YOUR ROAD MAP TO ISO COMPLIANCE
FOR HOSPITALS ACCREDITED WITH THE DNV GL HEALTHCARE NIAHO® PROGRAM

SAFER, SMARTER, GREENER

PLANNING
NIAHO® Accredited & Compliant With CMS
- Lessons learned
- “Control” of existing documents
Pre-Assessment
- Identify the gap from current quality management of program and ISO compliant quality management system
Map Key Processes
- Chart and audit Pre-Assessment
- Identify process owner and interaction with hospital functions
Training & Competence
Document & Records
Monitoring & Measurement, Including Calibration

SYSTEM DEVELOPMENT
Document and Record Controls
- Inventory and catalog
- Awareness, training and implementation
Management Responsibility
- Construction & operational
- Quality policy, quality objectives
Internal Audit
- Assessment of current practices
- Status of meeting quality objectives
Corrective & Preventive Action
- Prepare documented procedures and procedures and instructions for all required system tasks
- Evaluate system for any deficiencies
Competency Requirements
Facilities, Equipment & Work Environment
Purchasing, Suppliers & Contracted Services
Monitoring & Measurement (Including Calibration)

IMPLEMENTATION
Internal Audit
- Implement audit procedure and plan
- Assess auditor competence and objectivity
Management Review Inputs
- Results of audits
- Customer feedback
- Focus performance and product continuity
- Status of preventative and corrective actions
- Follow-up actions from previous management reviews
- Changes that could affect the quality management system
- Recommendations for improvement
Prepare for Stage 1 Pre-Assessment

Corrective and Preventive Action
- Determine causes, actions, individual(s) responsible for action
- Measure and evaluate effectiveness
Outputs
- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Other needs
- “Will Consultants Bring Value?”
- Considering all of the above, do you need them?
- If you use them, use them to help integrate the process
- Avoid cookie-cutter approach individual decision
This phase helps you prepare for Stage 1 initial visit/Pre-Assessment that is conducted at the beginning of Year 2

CONFORMANCE
Management Review
- Consider audit results, recommendations, improvement actions, recommendations, monitoring and measurement
Stage 1 Initial Visit/Pre-Assessment
- A complete survey that provides a full understanding of the ISO 9001 standard
- This has proven to best prepare for the full comprehensive audit (Stage 2) that follows at the beginning of Year 4
Prepare for Stage 2 Survey
Reaccreditation, ISO Compliance (Certification Optional) & Continued CMS Compliance

CERTIFICATION-REACCREDITATION
NIAHO® Reaccreditation Compliant With ISO 9001 Certification
Single Survey Focused on:
- Redundancy, breadth, results, evaluating in properly structured level
- Reliability, adequacy
- Opportunities for improvement
- Non-conformities
Cal. 2: robust action plan
Cal. 3: validation of improvement
- Corrective and preventive actions implemented with clear understanding of process improvement

CONTINUOUS IMPROVEMENT
Quality Management System
Management Responsibility
Resource Management
Product/Service Realization
Measurement Analysis & Improvement
Customer Satisfaction

NIAHO®: Notable, Incredibly Accurate, Notable Hospitals
DNV GL: Det Norske Veritas GL Healthcare
The path from NIAHO® to ISO

Planning
Get leadership behind the process
Utilize results of accreditation survey

System Development
Aligning your system with ISO
Avail yourself of DNV GL training courses

Implementation
With consultants? Or without?
Use of quality 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

Continual Improvement

Most hospitals are 75% of the way to ISO compliance even before they start the formal process.

Yehuda Dror, President
DNV GL - Healthcare

Your Goal for YEAR

1. NIAHO® ACCREDITATION
2. NIAHO® ACCREDITATION + ISO 9001 PRE-ASSESSMENT
3. NIAHO® ACCREDITATION + ISO 9001 INITIAL VISIT (STAGE 1)
4. NIAHO® REACCREDITATION + ISO 9001 CERTIFICATION (STAGE 2)