

DNV GL - HEALTHCARE ACCREDITATION PROGRAM FREQUENTLY ASKED QUESTIONS

Who is DNV GL - Healthcare?

DNV GL - Healthcare is an operating company of DNV GL – Business Assurance and The DNV GL Group. DNV GL - Healthcare has corporate offices in Houston, Texas and Cincinnati, Ohio. DNV GL is an international organization with 300 offices in over 100 countries and more than 16,000 employees.

DNV GL was established in 1864 in Oslo, Norway and has had operations in the United States since 1898. The corporate purpose of DNV GL is safeguarding life, property, and the environment. DNV GL has a worldwide reputation for quality and integrity in certification, standards development and risk management in a wide range of industries, including extensive international healthcare experience. On September 26, 2008 the US Centers for Medicare and Medicaid (CMS) approved DNV GL - Healthcare by granting it deeming authority for hospitals. Any hospitals accredited by DNV GL - Healthcare after that date is deemed to be in compliance with the Medicare Conditions of Participation (CoPs).

Who manages DNV GL - Healthcare?

DNV GL - Healthcare is managed by a dedicated group of degreed professionals, each with many years of experience in their respective field of healthcare management, clinical services, health law, ISO certification and engineering. The accreditation management team has extensive healthcare operational experience in the U.S. and understands the dynamics of a complex healthcare organization.

What does NIAHO® stand for?

NIAHO® is the acronym for the National Integrated Accreditation for Healthcare Organizations. NIAHO® is the name of the DNV GL's hospital accreditation program. The NIAHO® standards integrate requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standard for the formation and implementation of the Quality Management System. ISO 9001 is the infrastructure of quality that infiltrates every aspect of your organization – it enables an organization to reach maximum effectiveness and efficiency in its processes that leads to improved outcomes, both clinically and financially. These two sets of standards form the basis of DNV GL's Integrated Accreditation concept in NIAHO®.

Does the hospital have to be ISO compliant before it can receive DNV GL accreditation?

No. The hospital can be accredited by DNV GL immediately after the first survey without being in compliance with ISO 9001. In fact, unless the hospital is currently involved with ISO, it is not expected to be in ISO 9001 compliance at the time of the first survey. The hospital has three years to become compliant with ISO 9001 after the first DNV GL survey. The first survey has two goals – conduct a CMS deemed-status accreditation survey for Medicare certification and introduce the hospital to ISO 9001 Standard. The second year accreditation survey includes an ISO 9001 pre-assessment. It should be noted that most hospitals currently accredited by DNV GL have become ISO 9001 compliant without adding any additional staff.

Can the hospital immediately switch its accreditation to DNV GL– Healthcare without interruption in Medicare reimbursement?

Yes. If a hospital wants to switch its accreditation to DNV GL, it can notify its current accreditation organization (AO) as soon as it has made its decision. Hopefully, the hospital and the AO will work out a plan for an orderly transition. If the hospital and AO cannot agree and the AO immediately withdraws its accreditation, the hospital's Medicare provider agreement is not affected. The current AO will notify the CMS Central Office (CO) and applicable Regional Office (RO) that it has withdrawn its accreditation and the effective date.

If the hospital's termination by one AO is concurrent with the new recommendation for accredited, deemed status by DNV GL - Healthcare, then it may remain under DNV GL - Healthcare rather than State Survey Agency (SA) jurisdiction.

If the hospital's termination by its current AO is not concurrent with a new recommendation for accredited, deemed status by DNV GL - Healthcare, the hospital is not accredited during this interim period but its Medicare reimbursement is not affected. The hospital is placed under SA jurisdiction until such time as a new recommendation for accredited, deemed status by DNV GL - Healthcare is received and approved by the CMS CO and appropriate RO. The hospital's accredited, deemed status is then reestablished and the hospital is placed under DNV GL - Healthcare for ongoing monitoring and oversight. During the transition from the hospital's current AO to DNV GL - Healthcare or, if the transition is not concurrent, from the hospital's current AO to the SA then to DNV GL - Healthcare, **there is no interruption in the Medicare provider agreement, and thus, no break in Medicare reimbursement.**

What is ISO 9001?

The ISO 9001 Standard was first published in 1987 and was recently revised in 2008 to address the issues encountered by facilities in the service industries, including healthcare. ISO changes the standards no more frequently than every six years. This allows the hospitals to stabilize their processes and ensure effectiveness instead of forcing the hospitals to chase a constantly moving target of changing standards.

How is the NIAHO® survey performed and when does DNV GL - Healthcare's accreditation become effective in terms of Medicare and Medicaid reimbursement?

The NIAHO® and ISO surveys are done together through Tracer Methodology as well as staff and patient interviews. While surveying the hospital to the NIAHO® Requirements, DNV GL - Healthcare surveyors also ensure the applicability of the ISO 9001 standard. Tracer Methodology has been a staple of ISO 9001 surveys since ISO 9001's inception in 1987. All areas of the hospital are surveyed, both clinical and non-clinical. Tracer Methodology is a tool to identify and document effective processes. Each survey team includes three surveyor qualifications; generalist, clinical and physical environment. The number of surveyors and the mix of qualifications are determined specifically for each hospital and type of survey being performed. The PE specialist is a fully functioning team member and will be there throughout the entire survey. All teams include surveyors with extensive healthcare clinical and management background. The hospital will receive a final report from DNV GL - Healthcare within ten business days. The hospital will then have ten calendar days to submit its Corrective Action Plan with timelines for implementation. Once the Corrective Action Plan has been approved, the documentation is submitted to the Accreditation Committee for the final accreditation decision.

Upon approval by the Accreditation Committee, DNV GL's accreditation is effective the last day of the survey, or the date of receipt of an approved corrective action plan. For hospitals new to the Medicare program, the effective date for Medicare participation is always determined by CMS?

How long does a hospital have to become compliant with the ISO 9001 Standard?

The NIAHO[®] standards allow up to three years from the initial NIAHO[®] survey to become ISO 9001 compliant. Our experience shows, however, hospitals can begin to realize positive outcomes in the first year. If a hospital is currently accredited by TJS or AOA or has received State survey, it is basically 65-75% of the way to ISO 9001 compliance. The schedule we follow is outlined below.

These are **annual** on-site visits.

- Year One – NIAHO[®] Accreditation and Introduction to ISO 9001
- Year Two - NIAHO[®] Accreditation and ISO 9001 Pre-assessment (The pre-assessment is an analysis to show the hospital where it is currently compliant with ISO and any gaps that need to be addressed to become ISO 9001 compliant.)
- Year Three - NIAHO[®] Accreditation and Stage One ISO 9001 (Stage One is designed to confirm hospital readiness for an ISO 9001 compliance/certification audit.)
- Year Four - NIAHO[®] Accreditation and ISO 9001 Compliance/Certification Audit
- Year Five - NIAHO[®] Accreditation and ISO 9001 periodic audit
- Year Six - NIAHO[®] Accreditation and ISO 9001 periodic audit

The first contract for accreditation services is a three year contract (see above) in order to confirm the hospital's readiness for an ISO 9001 Compliance/Certification Audit, unless the hospital is already certified to ISO 9001. ISO 9001 compliance/certification is determined in the Year Four survey. The next and subsequent three-year contract would be identical to Years Four, Five and Six.

In terms of CMS deeming authority, DNV GL - Healthcare can accredit any part of the organization that is included under the hospital CCN Number (formerly Medicare Provider Number). However, even if some parts of the organization are not surveyed for accreditation, these functions can still be audited for compliance/certification to ISO 9001. DNV GL - Healthcare encourages this because it drives consistency and best practices throughout the organization.

How often do the NIAHO[®] standards change?

There are two types of changes to the NIAHO[®] standards – mandatory and discretionary.

Mandatory – DNV GL - Healthcare is required to change NIAHO[®] standards to conform to any CMS change in the Medicare CoPs. DNV GL - Healthcare is required to implement these changes in NIAHO[®] standards within thirty (30) days of the new CoP effective date.

Discretionary – DNV GL -Healthcare may add, remove or amend any NIAHO[®] standard that is not required by the CoPs. Discretionary changes will clarify existing standards and incorporate practices, principles and processes that will enhance the NIAHO[®] accreditation program. Such changes will be implemented only if they can be expected to improve the overall quality and safety of patient care. Discretionary changes will occur through a dynamic review process that will involve input from the field, comments from applicable agencies and organizations and review by the

DNV GL - Healthcare accreditation management team. Any discretionary change to the NIAHO[®] standards must be approved by the DNV GL - Healthcare Standards and Appeals Board (SAB). The SAB is comprised of representatives active in medicine, nursing and hospital management. Since ISO 9001 is already designed to encourage and accommodate contemporary best practices, discretionary changes should be infrequent.

How long have hospitals been surveyed to the NIAHO[®] standards?

The NIAHO[®] application process to CMS took approximately four years. CMS requires that an applicant organization for deeming authority continue its survey program throughout the submission process. DNV GL - Healthcare worked with many hospitals throughout the United States to develop standards, field train surveyors and submit to the entire NIAHO[®] hospital program. This participation has occurred despite the need to maintain TJC (or other) accreditation because these hospitals were looking for an alternative accreditation. NIAHO[®] standards and survey process have been in place since 2008.

What are the training and qualifications of DNV GL - Healthcare surveyors?

There are three classifications of DNV GL - Healthcare surveyors: Clinical Surveyors, Generalist Surveyors, and Physical Environment (PE) Specialists. The Clinical Surveyor is either a physician or a registered nurse; the Generalist Surveyors may have a clinical or nonclinical hospital background. The PE Specialists come with a facilities and safety background.

All DNV GL - Healthcare surveyors must successfully complete NIAHO[®] Surveyor training and separate ISO 9001 Lead Auditor training. The PE Specialists receive further training in the NFPA[®] Life Safety Code. Following the classroom, each surveyor completes a sufficient number of surveys in a student role until their trainer validates that the surveyor is ready to perform as a Team Member.

In addition to the surveyor background and competency, all surveyors are evaluated in terms of their interpersonal skills. Surveyors must possess sufficient interpersonal skills to translate into a collegial, non-confrontational survey.

All surveyors must complete 45 hours of continuing educations in their discipline within every three year period. Additionally all surveyors must participate in annual surveyor training as well as other courses offered throughout the year by DNV GL and DNV GL - Healthcare staff.

The NIAHO® standards require either ISO Certification or ISO Compliance. What is the difference between ISO Certification and ISO Compliance?

The NIAHO® standards require that a hospital become **Compliant** with ISO 9001 within three years of the first NIAHO® survey but **Certification** to ISO 9001 is an option that the hospital may select.

Compliance means that the hospital has implemented all requirements of ISO 9001 and is **compliant** with the ISO 9001 standard. The hospital will receive **one** Certificate for NIAHO® accreditation that includes confirmation that the hospital is also compliant with the ISO 9001 standards.

In a competitive marketplace, a hospital may want to further publicize its ISO compliance by displaying the separate internationally-recognized ISO 9001 certificate. When a hospital is ISO certified, it will receive **two** certificates, one for NIAHO® accreditation and another certificate for ISO 9001 Certification.

Does DNV GL provide any resources for ISO 9001 and/or NIAHO® implementation?

Yes. DNV GL - Healthcare offers a 3-day ISO 9001/NIAHO® Implementation course. This course is offered to the public and on-site to an individual organization for a fee and expenses. Visit www.dnvglstore.com for more information.

What other training does DNV GL offer to the healthcare field?

DNV GL provides several offerings to assist organizations in their Accreditation journey. We provide 4-hour Leadership presentations as well as fundamental courses such as our 3-day Accreditation course. We do offer 3-day ISO/NIAHO® Implementation courses and 3-day Internal Auditing courses for organizations in locations across the country as demand requires. There is a charge for these programs. See www.dnvglhealthcare.com for information on when these programs are offered or go to www.dnvglstore.com to conveniently register online for our "Healthcare" specific public courses. DNV GL is also willing to come on-site to individual organizations for a fee and expenses. We will soon offer several new training programs such as Proactive Risk Assessment, Physical Environment, ISO 9001:2015 Transition, ISO 9001 Interpretation and more. Call 1-866-523-6823 or email healthcare@dnvgl.com for more information.

If a hospital changes its mind about DNV GL accreditation, can the hospital terminate the contract?

Contracts are quoted in multiyear cycles to maintain accreditation and ISO continuity. If a hospital does not want to continue DNV GL - Healthcare accreditation, it may terminate its contract at any time with a 60-day written notice.

How does the number of findings during a survey affect the hospital's accreditation decision?

The number of findings during a survey has no effect on accreditation. There is no tipping point of findings such that one more finding will lead to non-accreditation. Continual improvement and adherence to the Corrective Action Plan is the key to DNV GL - Healthcare Accreditation.

(More detailed information pertaining to Nonconformities can be obtained in the *Accreditation Process* document that can be downloaded at no charge from our website www.dnvglhealthcare.com.)

Do the NIAHO[®] standards contain patient safety goals?

DNV GL - Healthcare supports the initiatives that hospitals have developed and implemented to guide safe patient care practices. We also support and foster innovations through development of hospital best practices, but clearly understand that some practices do not suit all organizations. DNV GL does not dismiss the notion that patient safety goals can be effective and many organizations may want to consider these “goals” in place of their current practices. However, we also realize that there are different avenues for achieving positive patient safety outcomes and the hospitals know their patient populations and resources best. The decision-makers in each individual hospital are certainly well-trained, qualified, and best equipped address these issues. DNV GL - Healthcare will look at the outcomes to validate problem resolution.

Hospitals can use innovation to develop new methods for producing positive results, but not by DNV GL forcing one practice over another when good outcomes are being achieved. At the same time, we hold hospitals accountable to ensure that processes are planned, managed, measured, documented and continually improved.

Does the DNV GL parent company in Oslo make accreditation decisions?

No. All accreditation decisions are made by DNV GL - Healthcare in the U.S. If a hospital is dissatisfied with an accreditation decision, it may appeal to the Standards and Appeals Board (SAB). The SAB is an independent body chartered but the DNV GL - Healthcare board of directors to hear accreditation appeals. All SAB members are Americans. They have extensive training and experience in the U.S. healthcare system and are eminently qualified in their respective fields of medicine, nursing and hospital management. The decision of the SAB is final.

What is the cost of purchasing the NIAHO[®] standards?

There is no charge for the NIAHO[®] Standards, Interpretive Guidelines, or Accreditation Process for non-commercial use. These can be downloaded at www.dnvglhealthcare.com .

The ISO 9001 standards can be purchased at www.iso.org or www.asq.org .

What costs are associated with a NIAHO® accreditation?

The cost of the survey is based on the number of surveyors and the length of the survey. Survey team size and number of survey days are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census (ADC) and **number of FTEs**
- Complexity of services offered, including outpatient services
- Type of survey being conducted
- Whether the facility has special care units or off-site clinics or locations and the distance from the main campus

Contracts are typically for three years. However, a hospital may terminate its contract at any time with a 60-day written notice.

It is important to remember that the hospital will receive an on-site visit **every year** (e.g., in three years the hospital would have **three on-site surveys** instead of one survey every three years). Current DNV GL - Healthcare hospitals view this as a significant benefit.

Please note the higher number of on-site survey days the hospital will receive with DNV GL - Healthcare as compared to the number of on-site survey days that the hospital has been receiving in its current accreditation program. **It is the increase in survey days that will reduce (and in most cases eliminate) the ramp up costs that the hospital currently incurs.**

There is no charge for the NIAHO® Requirements and Interpretive Guidelines for non-commercial use and you may contact us for standards interpretation or other questions by email or telephone on an unlimited basis at no charge.

The number of FTEs is the single most important factor when determining survey fees. It is essential that the hospital FTE count on the DNV GL - Healthcare Application for Accreditation is completely accurate. Please call our toll-free number 866-523-6842 for more information on pricing.

Are there indirect costs associated with DNV GL - Healthcare accreditation?

No. There are no annual charges, consulting costs or additional staff necessary to maintain the NIAHO® accreditation program or the ISO 9001 quality management system. Hospitals accredited by other organizations can spend thousands of dollars preparing for a survey. This does not count the indirect internal costs hospitals may spend ramping up for a survey from another accreditation organization. **There are no ramp-up or maintenance costs for DNV GL accreditation.** Hospitals are just using existing staff to do different things. **There is no need to incur the expense of preparing for and undergoing “mock surveys” to prepare for DNV GL accreditation. For many hospitals, this can equal the cost of actual accreditation.**

Any other questions

Please contact: healthcare@dnvgl.com or call 1-866-523-6842