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DNV ACCREDITATION PROGRAM FREQUENTLY ASKED QUESTIONS OCTOBER 1, 2009

Who is DNV Healthcare Inc?

DNV Healthcare Inc. (DNVHC) is an operating company of Det Norske Veritas (DNV). DNVHC has corporate offices in Houston, Texas and Cincinnati, Ohio. DNV is an international, independent, self-supported, tax-paying foundation that has more than 300 offices in over 100 countries and more than 9,000 employees. Established in 1864 in Oslo, Norway, DNV operates 15 offices in the United States and has been in this country since 1898. The corporate purpose of DNV is safeguarding life, property, and the environment. DNV 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 DNVHC by granting it deeming authority for hospitals. Any hospital accredited by DNVHC after that date is deemed to be in compliance with the Medicare Conditions of Participation (CoP).

Who manages DNVHC?

DNVHC 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 NIAHOSM stand for?

NIAHOSM is the acronym for the National Integrated Accreditation for Healthcare Organizations. NIAHOSM is the name of DNVHC's hospital accreditation program. The NIAHOSM 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 DNVHC's revolutionary Integrated Accreditation concept in NIAHOSM.

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

No. You can be accredited by DNV 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 survey. After submitting an acceptable Corrective Action Plan, if needed, and upon approval by the Accreditation Committee, DNV's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is

determined by CMS. The hospital then has up to three years to become ISO 9001 compliant. 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 preassessment. These two activities are conducted by one survey team during the initial survey. It should be noted that most hospitals currently accredited by DNV have become ISO 9001 compliant without adding any additional staff.

Can the hospital immediately switch its accreditation to DNVHC without interruption in Medicare reimbursement?

Yes. If a hospital wants to switch its accreditation to DNVHC, 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 DNVHC, then it may remain under DNVHC 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 DNVHC, the hospital is placed under SA jurisdiction until such time as a new recommendation for accredited, deemed status by DNVHC 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 DNVHC for ongoing monitoring and oversight. During the transition from the hospital's current AO to DNVHC or, if the transition is not concurrent, from the hospital's current AO to the SA then to DNVHC, **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 were 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 NIAHOSM survey performed and when does DNVHC's accreditation become effective in terms of Medicare and Medicaid reimbursement?

The NIAHOSM and ISO surveys are done together through Tracer Methodology as well as staff and patient interviews. While surveying the hospital to the CoP criteria, DNVHC 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.

DNVHC surveyors are recruited from the hospital and related sectors and trained extensively in the classroom and in the field by DNV in NIAHOSM and the ISO 9001 Standard.

There are always at least two surveyors on site (two for small hospitals and three to five for larger hospitals). There will always be either a physician or registered nurse and a physical environment (PE) specialist on site. A Generalist will also be a part of the team for larger hospitals. 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.

Once the survey is completed the hospital will receive a preliminary report from the survey team. The hospital will receive a final report from DNVHC within ten days. The hospital will then have ten 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's accreditation is effective the last day of the survey. For hospitals new to the Medicare program, the effective date for Medicare participation is determined by CMS.

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

The NIAHOSM standards allow up to three years from the initial NIAHOSM survey to become ISO 9001 compliant. Our experience shows, however, hospitals can begin to realize positive outcomes in the first year.

While an additional two years beyond the initial period (described above) to obtain ISO compliance is permitted, these additional two year were designed for the hospital that wants to take extra time to implement ISO 9001 or incurs delays forced by abrupt changes in leadership, ownership, or other extraordinary circumstances.

If a hospital is currently accredited by TJC or AOA or has received a State survey, it is basically 65-75% of the way to ISO 9001 compliance. The hospitals we have surveyed that have implemented ISO have taken 3-6 months for ISO implementations. The schedule we follow is outlined below. These are **annual** on-site visits.

- Year One – NIAHOSM Accreditation and Introduction to ISO 9001
- Year Two – NIAHOSM Accreditation and ISO 9001 Pre-assessment Survey (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- NIAHOSM Accreditation and Stage One ISO 9001 Surveys (Stage One is designed to confirm hospital readiness for an ISO 9001 compliance/certification audit.)

Year Four- NIAHOSM Accreditation and ISO 9001 Compliance/Certification Audit.

Years Five- NIAHOSM Accreditation and ISO 9001 periodic audit.

Year Six- NIAHOSM 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. Existing hospital certification to ISO 9001 is typically not the case. ISO 9001 compliance/certification is determined in Year Four. Hospitals that want to move forward with the ISO 9001 process at an accelerated rate will be able to work with DNV to develop a strategy that meets their particular needs and allows them to achieve their objectives within an agreed time frame.

The next and subsequent three-year contracts would be identical to Years Four, Five and Six.

In terms of CMS deeming authority, DNVHC 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. DNVHC encourages this because it drives consistency and best practices throughout the organization.

How often do the NIAHOSM standards change?

There are two types of changes to the NIAHOSM standards - mandatory and discretionary:

Mandatory- DNVHC is required to change NIAHOSM standards to conform to any CMS change in the Medicare CoPs. DNVHC is required to implement these changes in NIAHOSM standards within thirty (30) days of the new CoP effective date.

Discretionary- DNVHC may add, remove or amend any NIAHOSM standard that is not required by the CoPs. Discretionary changes will clarify existing standards and incorporate practices, principles and processes that will enhance the NIAHOSM 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 DNVHC accreditation management team. Any discretionary change to the NIAHOSM standards must be approved by the DNVHC 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 NIAHOSM standards?

The NIAHOSM 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. DNVHC worked with many hospitals throughout the United States to develop standards, field train surveyors and submit to the entire NIAHOSM hospital program. This participation has occurred despite the need to maintain TJC accreditation (or other) accreditation because these hospitals were looking for an alternative accreditation. As a result the NIAHOSM standards and survey process have been in place continuously for five years.

What are the training and qualifications of DNVHC surveyors?

There are three classifications of DNVHC 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 (not a physician or registered nurse) or nonclinical hospital background. The PE Specialists come with a facilities and safety background.

All DNVHC surveyors must successfully complete NIAHOSM Surveyor didactic training and separate ISO 9001 Lead Auditor didactic 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. The surveyors clearly understand that anything less is unacceptable.

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 and DNVHC staff.

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

The NIAHOSM standards require that a hospital become **Compliant** with ISO 9001 within three years of the first NIAHOSM 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 NIAHOSM 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 NIAHOSM Accreditation and another certificate for ISO 9001 Certification.

Certification involves significant additional DNVHC documentation apart from CMS requirements. Issuance of a separate ISO certificate requires this additional documentation to be prepared by DNVHC and sent to a separate ISO Certification Body to provide the international ISO recognition. This additional work by DNVHC requires an additional charge to the hospital of \$3,500. If Certification is requested by the hospital, the ISO Certification Body will determine the number of survey days required for the survey. If Compliance only is selected, DNVHC will have more latitude in determining the number of survey days. Since survey days drive the cost, DNVHC would have more latitude in determining costs.

In either case, the hospital will have to be fully compliant with the ISO 9001 standards within three years. There is no difference in meeting the ISO 9001 requirements whether it is a Compliance Survey or a Certification Survey. The only difference is in the cost of the internationally-recognized ISO certificate. It is a decision for the hospital to make based on its market.

Does DNVHC provide any resources for ISO 9001 and/or NIAHOSM implementation?

Yes. DNVHC publishes a roster of consultants who have successfully completed the DNVHC NIAHOSM Accreditation Standards course and the specific ISO 9001 Lead Auditor course approved by DNVHC for healthcare organizations.

DNVHC maintains and publishes this roster solely as a convenience to the healthcare public for organizations that are interested in pursuing or maintaining DNVHC accreditation and/or becoming ISO 9001 compliant. DNVHC has no financial relationship with these persons when they are providing these services. DNVHC does not endorse, approve or recommend any person listed on the roster.

The roster is available on website www.dnvaccreditation.com under the Resources tab.

If a hospital changes its mind about DNV 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 DNVHC accreditation, it may terminate its contract at any time with a 60-day written notice.

How do 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 DNVHC Accreditation.

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

Do the NIAHOSM standards contain patient safety goals?

DNVHC 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. DNVHC 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. DNVHC will look at the outcomes to validate problem resolution.

DNVHC has two major goals – to assess compliance and educate hospitals in best practices. Hospitals can use innovation to develop new methods for producing positive results, but not by DNVHC 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 parent company in Oslo make accreditation decisions?

No. All accreditation decisions are made by DNVHC 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 by the DNVHC 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 type of training does DNVHC offer to the hospital field?

DNVHC offers free 90 minute webinars from time to time. Additionally DNVHC offers full- day and week-long training programs in NIAHOSM and ISO 9001 in locations across the country as demand requires. There is a charge for these programs. See www.dnvaccreditation.com for information when these webinars and programs are offered.

DNVHC is also willing to come on-site to individual organizations for a fee and expenses. Call DNVHC contacts for more information.

DNVHC also has a unique program that is offered to its customers. DNVHC will train one individual in the organization to the NIAHOSM and ISO 9001 Standards. DNVHC does not pay these individuals a salary or reimburse their expenses during training, nor do we charge for the training or related literature and training tools. The ISO 9001 Lead Auditor training involves 5 days and the NIAHOSM training takes 4 days, both weeks in our Cincinnati offices.

The hospital must agree to allow the staff member to survey three times per year as a fully qualified surveyor and a full member of the survey team – obviously not in their market area. It typically takes 2-3 surveys after training for the staff member to become comfortable with being a full team member. Once they successfully complete the didactic training here in Cincinnati, all travel expenses of surveying are paid by DNVHC and salary remains the hospital's responsibility.

These staff members would receive all changes and documentation that any other surveyor for DNVHC receives and will always be current with CMS changes in requirements as well as NIAHOSM and ISO 9001 changes or modifications and survey nuances. While the hospital will receive all standards updates, these staff members would be on all surveyor conference calls, emails, or other training and/or communication. This is DNVHC's commitment to a totally transparent survey process.

What is the cost of purchasing the NIAHOSM standards?

- ◆ There is no charge for the NIAHOSM Standards, Interpretive Guidelines, or Accreditation Process for non-commercial use. These can all be downloaded at www.dnvaccreditation.com.
- ◆ The ISO 9001 standards can be purchased at www.iso.ch or www.asq.com.
- ◆ Another excellent source for ISO in healthcare is a publication from Australia. It may be purchased at <http://www.saiglobal.com/shop/Script/Details.asp?DocN=AS318210814901>. It is the Australia Standards Guide and the purchase information is: HB 90.8-2000: Healthcare Services – Guide to ISO 9001.

What are the costs associated with a NIAHOSM 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 to be 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 can it may terminate its contract at any time with a 60-day written notice. The attached Appendix contains several scenarios that outline approximate costs based on the size and complexity of the hospital. Please understand that the number of off-sites and the distance from the hospital may have an impact on the number of surveyor days. For purposes of these scenarios, 3-4 off-sites are assumed to be present and within 20 miles of the hospital.

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 DNVHC hospitals view this as a significant benefit.

Please note the higher number of on-site survey days the hospital will receive with DNVHC 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.**

Quotations for annual surveys include all fees and expenses. There is no charge for the NIAHOSM 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. There are no hidden charges.

The attached Appendix depicts a fee schedule for various sized hospitals. The schedules include the time and fee structure for the first 4-year cycle and the subsequent 3-year cycles, based on average daily census (ADC) and number of FTEs. **The number of FTEs is the single most important factor when determining costs. It is essential that the hospital FTE count on the DNVHC Application for Accreditation is completely accurate.**

Do hospitals have to sign a multiyear contract?

No. Hospitals may sign a one-year contract, however, prices are subject to change each year. A multiyear contract provides price stability and can be terminated at any time with a 60-day written notice.

Are there indirect costs associated with DNVHC accreditation?

No. Quotations include all fees and expenses. There are no annual charges, consulting costs, additional staff or other expenses necessary to maintain the NIAHOSM accreditation program or the ISO 9001 quality management system. TJC hospitals can spend thousands of dollars each with TJC's affiliate, Joint Commission Resources (JCR) preparing for a TJC survey. This does not count the indirect internal costs hospitals may spend ramping up for a TJC survey. JCR sells consulting and publications to hospitals to help them prepare and maintain TJC accreditation and keep abreast of ever-changing TJC standards.

JCR had revenue in excess of \$40 million in 2006 (latest available). **There are no ramp-up or maintenance costs for DNVHC accreditation.** Hospitals are just using existing staff to do different things.

Are the costs computed differently for Hospital Systems?

Yes. An economy of scale is built into the ISO formula that determines the number of survey days. A Hospital System (HS) can be surveyed in one of two ways. The HS can implement one Quality Management System (QMS) using the principles of ISO 9001, or the individual hospitals in the HS can each implement their own QMS.

If the HS selects a single QMS the corporate office would oversee the QMS and the principles would reach through all the HS hospitals, assuring consistency and best practice across all hospitals. Because it is a single QMS, the ISO table dictating survey days compresses as the number of employees increases; therefore, the cost of the contract is significantly less if the HS implements a single Quality Management across the organization because the survey days are reduced.

If the HS decides to have individual Quality Management Systems, DNVHC would be required to validate compliance with each individual QMS within the system and that involves many more days, resulting in higher costs.

DNVHC recommends that the HS select the single QMS to maximize the opportunity to bring consistency and known best practice across the organization. In either scenario, all hospitals in the HS would receive an on-site survey each year.

Any other questions? Contact:

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Appendix A: Time and Fee Schedule Examples

The following examples are for reference only; actual costs will be based on the hospital’s size and complexity as outlined in the individual hospital’s Application for Accreditation.

Ex.	Average Daily Census (ADC)	Employees (FTEs)	Average Survey Days on Site Each Year	Average Number of Surveyors On Annual Survey	Average Surveyor Days On-Site Each Year	Average Annual Cost	Hospital’s Current Accreditation Fees (to be completed by hospital)		
							Number of Days On Site In 3-Year Period	Direct Cost (annual fee + survey every 3 years)	Indirect Costs (consulting, standards and publications, mock surveys)
1	10	85	1 - 2	2	2.5	\$7,800			
2	30	210	1.5 - 2	2	3.5	\$11,800			
3	75	375	2	2-3	4.5	\$15,100			
4	125	625	2 – 2.5	2-3	5	\$17,000			
5	180	900	2.5 - 3	2-3	6.5	\$21,000			
6	250	1250	3	2-3	7	\$23,100			
7	350	1760	3 – 3.5	3	8	\$27,000			
8	450	2250	3 – 3.5	3-4	9	\$29,500			
9	650	3250	3 - 4	3-4	10	\$33,000			

The above DNVHC fees are all-inclusive. These fees include all travel expenses, NIAHOSM standards and related documents and include an on-site visit every year.