Introduction to DNV Healthcare & NIAHO® Accreditation for Hospitals

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Senior Vice President, Regulatory & Legal Affairs

Simply Better Accreditation™
Presentation Objective

- Who is DNV Healthcare?
- The NIAHO® Standards Concept
- Integration of ISO 9001
- What is ISO 9001?
- Who are the DNV Surveyors?
- What do the Surveyors do and how do they do it?
- The Accreditation/Certification Cycle
- What about ACGME, third party payors/ managed care?
- Benefits of NIAHO®/ISO 9001
- How does the Hospital transition to DNV?
- Q&A
Integrity at the core

- Independent foundation established in 1864
- Self-owned with no shareholders
- In the US since 1898
- Our story...
Core Competence: Third Party Evaluations

Managing risk

Maritime
Defense
Food & Beverage
Transportation
Energy
IT & Telecom
Public Sector
Automotive
Finance
Health Care
Highly skilled people across the world

- 15 offices in the U.S.
- 300 offices world-wide
- 100 countries
- 10,000 employees, of which 82% have university degree
A global third party evaluator

Top 3
DNV is among the world’s top three certification companies

2,200
2,200 healthcare-related organisations have had their quality management system certified by DNV

1st
Developed first and only management standard on Biorisk – CWA 15793

85,000
More than 85,000 management system certificates under more than 80 accreditations
Our Purpose
To safeguard life, property and the environment

Our Vision
Global impact for a safe and sustainable future
Prescriptive Requirements ("How-To Policies") Frequently Changing

- DNVHC Accreditation Requirements are consistent with the CMS Conditions of Participation
- Introduction of the ISO Quality Management System Infrastructure
- Comply with ISO 9001 within 3 years (OPTIONAL ISO 9001 Certification)
- Annual Surveys lead to more sustainable, consistent, effective accreditation
- Culture change regarding approach to accreditation, improving use of resources within the organization
- ACCREDITATION = Management Asset for quality and patient safety improvement

CMS Conditions of Participation

Objectives

Best Practices Innovation Demonstrated Outcomes

Internal Audits
Management Review Corrective / Preventive Actions
Accreditation/QMS Concept

CMS (CoPs)
(Accreditation Oversight)

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

Hospital / Medical Center
Quality Management System
(Compatible and Compliant with ISO 9001:2008)
Hospital Accreditation

NIAHO® Standards Platform

SIMPLY BETTER ACCREDITATION

FACT

Approved by CMS

+ Integrates ISO 9001 quality management

RESULT

Meets or exceeds CoP requirements

+ Introduces world-class quality procedures/practices
Performance Based Approach

Quality Improvement Cycle

- Plan
- Do
- Check
- Act

Regulatory requirements and YOUR quality program

ISO

DNV Accreditation
NIAHO®

Sustainable and Continual improvement

Performance

process

time
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

- Combined result drives quality transformation into the organization’s core processes
ISO 9001 As the Infrastructure for NIAHO® Accreditation

- 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

- ISO determines **WHAT** has to be done but leaves the **HOW** up to the organization

- Requires hospital to use their own innovation to determine how best to assure safe and sustainable **best practices** that outcomes prove effective and efficient
Advantages to DNV Healthcare Accreditation

- Meets and exceeds CoP requirements
- Includes ISO 9001 Quality Management System (proven basis for continual improvement)
- Focus on sequence and interactions of processes throughout the hospital
- No additional staff required to implement ISO & NIAHO®
- Annual visits – added accountability
- Demeanor of the Survey Team
- 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
NIAHO® 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
The ISO Quality Management System..

QUALITY MANAGEMENT SYSTEM
(CONTINUAL IMPROVEMENT)

Management Responsibility

Resource Management

Service Realization

Measurement Analysis & Improvement

INPUTS

OUTPUTS

CUSTOMER REQUIREMENTS

CUSTOMER SATISFACTION

Customer Satisfaction (Continual Improvement)
ISO 9001:2008

4.0 Quality Management System
- Quality Manual
- Documentation
- Records

5.0 Management Responsibility
- Management Commitment
- Customer Focus
- Quality Policy
- Planning Objectives
- Responsibility & Authority
- Management Review

6.0 Resource Management
- Resources
- Human Resources
- Infrastructure
- Work Environment

7.0 Product/Service Realization
- Customer Related Processes
- Purchasing
- Service
- Calibration

8.0 Measurement
- Satisfaction
- Internal Audits
- Processes
- Product NCs
- Corrective/Preventive
## ISO 9001:2008

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<td>Certain requirements may be excluded</td>
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<tr>
<td>8. Measurement, analysis and improvement</td>
<td>Mandatory requirements</td>
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Some Examples of Hospital Processes

- Inpatient Care
- Outpatient Care
- Ambulatory Surgery
- Emergency Care
- Critical Care Delivery
- Medication Delivery
- Transfusion and Blood Product Administration
Customer Relationships – Internal – External

(Product/Service Realization Processes)

Pt. Needs Hip Replacement

1  Physician’s Office
2  Scheduling
3  Admitting
4  Pre-Admission Testing

5  Operating Room
6  Med/Surg IP Unit
7  Home Care

Pt. Has Hip Replaced and returns home
Example of ISO 9001:2008 Clauses

- 4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed
- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.
Example of ISO 9001:2008 Clauses

5.6 Management review

5.6.1 General
Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input
The input to management review shall include information on

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review output
The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.
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<td>ED.4 OFF-CAMPUS DEPARTMENTS</td>
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ISO and Lean; ISO to Baldrige

- 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.asqwindsor.ca/calendarFiles/2009Jan15AppendixB.pdf)

- ISO to Baldrige
ISO 9001 and Baldrige

- Would achieving ISO 9001:2008 compliance or certification help an organization prepare to achieve Baldrige-level performance excellence?
  - Yes, especially in the area of Process Management (Baldrige Category 6). That is, implementing ISO 9001 would provide the most usable feedback regarding the Baldrige criteria.

- What are the areas where the Baldrige and ISO systems are most closely aligned?
  - The strongest alignment exists between Baldrige Category 6 (Process Management) and ISO Clauses 4 through 8. Conversely, the Baldrige criteria are most strongly represented in ISO Clauses 7 and 8 (Product Realization and Measurement/Analysis/Improvement)
# Alignment...ISO and Baldrige

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**Legend:**
- Good alignment
- Some alignment
- Blank indicates very little or no alignment
- § indicates somewhat less alignment than for the other similarly color-coded cells

**Figure 6.** General Degree of Alignment between Baldrige Categories and ISO 9001 Clauses.
Performance Improvement Communication Grid

Department Improvement Teams (DITs)
Performance Improvement Teams (PITs)

MISSION AND STRATEGIC PLAN
OVERSIGHT COMMITTEES
Governing Board
Medical Executive Administration

PATIENT SATISFACTION
Satisfaction Surveys

STAFF INPUT
- Quality Consults
- Incident Reports
- Department Meetings
- Employee Satisfaction Survey

Performance Improvement Council/Committee

DEPARTMENTAL ACTION
- PI Activities
- Competency Reviews
- Education
- Performance Evaluation

PATIENT OUTCOMES

ADVISORY GROUPS
- Community
- Attorneys
- Employers
- Physicians

COMMITTEES
- Exec P & T
- IC Risk
- EOC Med Rec
- Crit Care CME
ISO Quality Management System Communication Grid

- Quality Manual (4.2.2)
- Quality Policy (5.3)
- Management Commitment (5.1)
- Customer Satisfaction (8.2.1)
- Internal Audits (8.2.2)
- Monitoring and Measuring (8.2.3 / 8.2.4)
- Data Analysis (8.4)
- Continual Improvement (8.5.1)
- Corrective / Preventive Action (8.5.2 / 8.5.3)
- Control of Nonconforming Services (8.3)
- Management Review (5.6.2 / 5.6.3)
- Responsibility and Authority (5.5.1)
- Management Representative (5.5.2)
- Quality Management System Planning (5.4.2)
What ISO Should NOT Be!

Stressful About Creating Paperwork
Dispelling Some of the Myths of ISO 9001…

- **ISO 9001 is a bureaucratic nightmare**
  - Done badly, it can be; there have been systems with documentation that fills shelf space and is mind-numbing to use! Done well, it certainly isn’t – it can be lean, easy-to-use and with minimal bureaucracy. You have a choice.

- **ISO 9001 will slow us down and be very costly to operate**
  - Done badly, this can be the case. Done well, the opposite is true. Quality and timescales are not mutually exclusive, they are on opposite sides of the same coin. You can’t reduce timescales unless you eliminate problems or inefficiencies in the processes; doing things right first time is invariably quicker and cheaper than undertaking rework or remedial measures at a later stage.

Source: Gaskell, Tom - Quality and Product Insights - ISO 9001 myths dispelled
Dispelling Some of the Myths of ISO 9001…

- **ISO 9001 is very costly and time-consuming to put in place**
  - It can be done quickly for a modest cost. It is possible to put in a comprehensive system in 6-8 months if it is well organized, or you could take longer to reduce the demand on people’s time.
  - If it takes longer than a year, or needs several Full Time Equivalent staff, then you may not be doing it as efficiently as you could.

- **ISO 9001 doesn’t improve quality**
  - Implemented properly it improves the consistency of activities and enables monitoring and continuous improvement of quality.
  - By optimizing processes, sharing best-practice across the company, and reducing customer complaints and re-work which reduces cost.

Source: Gaskell, Tom - Quality and Product Insights - ISO 9001 myth dispelled
Dispelling Some of the Myths of ISO 9001…

- **ISO 9001 destroys creativity and innovation**
  - It is often appropriate to allow complete freedom in some areas.
  - ISO 9001 enables you to be as creative and innovative as you like in specific areas, but do you want a complete lack of consistency or established ways of working across your operations?.... I suspect not!

Source: Gaskell, Tom - Quality and Product Insights - ISO 9001 myths dispelled
NIAHO® Surveyors & Survey Activities

The Surveyors Make the Difference
Surveyor Competency & Consistency

- Clinical, Generalist, and Physical Environment expertise
- Complete the DNVHC NIAHO® Surveyor Training
- Complete the DNV ISO 9001 for Healthcare Lead Auditor Course
- Physical Environment Specialists must successfully complete the NFPA Life Safety Code for Hospitals training
- Fluency in Accreditation Process
- Mentored surveys
- All must attend annual surveyor training & complete 45 hours CEUs every 3 years

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Survey Team – Typical Activities

- **Clinical Surveyors**
  - 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
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.

- Tracing process (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
Compliance, 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
From NIAHO® to ISO

Phase 1 - Planning

Phase 2 – System Development

Phase 3 – Implementation

Phase 4 – Conformance

Phase 5 – Certification

NIAHO Accreditation
+ ISO 9001 Pre-assessment

NIAHO Accreditation
+ ISO 9001 Initial Visit (Stage I)

NIAHO Accreditation
+ ISO 9001 Certification (Stage II)

Year 1
Year 2
Year 3
Year 4

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Transformation Phases

- **Planning**
  - Get Leadership behind the process
  - Utilize results of Accreditation Survey

- **System development**
  - Aligning your system with ISO
  - If you wish to have DNV Training, this is the phase

- **Implementation**
  - With or without Consultants
  - Use of Accreditation Committee
  - Learn from corrective and preventive actions

- **Conformance**
  - Measure and check with Internal Audits and Management reviews

- **Certification**
  - If you are conforming, this is an “automatic” outcome
Innovative Approach

- Annual on-site surveys
- Collaborative
- Less prescriptive
- Allows organization innovation
  - More than one way to accomplish a goal
  - Encourages best practices
  - ISO “Cliff Notes”
    - Document what you do
    - Do what you document
    - Prove it
    - Improve it
Where infrastructure helps….

- Besides providing assurance to customers, a quality management system can also be used to—

- provide a common framework for coordination and communication between units/departments and healthcare organizations;

- improve systems, processes and efficiency and effectiveness;

- identify objectives and focus on needs and expectations of patients/customers;

- achieve and maintain the desired quality of products and services, to consistently meet customers’ stated or implied needs;

- monitor health outcomes or objectives agreed between organizations or departments, (e.g. service agreements, contracts);

- provide evidence of capability to customers and potential customers;

Source: HB.90 Health Services Guide to ISO 9001:2000 (Standards Australia)
Benefits of Accreditation for Physicians

- Removing some of the complexity and demands on the medical staff to focus on patient care
- Decreasing the occurrence of preventable adverse events
- Benefiting the effects on clinical practice
- Improving communication and engagement of physicians in hospital processes
Benefits of Accreditation for Leadership

- Leading a transformational change to the quality management system for the hospital
- Improving the channels of communication between leadership, management, staff and physicians
- Recognition of the level of quality of the hospital based on evaluation from a third party healthcare accreditation organization
- Enhancing the clinical and supportive operations of the hospital
Benefits of Accreditation for Hospital Staff

- Increased involvement and accountability of staff to improve processes
- Focus on the important fundamental aspects of compliance with accreditation requirements
- Improving communication among staff and developing a better understanding of the relationships with other departments and services within the hospital
- Enhancing the efficiency and effectiveness within the infrastructure of a sound quality management system and applying requirements directly related to the aspects of patient care
Benefits of Accreditation for Patients

- Improving patient satisfaction

- Focus on the needs of the patients and developing effective processes for patient care

- Promotion of the quality initiatives and focus of the hospital

- Building confidence of the patients to demonstrate the hospital’s commitment to quality
Benefits of Accreditation to Insurance Companies

- A means for evaluating health care organizations to ensure a specified level of quality, as defined by a set of industry standards as an approval of services provided

- To differentiate healthcare providers who have achieved and maintain accreditation to ensure the effectiveness and efficiency of services provided

- Requirement to meet the quality of care expectations and reflect the reputation of the hospital to their insured individuals
Hospital System CEO e-mail to the DNV Surveyor Team Leader

“I am so impressed with the DNV philosophy of teaching, celebrating, analyzing, confronting and correcting. I can speak on behalf of our entire Kaleida Health family that we are motivated to do better, embrace the process while we continue to learn and grow. I am confident it will be a strong partnership for each of us with our patients benefiting the most.”
Citizens Medical Center now recognizes DNV Healthcare Inc. as its accrediting agency of choice, DNV Healthcare bases its program on the integration of ISO 9001 Quality Management System with standards set by the Centers for Medicare and Medicaid. This innovative approach to an aging accrediting model emphasizes organization-wide improvements. In turn, it increases the quality of patient care. An intimidating task for some, however, Citizens is up to the challenge.
Why NIAHO® - Hospital’s Testimonial

- Approximately 350 hospitals already switched to DNV Accreditation

- What do they say?
  - Enhances our continuous improvement
  - Embraces our ability to utilize our competence to innovate
  - Drives us to adopt best practices
  - Demands we discard ineffective practices
  - Improved communication between hospital and medical staff
  - Reduces the costly need for implementation and preparation for the program
  - Improves understanding of all hospital processes
  - Performed in a collaborative manner
“Change has a considerable psychological impact on the human mind. To the fearful it is threatening because it means that things may get worse. To the hopeful it is encouraging because things may get better. To the confident it is inspiring because the challenge exists to make things better.”

- King Whitney Jr.
Anchored in the past….

…Balanced for the future
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