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 Services (CMS) approved DNV GL Healthcare by granting it deeming authority for hospitals. Hospitals accredited by DNV GL Healthcare after that date are 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 the physical environment. The accreditation management team has extensive healthcare operational experience in the US 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 and the accompanying standards approved by CMS. 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 a 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®.

What is ISO 9001?
ISO 9001 is a management system standard developed by the independent international organization ISO and adopted worldwide through the ISO member network of national standards bodies. In the US, The American National Standards Institute is the ISO member body. The ISO 9001 Standard was first published in 1987 and revised in 2000, 2008 and 2015. Each successive revision has enhanced applicability of the standard to service industries such as healthcare while reinforcing quality management principles such as a strong customer focus, the involvement of top management, process approach, and continual improvement. This deliberate pace of refinement allows hospitals to stabilize their processes and ensure effectiveness instead of forcing the hospitals to chase a constantly moving target of changing standards.
Does the hospital have to be ISO compliant before it can receive DNV GL accreditation?
No. The hospital can be accredited by DNV GL 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 first survey has two goals – conduct a CMS deemed-status accreditation survey for Medicare certification and introduce the hospital to the 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.

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, that hospitals can begin to realize positive outcomes in the first year. If a hospital is currently accredited or has operated under State Agency oversight, it is already well on the way to ISO 9001 compliance. The schedule we follow is outlined below:

- Year One - NIAHO® Accreditation survey and Introduction to ISO 9001
- Year Two - NIAHO® Accreditation survey and ISO 9001 Pre-assessment (The pre-assessment reveals gaps and prepares the hospital for ongoing development of its quality management system.)
- Year Three - NIAHO® Accreditation survey and ISO 9001 Stage One Audit (Stage One is designed to confirm hospital readiness for ISO 9001 compliance/certification by auditing required processes and monitoring the associated corrective actions.)
- Year Four - NIAHO® Re-Accreditation survey and ISO 9001 Stage Two Audit for Compliance/Certification
- Year Five - NIAHO® Accreditation survey and ISO 9001 periodic audit
- Year Six - NIAHO® Accreditation survey and ISO 9001 periodic audit

The first contract for accreditation services is a three year agreement which, in addition to accreditation, confirms the hospital’s readiness for an ISO 9001 compliance/certification audit by verifying implementation of the management system over time. ISO 9001 compliance/certification is determined in the Year Four survey. Each subsequent three-year contract would be structured like years Four, Five and Six.

In terms of CMS deeming authority, DNV GL Healthcare accreditation applies to all parts of the organization that are included under the hospital CCN 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.
The NIAHO® standards require either ISO Certification or ISO Compliance. What is the difference between Certification and Compliance?

The NIAHO® standards require that a hospital become Compliant with ISO 9001 within three years of the first NIAHO® survey. Certification to ISO 9001 is an option that the hospital may select to publicly demonstrate its ability to satisfy customers, meet all types of requirements, and continually improve quality and outcomes.

Compliance means that the hospital has implemented all requirements of ISO 9001 and has been determined to meet the ISO 9001 standard by DNV GL. The hospital will receive one certificate for NIAHO® accreditation which incorporates compliance with the ISO 9001 standard.

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 globally-recognized certificate for ISO 9001 Certification.

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 Central Office and appropriate Regional Office. 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.
How is the NIAHO® survey performed and when does DNV GL Healthcare’s accreditation become effective?

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 application of the ISO 9001 standard. Tracer Methodology has been a staple of ISO 9001 audits since ISO 9001’s inception in 1987. All areas of the hospital are surveyed, both clinical and non-clinical. The number of surveyors and the mix of qualifications are determined specifically for each hospital and type of survey being performed.

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 typically effective on the date of receipt of an approved corrective action plan. Individual survey results vary and certain circumstances may impact the initial accreditation effective date. For hospitals new to the Medicare program, or applying for new provider status, the effective date for Medicare participation is always determined by CMS.

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 effective implementation of Corrective Action Plans 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.dnvglcert.com/healthcare.)

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

All accreditation decisions are made by DNV GL Healthcare in the US, following a process approved by CMS. Adverse accreditation decisions may be appealed according to the established Accreditation Process.

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 notify CMS of plans to revise requirements within thirty (30) days of notification by CMS of a 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. Since ISO 9001 is already designed to encourage and accommodate contemporary best practices, discretionary changes are infrequent.

How long have hospitals been surveyed to the NIAHO® standards?
NIAHO® standards and survey process were approved by CMS in 2008, however the NIAHO® application process to CMS took approximately four years prior to that. CMS requires that an applicant organization for deeming authority operate its survey program throughout the submission process and 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.

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 Surveyors have 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. All surveyors must complete 45 hours of continuing education 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.

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.

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.dnvglcert.com/healthcare. The ISO 9001 standards can be purchased at www.iso.org or www.asq.org. Copies of standards are provided to registered attendees of DNV GL – Healthcare training programs.
Does DNV GL provide training or other resources for NIAHO® or ISO 9001 implementation?

Yes. DNV GL Healthcare offers a comprehensive menu of training programs, from NIAHO® Accreditation Program Overview to a complete Implementation Course for NIAHO® and ISO 9001. Courses are offered privately at the customer’s location or in various public venues on a regularly scheduled basis. New training programs are always in development, such as Proactive Risk Assessment, Physical Environment Compliance, ISO 9001:2015 Transition, ISO 9001 Interpretation and more.

To inquire about private training programs at your location, please call our business development representative at 281-396-1434, or e-mail healthcare@dnvgl.com

Visit www.dnvglcert.com/Training for information on the public course schedule, and to register online.

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 to 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.

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

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). Not every survey is a full accreditation survey – rather each annual or “periodic” visit after the accreditation
survey considers a different sample and reviews effectiveness of prior corrective actions. Current DNV GL - accredited hospitals view these periodic onsite activities as a significant benefit and help ensure their continual readiness for any hospital survey.

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 may receive in other accreditation programs. It is the increase in survey days that will reduce or eliminate the ramp up costs associated with less frequent surveys.

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 or hospital profile is completely accurate.

**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. DNV GL charges a nominal fee for each ISO 9001 Certificate. 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 or exceed the cost of actual accreditation.

**Any other questions**

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

Visit www.dnvglcustomers.com where our customers explain why they chose DNV GL and the value we bring to their organizations.

Visit our website www.dnvglcert.com/healthcare for information on all our accreditation, certification, and training programs, to download standards and other resources, or to view the list of hospitals that choose DNV GL Healthcare.