

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

Introduction to DNV Healthcare and NIAHOSM



Lab Quality Confab

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

We build trust
and confidence

We never compromise
on quality or integrity

We are committed to
teamwork and innovation

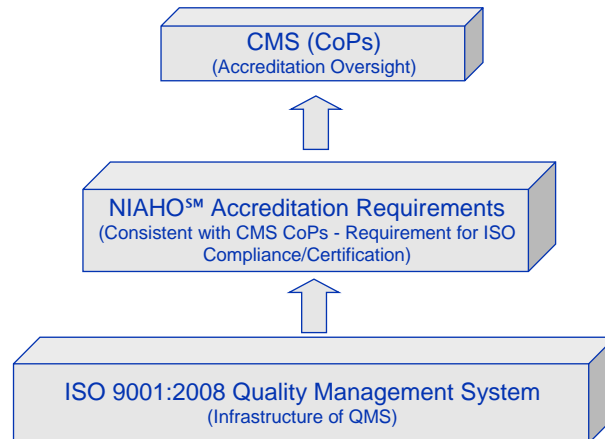
We care for our customers
and each other

NIAHOSM and ISO 9001 Quality Management System



Hospital Accreditation: Integration of NIAHOSM Standards with
ISO 9001 Quality Management System Standards

Infrastructure and Accreditation



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 NIAHOSM
 - 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 NIAHOSM
- 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

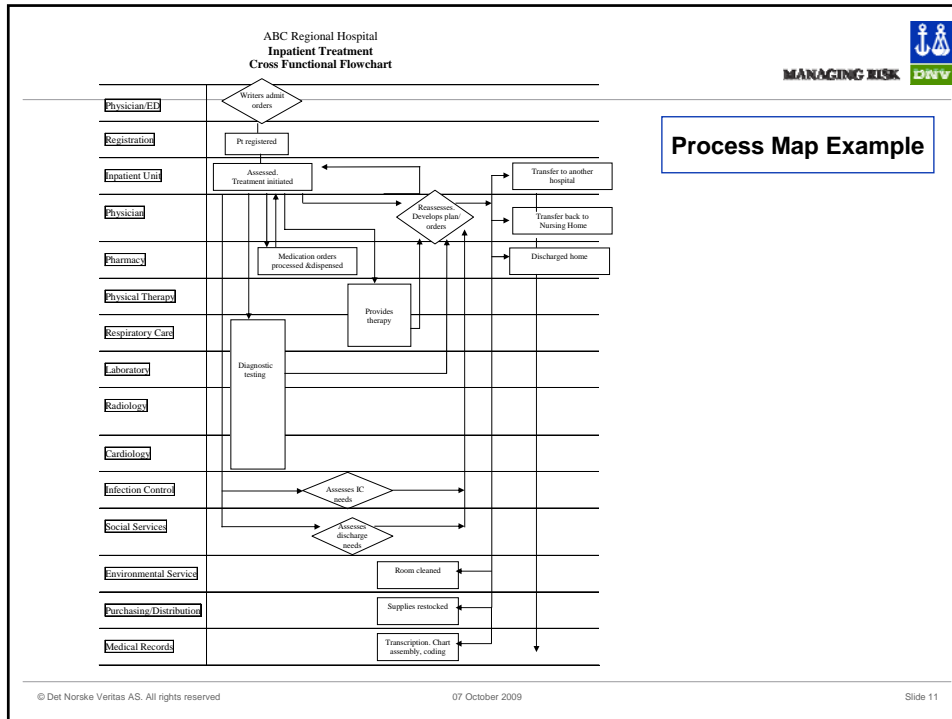
Preventive Action = FMEA Process


Internal Audit = Review of departmental & organization processes and outcomes; individual performing cannot come from area being audited

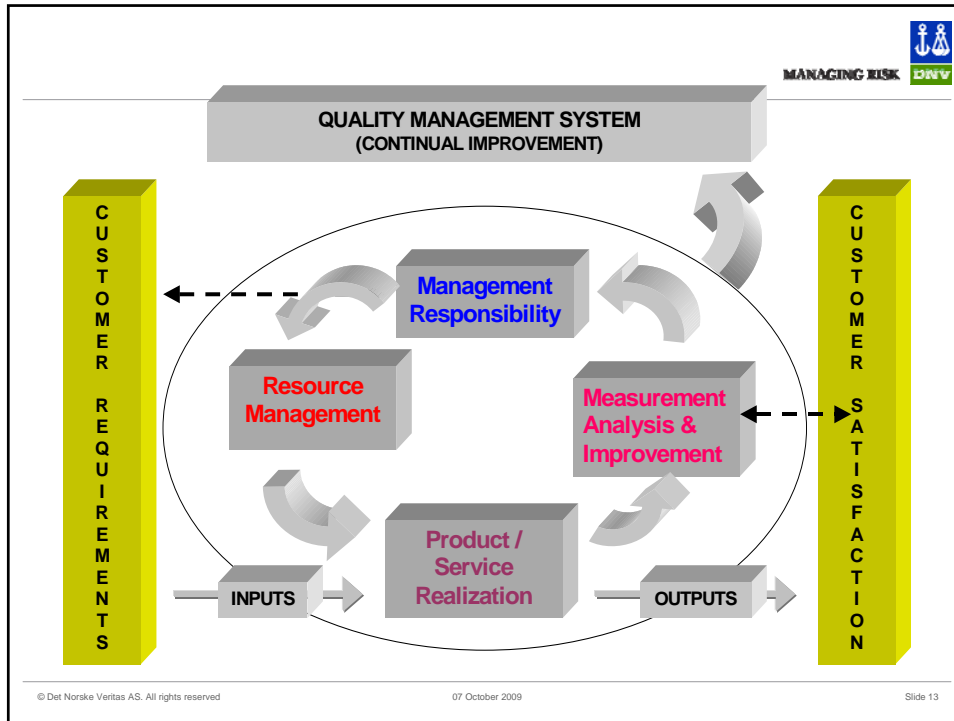
Document Control = Sundown provision

Management Representative = Quality Director

Management Review = Enlarged Quality Council Function



- ## NIAHOSM Standards - Chapters
- 
- | | |
|--|--|
| <ul style="list-style-type: none"> ■ 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 | <ul style="list-style-type: none"> ■ 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 |
|--|--|
- © Det Norske Veritas AS. All rights reserved 07 October 2009 Slide 12



- 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

NIAHOSM Surveyors & Survey Activities



Surveyor Competency and Consistency



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

- The DNVHC NIAHOSM 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		
Generalist	Clinical	Physical Environment / Life Safety
8:30a -9:00a Opening Meeting with Organization Leadership - Review Schedule and Plan for Survey Activities Participants: Director PI/Quality (Management Representative) and Other Administrative Staff (at organization's discretion)		
9:00a – 11:00a Quality Management System Review - Quality Objectives - Project(s) review - Monitoring and Measurement (Data Analysis and Reporting) - Corrective and Preventive Action	9:00a – 12:00p Operational Activities Review – Key Processes (Tracer Methodology – Inpatient Care Processes) - Patient Care Unit Visits	9:00a – 12:00p - Physical Environment (Document / Plans Review) - Begin Physical Environment / Life Safety Tour
11:00a – 12:00p Patient Grievance Process		
12:00p – 12:30p – Lunch (Cafeteria)		
12:30p – 1:00p – Surveyor Planning Session		
1:00p – 1:30p Organ, Tissue and Eye Procurement	1:00p – 2:30p Operational Activities Review – Key Processes (Tracer Methodology – Inpatient Care Processes) - Patient Care Unit Visits	1:00p – 2:30p Physical Environment (Continued)
1:30p – 2:30p- Care Management (Utilization Review / Discharge Planning Process)	- Include visit to Senior Care	Physical Environment / Life Safety Tour
2:30p – 4:00p - Document Review Session (See Document Request List)		
4:00p – 4:30p – Surveyor Meeting with Quality/Management Representatives (and other staff members, if requested)		

Survey Team		
Day Two		
Generalist	Clinical	(Physical Environment / Life Safety)
8:30a -9:00a Planning Session (Session with Organization – Review Schedule and Plan for Audit Activities) Participants: Director PI/Quality (Management Representative) and Other Administrative Staff (at organization's discretion)		
9:00a – 10:30a Ancillary / Support Services Review (Tracer Process Review) (This will include such areas as Laboratory, Medical Imaging PT/OT, Hemodialysis, Dietary Services and any other areas not reviewed as part of the Operational Activities Review)	9:00a – 11:00a Medical Records (Record Review) - Closed Medical Records - Include review of med/surg, restraint use, OP surgical patients, moderate sedation	9:00a – 12:30p - Physical Environment (Continued) Physical Environment / Life Safety Tour
10:30a – 11:30a Purchasing	11:00a – 12:30p Operational Activities Review – Key Processes (Tracer Methodology – Inpatient Care Process) - Patient Care Unit Visits	
11:30a – 12:30p 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 (Tracer Methodology – Surgical Care and Outpatient Care Process – Areas using Moderate/Conscious Sedation) - Areas to be selected during lunch	1:30p – 4:30p - Physical Environment (Continued) Physical Environment / Life Safety Tour Biomedical Engineering Review
2:30p – 3:30p Medication Management Review (Pharmacy)	- Include visit to SC Recovery	
4:00p – 4:30p – Auditor Meeting with Administration, Quality Management Representatives (and other staff members, if requested)		

Survey Team		
Day Three – January 15, 2009		
Paul Bailey	Mike Minter, MD	Randy Snelling / Troy McCann (Physical Environment / Life Safety)
8:30a – 8:45a Auditor Meeting with Quality/Management Representatives (and other staff members, if requested)		
8:45a – 10:00a – Ancillary / Support Services Review (Tracer Process Review) (This will include such areas not reviewed as part of the Operational Activities Review or prior Ancillary / Support Services Review Session)	8:45a – 10:00a Medical Staff (Credentialing and Privileging) Review	8:45a – 10:30a Physical Environment (Conclusion of Physical Environment / Life Safety Tour if necessary)
10:00a – 11:30a Surveyor Planning Session (Surveyors Only)		
11:30a – 12:00p Lunch		
12:00p – 12:30p Meeting with Management Representative		
12:30p – 1:30p Closing Meeting with Administration, Quality Management and Other Administrative/Management Staff (at organization's discretion)		

ISO 9001 and Lean



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

© Det Norske Veritas AS. All rights reserved

07 October 2009

Slide 24

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> - this is a valuable appendix
- <http://learnsigma.com/can-lean-and-iso-9001-be-integrated/>
- <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

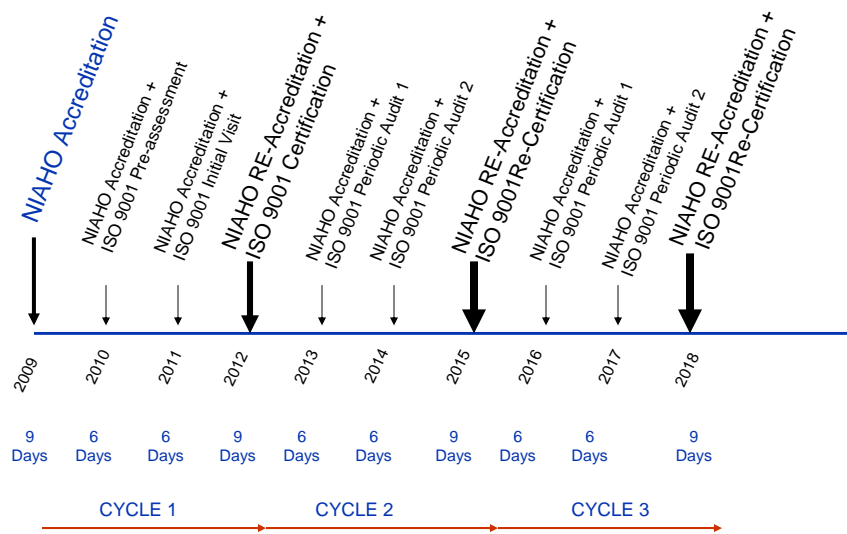
- Year 4 - NIAHO Accreditation and ISO Stage Two (ISO Compliance/Certification)
- Year 5 - NIAHO Accreditation and ISO Periodic
- Year 6 - NIAHO Accreditation and ISO Periodic

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

Accreditation/Certification Cycles



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

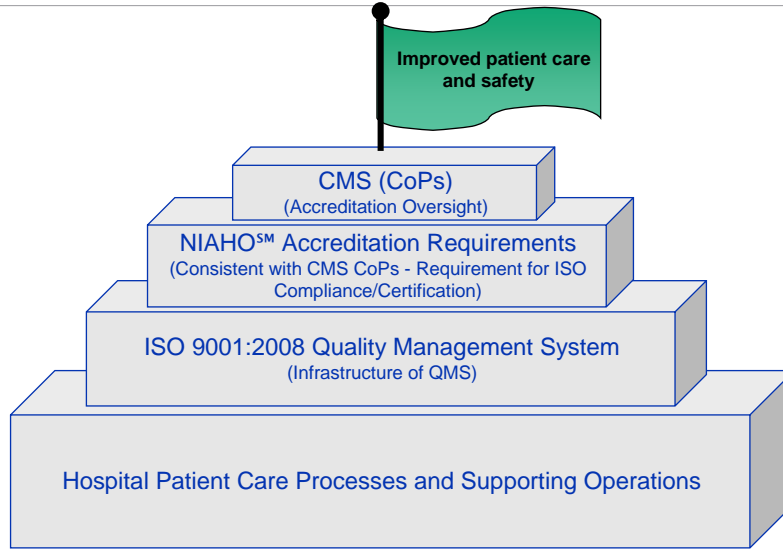
- To our knowledge no barriers have been encountered regarding bond covenants as a result of hospitals changing accreditation organizations.

Accreditation and Beyond

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



DNV HEALTHCARE INC. CERTIFICATE OF ACCREDITATION

Certificate No. 12345-AHC-USA-NIAHO

This is to certify that

ABC Medical Center

at

1234 Hospital Avenue, Cincinnati, OH 45255

Complies with the requirements of the

NIAHOSM Hospital Accreditation Program

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

Effective Date of Accreditation:
December 1, 2008

Patrick Horne
Executive Vice President, Accreditation



for the Accreditation Body:
DET NORSKE VERITAS
HEALTHCARE, INC.
HOUSTON, TEXAS

Steinar Dvor
President

Lack of continual fulfillment of the conditions set out in the Certification/Accreditation Agreement may render this Certificate invalid.

DET NORSKE VERITAS HEALTHCARE, INC., 14340 PARK TWIN PLAZA, HOUSTON, TX 77064. TEL: 281-721-6600 - WWW.DNVACCREDITATION.COM

What do our customers say?



- [\(DNV Healthcare – Video\)](#)

Question & Answer Session



www.dnv.com

Yehuda Dror, President
Yehuda.Dror@dnv.com

Rebecca (Becky) Wise, COO
rebecca.wise@dnv.com
513-388-4866

Patrick (Pat) Horine, EVP
patrick.horine@dnv.com
513-388-4888

Darrel Scott, SVP
darrel.scott@dnv.com
513-388-4862

www.dnvaccreditation.com