certify that
ABC Medical Center at
1234 Hospital Avenue, Cincinnati, OH 45215
Conforms with the requirements of the
NIAHO℠ Hospital Accreditation Program

Pursuant to the authority granted to Det Norske Veritas (US), Inc. by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, the organization is deemed in compliance with the Medicare Conditions of Participation for Hospitals (42CFR §482). This certificate is valid for a period of three (3) years from the Effective Date of Accreditation.

For the certification body:
Det Norske Veritas (US), Inc.
1620 Meridian Avenue, Suite 100
Cincinnati, OH 45215

For the Accreditation Body:
CMS

Date of Accreditation: December 1, 2008
Expiration Date: December 1, 2011

Lack of continued fulfillment of the conditions set out in the Certificate of Accreditation Agreement may render the Certificate invalid.

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What do our customers say?

- (DNV Healthcare – Video)

Question & Answer Session