



NIAHOSM Accreditation Program
Accreditation Process

DNV HEALTHCARE INC

NIAHOSM ACCREDITATION PROGRAM

ACCREDITATION PROCESS

INTRODUCTION

The National Integrated Accreditation for Healthcare Organizations (NIAHOSM) is a program offered by DNV Healthcare Inc. (DNVHC) and is the first integrated accreditation program for hospitals in the United States. Integrated Accreditation utilizes two or more independent sets of standards in the same survey process to produce one set of outcomes.

The NIAHOSM Hospital Accreditation Program integrates ISO 9001 Quality Management System requirements with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482) (CoPs). Healthcare systems that want to participate in the Medicare program must be found to be in compliance with the CoPs by the Centers for Medicare and Medicaid Services (CMS). CMS makes that determination by its own survey process through state agencies or by accepting the accreditation of a private national accreditation organization that has been approved by CMS to deem healthcare organizations in compliance with the CoPs.

DNVHC has been approved by CMS for deeming authority to determine healthcare organizations in compliance with the Conditions of Participation for Hospitals (CoPs) effective September 26, 2008. Compliance with the ISO 9001 standard must occur within two (2) years after the first deemed NIAHOSM accreditation survey.

This Accreditation Process addresses healthcare organizations that are either applying for DNV Healthcare Inc. accreditation or are currently accredited by DNVHC. When a healthcare organization has applied for but not received DNVHC accreditation, it is referred to as an "Applicant Organization." When a healthcare organization is currently accredited by DNVHC, it is referred to as an "Accredited Organization."

ACCREDITATION, MEDICARE DEEMED STATUS, AND ISO COMPLIANCE OR CERTIFICATION TIME FRAMES

A Medicare deemed status survey will consist of a survey for compliance with the NIAHOSM accreditation standards and compliance with or Certification to the ISO 9001 Quality Management System within two years of initial NIAHOSM accreditation. **Compliance** to ISO 9001 requirements must be done through DNVHC. **Certification** to ISO 9001 can be achieved either through DNVHC or by another Accredited Registrar as outlined in NIAHOSM Standard QM.1, SR 1-3.

Continuing NIAHOSM accreditation will require a successful annual survey that validates continuing compliance with NIAHOSM Standards as well as continued ISO 9001 compliance or Certification following the ISO 9001 two-year grace period described in the above Introduction.

Once ISO 9001 compliance or Certification is achieved, continued compliance or Certification will depend on annual ISO Periodic Surveys (limited in scope to full ISO compliance or Certification Survey) and a full ISO compliance or Certification Survey done triennially. The triennial ISO compliance or Certification Survey as well as the annual ISO Periodic Surveys, done in intervening years, will take place concurrently with the annual NIAHOSM Accreditation Survey.

Assuming the Applicant Organization elects to obtain NIAHOSM Accreditation and ISO 9001 compliance or Certification at the same time, the schedule of Surveys will typically take place according to the following schedule:

- Year One: NIAHOSM Accreditation Survey and ISO 9001 Pre-assessment Survey
- Year Two: NIAHOSM Accreditation Survey and ISO 9001 compliance or Certification Survey
- Year Three: NIAHOSM Accreditation Survey and ISO 9001 Periodic Survey
- Year Four: NIAHOSM Accreditation Survey and ISO 9001 Periodic Survey
- Year Five: NIAHOSM Accreditation Survey and ISO 9001 compliance or Re-Certification Survey
- Year 6 through Year 8 and Beyond: Continue to repeat Year 3 through Year 5.

If the Applicant Organization elects to delay ISO 9001 compliance or Certification for up to two years, ISO 9001 compliance or Certification must be obtained no later than during the NIAHOSM Accreditation Survey done at Year Three. Failure to obtain this ISO compliance or Certification in this timeframe will result in Accreditation Jeopardy Status for the Accredited Organization.

REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for hospitals are in 42 CFR Part 482.
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A.
- Should an individual or entity (hospital) refuse to allow immediate access upon reasonable request to a State Agency, CMS surveyor, or DNV Healthcare Inc, (DNVHC) staff, the Office of the Inspector General (OIG) may exclude the hospital from participation in all Federal healthcare programs in accordance with 42 CFR §1001.1301.
- The regulatory authority for the photocopying of records and information during the survey is found at 42 CFR §489.53(a)(13).
- The NIAHOSM Accreditation Requirements and Interpretive Guidelines, and CMS State Operations Manual (SOM) provide the policies and procedures regarding NIAHOSM survey activities.
- The ISO 9001 (Quality Management System [QMS]) and ISO 14001 (Environmental Management System [EMS]) and ISO 19011 (Guidelines for Quality and/or Environmental Management Systems Auditing as well as related NIAHOSM Standards and Interpretive Guidelines provide the basis for the ISO survey activities

Surveyors assess the organization's compliance with the NIAHOSM Standards for all services and locations in which the provider receives reimbursement for patient care services billed under its provider number. Surveyors assess the organization's compliance with the applicable ISO Standards for all services and locations included in the organization's scope statement.

All hospital surveys are unannounced. DNVHC will not provide hospitals with advance notice of the upcoming survey.

SURVEYS AND CLASSIFICATIONS

Annual NIAHOSM Accreditation Survey and ISO 9001 Compliance or Certification Survey

The length of the Accreditation/Compliance/Certification Survey and the number of survey team members are determined by the size and complexity of the Applicant Organization and will be determined in the application process. Regardless of the size and complexity of the Applicant Organization, the team will consist of at least two members, a nurse or physician and a Life Safety Specialist. The following activities apply whether the survey is for a *combined* ISO and NIAHOSM or just ISO. In any of these survey scenarios the team shall include at least the following activities:

- Introduction to the Applicant Organization and discussion with the Applicant Organization's leadership, to include executive and medical staff leadership and board members;
- Document Review (3-6 hours, depending on size of the Applicant Organization);

The Team Leader will request that the following documents be produced no later than 3 hours after the request is made. If available, a hard copy of the documents requested is preferred. Computer access is also acceptable.

The Team Leader may use a worksheet to give to the facility for obtaining this information;

- Organizational Chart
- Organizational chart for nursing services
- A map/floor plan, indicating locations for patient care and treatment areas
- A list of current inpatients with each patient's room number, age, primary diagnosis, attending physician, admission date, and other significant information as it applies to that patient.
- Current Surgical Schedule
- Most recent ISO certification report unless provided by DNV
- Most recent healthcare accreditation report (if applicable)
- Bylaws of the Governing Body
- Minutes of the Governing Body
- Medical Staff Bylaws, Rules and Regulations
- Minutes of the Medical Executive Committee
- Organizational Plan for Patient Care/Scope of service for each department and patient care unit
- Minutes of the Quality Oversight/Management Review Committee – including Performance Improvement data for the previous 12 months
- Minutes from Environment of Care/Safety Committee
- Management plans for the physical environment and annual evaluations
- List of contracted services, companies and individuals- Surveyors will select a sample for review
- Nursing service plan of administrative authority/delineation of responsibilities for delivery of pt. care
- Infection Control Plan with risk assessment/hazard vulnerability analysis
- List of employees including name, title, unit, and hire date
- List of current patients who have had restraint or seclusion used during hospitalization
- List of patients discharged with the past 6 months who had restraint or seclusion used violent or self-destructive behavior during their hospitalization
- P&P: Autopsies
- P&P: Blood & Blood Product Administration
- P&P: History and Physical Examination
- P&P: Informed Consent
- P&P: Medication Security
- P&P: Moderate Sedation
- P&P: Patient Assessment (Nursing, respiratory, nutritional services, etc.)
- P&P: Pain Management
- P&P: Patient Care Planning/Interdisciplinary Treatment Plan
- P&P: Patient Grievance
- P&P: Procedural Verification Process (Practices ensuring the correct patient, site & procedure)
- P&P: Restraint or Seclusion
- P&P: Verbal/Telephone Orders

As applicable, to assess compliance with the ISO 9001 requirements the following documents will also be incorporated into this review process.

- Control of Documents;
 - Control of Records;
 - Control of Non-Conformity;
 - Internal Reviews (Internal Audits);
 - Corrective Action;
 - Preventive Action;
 - Quality Manual;
 - Quality Policy;
 - Quality Objectives;
 - Management Reviews, and
 - Various policies and procedures
-
- Leadership Interview following document review for clarification of any identified issues;

 - Using Tracer Methodology, department/patient unit audits to include staff interviews and open medical record review as appropriate (both clinical and support departments)
 1. The department/units of the organization will be surveyed through the use of tracer methodology. Use of tracer methodology shall be the means by which the surveyors will select records and then follow the patient care and other process(es) to verify various aspects of the organization as they are applied against the NIAHOSM and ISO 9001 standards and organization policies.
 2. The organization can expect visits to multiple areas of the organization to include, but not limited to, patient care units, ancillary services, human resources/personnel office, medical staff office, purchasing, bio-med/clinical engineering and/or facilities management.
 3. The Tracer methodology process may identify performance issues as a result of reviewing an individual patient's case, in one or more steps in the process or perhaps the interfaces between steps that affect the care of the patient/family as well as staff and organization performance.

 - Human Resources Interview to verify compliance with staff requirements
 - Medical Staff credentialing session to verify compliance with Medical Staff requirements
 - Building Tour (4-12 hours, dependent on Applicant Organization size);
 - Interviews with individuals who oversee core processes (e.g. patient safety and infection control, etc.) and appropriate staff if deemed necessary by survey findings;
 - Interviews with leadership, other management staff, physicians, and board members
 - Interviews with patients
 - Additional document review if deemed necessary by survey findings;
 - Oral presentation of Preliminary Findings to Applicant Organization Leadership Team.

ACCREDITATION AND CERTIFICATION PROCESS

The Accreditation and Certification process begins when the Applicant Organization submits a completed DNV Healthcare Inc. Accreditation Application, to include an ISO 9001 Certification Application if DNVHC is to be the ISO Registrar. Upon receipt of a completed Application(s), DNVHC will review the information and provide a fee structure based on the Applicant Organization's complexity and services requested.

For new enrollees in the Medicare program and prior to issuance of a quote for an accreditation survey, the applicant organization must submit evidence of its 855A completeness notification by CMS. A survey may only be scheduled if the applicant organization has received their 855A enrollment completeness notification from CMS.

If the Applicant Organization requires a Business Associate Agreement, it must be submitted to DNVHC and executed prior to the on-site survey.

DNVHC shall identify a survey team to conduct the on-site survey and confirm acceptable dates when the survey may be conducted. As the survey is unannounced, the survey team and the dates will NOT be shared with the Applicant Organization.

Following the on-site accreditation survey the Applicant Organization will be made aware that the next survey (pending closure of any open issues) will occur any time from the ninth to the fifteenth month following the initial Accreditation Survey. The same timeframes will apply for subsequent NIAHO surveys conducted by DNVHC.

SURVEY LOCATIONS

For hospitals with either no or a small number of off-campus provider-based locations, the team will survey all departments, services, and locations that bill for services under the organization's provider number and included in the scope statement (as ISO required) and are considered part of the organization.

For organizations with many provider-based locations survey:

- All hospital departments and services at the primary organization campus and on the campuses of other remote locations of the hospital
- All satellite locations of the hospital
- All inpatient care locations of the hospital
- All out-patient surgery locations of the hospital
- All locations where complex out-patient care is provided by the hospital
- The surveyors will select a **sample** of each type of other services provided at additional provider-based locations.

CONTRACTED SERVICES

On any organization NIAHO survey, contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on organization campuses or organization provider based locations should be surveyed as part of the organization for compliance with appropriate requirements.

SURVEY TEAM SIZE AND COMPOSITION

DNVHC decides the composition and size of the team. In general, a suggested survey team for a full survey of a mid-size (200 bed) hospital would typically include 3 surveyors who will be at the facility for 2 or more days. Each hospital survey team will include at least one RN or Physician with hospital survey experience and a Life Safety Specialist as well as other surveyors who have the training and expertise needed to determine whether the facility is in compliance. Survey team size and composition are normally based on the following factors:

- Size of the facility to be surveyed, based on average daily census and number of employees
- 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;
- Whether the facility has a historical pattern of serious deficiencies or complaints

Prior to the on-site survey, DNVHC shall verify that all members of the survey team have confirmed that there is no present conflict of interest and they have in no manner assisted the Applicant Organization in preparation or otherwise served in the capacity as a consultant or as a former or current employee of the Applicant Organization. In the event a conflict of interest is apparent or suspected, DNVHC will remove any surveyor and replace that individual with another surveyor free of any conflict of interest.

TRAINING FOR SURVEYORS

Clinical, Life Safety, and Generalist Surveyors must successfully complete the following:

- The DNVHC NIAHOSM Surveyor Training
- The DNV Quality Lead Auditor or an equivalent course accredited by IRCA or RAB-QSA
- The DNV Risk-Based Certification methodology training
- Orientation to DNVHC policies, procedures and software requirements

Additionally, the Life Safety Specialists must successfully complete the following:

- Successful completion of a NFPA (National Fire Protection Association) Life Safety Code training with an additional focus on hospital requirements.
- Alternatively, 5 years or more of experience within facilities management including safety programs, direct involvement in the environment where patient care services are provided and knowledge of the Life Safety Code will satisfy this requirement.

LEAD SURVEYOR (TEAM LEADER)

The survey is conducted under the leadership of a Lead Surveyor (Team Leader), designated by DNVHC staff. The Lead Surveyor (Team Leader) is responsible for assuring that all survey activities are completed within the specified time frames and in a manner consistent with this protocol and other DNVHC policies and procedures. Responsibilities of the Lead Surveyor (Team Leader) include:

- Acting as the spokesperson for the team on site
- Facilitating management of the survey
- Encouraging communication among team members
- Evaluating team progress and coordinating meetings with team members and hospital staff as needed
- Coordinating any ongoing conferences with organization leadership and providing feedback, as appropriate, to organization leadership on the status of the survey
- Facilitating Opening and Closing Meetings
- Coordination and preparation of Preliminary Survey Report, with active participation of all survey team members
- Submission of preliminary report to DNVHC

SURVEY PLAN PREPARATION

The objective of this activity is to analyze information about the organization in order to identify areas of potential concern to be investigated during the survey and to determine if those areas, or any special features of the organization (e.g., provider-based clinics, remote locations, satellites, specialty units, PPS-exempt units, services offered, scope statement, etc.) require additional surveyors to the team beyond those assigned based on average daily census, number of employees and complexity of the organization. Information obtained about the organization will also allow DNVHC to develop a preliminary survey plan. The type of provider information needed includes:

- Information from the provider file (to be updated annually using the completed organization application)

Currently accredited organizations will be required to provide information to DNVHC by completing an Annual Update to the application. The information contained within the Annual Update will identify:

- Accurate contact information for the organization
 - Names of members of Senior Leadership
 - Any off-site locations that have been added since the prior survey
 - Volume information from the prior year of the annual survey
 - Any new services that have been added since the prior survey
 - Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc). (If applicable)
- If applicable review previous survey results for patterns, number, and nature of deficiencies, as well as the number, frequency, and types of complaint investigations and the findings
 - Any additional information available about the facility (e.g., the hospital's Web site, any media reports about the hospital, etc).
 - The annual survey will be unannounced.

SURVEY TEAM OFF-SITE SURVEY PREPARATION

The team should prepare for the survey offsite by sharing organization pertinent information so they are ready to begin the survey immediately upon entering the facility. This can best be accomplished electronically (from the Lead Surveyor (Team Leader) to other team members) with a follow-up conference call if necessary. The following should be included in this preliminary exchange and/or discussion:

- Organization demographics & services offered
- Layout of facility if available
- Survey schedule
- Timing of survey activities, including beginning and ending times

- Suggested lodging and transportation options
- Directions to facility

SURVEY TEAM ARRIVAL

The entire survey team should enter the organization together. Upon arrival, surveyors shall present their identification along with the announcement letter to the receptionist or other hospital representative upon entering the building.

The Lead Surveyor (Team Leader) will announce to the CEO or Executive in charge or organization contact, that a survey is being conducted. If the CEO (or executive in charge) is not onsite or available, the Lead Surveyor (Team Leader) will ask that they are notified that a survey is being conducted. The Survey Team will not delay the survey because the CEO or other hospital staff is/are not on site or available.

OPENING MEETING

- Explanation of the purpose, scope of the survey, and provide a schedule of survey activities to the organization (the schedule may be adjusted as necessary)
- Brief explanation of the survey process;
- Introduction of survey team members, including any additional surveyors who may join the team at a later time, the general area that each will be responsible for, and the various documents that they may request;
- Clarification of all organization areas and locations, departments, and patient care settings under the hospital provider number and/or scope statement that will be surveyed, including any contracted patient care activities or patient services located on organization campuses or organization provider based locations
- Discuss the location (e.g., conference room) where the team may meet privately during the survey
- A telephone and internet connection for team communications (or access to these services if needed), preferably in the team meeting location
- Determine how the facility will ensure that surveyors are able to obtain the photocopies of material, records, and other information as they are needed
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed
- Discuss the approximate time, location, and possible attendees of any meetings to be held during the survey.
- Propose a preliminary date and time for the Closing Meeting.
- During the Opening Meeting, the Lead Surveyor (Team Leader) will request that the organization provide the survey team with the documents requested for Document Review as listed. The Lead Surveyor (Team Leader) will request that the documents be produced no later than 3 hours after the request is made.

INITIAL ON-SITE SURVEY TEAM MEETING

After the conclusion of the Opening Meeting, the survey team will meet in order to evaluate information gathered, and modify surveyor assignments, as necessary. The surveyors will not delay the continuation of the survey process waiting for information from the organization, but rather will adjust survey activities as necessary. During the on-site team meeting, team members should:

- Review the scope of hospital services
- Identify hospital locations to be surveyed, including any off-site locations
- Adjust surveyor assignments, as necessary, based on information provided
- Discuss issues such as change of ownership, adverse events, construction activities, and disasters, if they have been reported
- Make an initial patient sample selection (The patient list may not be available immediately after the opening meeting and the team may delay completing the initial patient sample selection a few hours as meets the needs of the survey team)

PATIENT SAMPLE SIZE AND SELECTION

To select the patient sample, the surveyors will review the patient list provided and select patients who represent a cross-section of the patient population and the services provided. Patient logs (ER, OB, OR, restraint, etc) may be used in conjunction with the patient list to assure the sample is reflective of the scope of services provided by the organization.

Whenever possible and appropriate, select patients that are in the facility during the time of survey (i.e., open records). Open records allow surveyors to conduct a patient-focused survey and enable surveyors to validate the information obtained through record reviews with observations and patient and staff interviews. There may be situations where closed records are needed to supplement the open records reviewed (e.g., too few open records, complaint

investigation, etc), surveyors will use their professional judgment in these situations and select a sample size that will enable them to make compliance determinations and verify consistency.

If it is necessary to remove a patient from the sample during the survey, (e.g., the patient refuses to participate in an interview), the surveyors will replace the patient with another who fits a similar profile. This will be done as soon as possible in the survey.

The number of clinical records selected for review will typically be based on the organization's Average Daily Census (ADC). A guiding principle when selecting clinical records is to consider 10% of the ADC as sufficient to determine compliance in most instances in a hospital with an ADC of 180 or more. For smaller hospitals the sample should not be fewer than 10 inpatient records, provided that the number of records is adequate to determine compliance with any given requirement.

Within the sample, the surveyors will select at least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc). In addition to the inpatient sample, the surveyors will select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations. The sample size may be expanded as needed to assess the organization's compliance with all applicable standards.

If a complaint is being investigated during the survey, the survey team will include patients who have been identified as part of the complaint in the sample. Issues or concerns identified through complaints may be an area of focus when selecting the patient sample.

SURVEYOR INFORMATION GATHERING AND INVESTIGATION

The objective of this activity is to determine the hospital's compliance with the requirements through observations, interviews, and document review.

- The surveyors will focus attention on actual and potential patient outcomes, as well as required processes.
- The surveyors will assess the care and services provided, including the appropriateness of the care and services within the context of the Standards.
- The surveyors will visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
- The surveyors will observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.

DURING THE SURVEY

Typically the survey team will be accompanied by assigned organization staff as the survey is conducted. However the surveyors have discretion whether to allow, or refuse to allow, organization staff to accompany the surveyors during a survey or a selected activity of the survey. Surveyors will make a decision whether to allow organization staff to accompany them based on the circumstances at the time of the survey activity.

The survey team will meet at least daily (typically each morning) with organization leadership in order to assess the status of the survey, progress of completion of assigned activities, areas of concern, and to identify areas for additional investigations. The meetings will include an update by each surveyor that addresses findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the survey team and the organization staff will coordinate efforts to obtain additional information, if appropriate. The organization staff will have the opportunity to present additional information or to offer explanations concerning identified issues. Survey information will not be discussed unless the investigation process and data collection for the specific concerns is completed.

Additional team meetings can be called at any time during the survey to discuss crucial problems or issues. Any significant issues or significant adverse events must be brought to the Lead Surveyor's attention immediately.

Although non-consultative information may be provided upon request, the surveyor is not a consultant. However, it is common to educate the hospital staff on aspects of the requirements and their application to the hospital processes.

PATIENT CARE REVIEW

A comprehensive review of care and services received by patients in the sample will be part of the survey. A comprehensive review includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review. After obtaining the patient's permission, the surveyors will observe

sample patients receiving treatments (e.g., intravenous therapy, tube feedings, wound dressing changes) and observe the care provided in a variety of treatment settings, as necessary, to determine if patient needs are met.

SURVEYOR ASSESSMENTS

The team will observe the care environment to obtain information about how the care delivery system works and how the organization's departments work together to provide care. Surveyors will review services provided, conduct interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review the surveyor may also observe patient care, the environment, staff interactions with patients, safety hazards, infection control practices, or any other activity that affects patient care or staff performance.

During the survey, the surveyors will pay particular attention to the following:

- Patient care, including treatments and therapies in all patient care settings;
- Staff member activities, equipment, documentation, building structure, sounds and smells;
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present as well as those that are not present that should be present;
- Integration of all services to determine that the facility is functioning as one integrated whole
- Whether quality improvement is a organization-wide activity, incorporating every service and activity of the organization
- Whether every organization department and activity reports to and receives reports from the organization's quality management oversight, facilitating the organization-wide quality management system.
- Awareness and the effectiveness of the hospital's quality management system
- Storage, security and confidentiality of medical records.

Surveyors will record notes of findings/issues and should document for objective evidence:

- The date and time of the observation(s)
- Location
- Patient identifiers
- Individuals present during the observation
- Activity being observed (e.g., therapy, treatment modality, etc).
- Document / Form names and/or numbers (if applicable)

The surveyor will try to have findings verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding an out-dated medication in the pharmacy, the surveyor will ask the pharmacist to verify that the drug is out-dated. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

INTERVIEWS

Interviews provide a method to collect information, and to verify and validate information obtained through observations. Informal interviews will be conducted throughout the survey. The surveyors will use the information obtained from interviews to determine what additional observations, interviews, and record reviews are necessary.

When conducting interviews, the surveyors will do the following:

- Maintain documentation of each interview conducted. Document the interview date, time, and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.
- The surveyors will conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interviews may include patient rights, advanced directives, and the facility's grievance/complaint procedure.
- Interviews with patients will be conducted in private and with the patient's prior permission.
- The surveyors will interview staff to gather information about the staff's knowledge of the patient's needs, plan of care, and progress toward goals. Problems or concerns identified during a patient or family interview will be addressed in the staff interview in order to validate the patient's perception or to gather additional information.
- Telephone interviews will be conducted if necessary, but the preference is for in-person interviews.
- The surveyors will integrate the data from interviews with data gathered through observations and document reviews.

ORGANIZATION DOCUMENTATION

Documents reviewed by the survey team during the survey, in addition to the formal Document Review, may be both written and electronic and include the following:

- Patient's clinical records to validate information gained during the interviews as well as for evidence of advanced directives, discharge planning instructions, patient teaching etc. This review will provide a broad picture of the patient's care.
- Plans of care and discharge plans should be initiated immediately upon admission, and be modified as patient care needs change. As an example, the record review for that patient who has undergone surgery would include a review of the pre-surgical assessment, informed consent, operative report, and pre-, inter-, and post-operative anesthesia notes.
- Although team members may have a specific area assigned during the survey, the team will avoid duplication of efforts during review of medical records and each surveyor will typically review the record as a whole instead of targeting the assigned area of concern.
- Surveyors should use open patient records rather than closed records whenever possible
- Closed medical records may be used to determine past practice, and the scope or frequency of a deficient practice. Closed records should also be reviewed to provide information about services that are not being provided by the hospital at the time of the survey. (For example, if there are no obstetrical patients in the facility at the time of the survey, the surveyors will review closed OB records to determine care practices, or to evaluate past activities that cannot be evaluated using open records.)
- In the review of closed clinical records, the surveyors will review all selected medical records for an integrated plan of care, timelines of implementation of the plan of care, and the patient responses to the interventions.
- Personnel files to determine if staff members have the appropriate educational and training, pre-employment requirements, competency/performance assessments, and are licensed if it is required;
- Physician and allied health credential files to determine if the facility complies with Standards requirements and State law and follows its own written policies for medical staff privileges and credentialing;
- Maintenance and calibration records to determine if equipment is periodically attested and/or calibrated to determine if it is in good working order and if environmental requirements have been met
- Staffing documents to determine if adequate numbers of staff are provided according to the number and acuity of patients
- Policy and Procedure Manuals
- Contracts, if applicable
- Organization activities minutes as requested

ANALYSIS OF FINDINGS

The objectives of this survey team meeting are to integrate findings, review and analyze all information collected from surveyor observations, interviews, and record reviews, and to determine whether or not the organization meets the appropriate Standard requirements. Each team member will review his/her notes, worksheets, records, observations, interviews, and document reviews to assure that all investigations are complete and organized for presentation to the team. Based on the team's decisions, additional activities may need to be initiated. The meeting will include the following: The surveyors will share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. Decisions about deficiencies will be based on input from the team members but the final decision shall always be the responsibility of the Lead Surveyor. (Team Leader).

- The team will document their decisions, the substance of the evidence, and the numbers of patients impacted, in order to identify the extent of any facility Nonconformity.
- The team will ensure that their findings are supported by adequate documentation of surveyor observations, interviews and document reviews.
- Any additional documentation or evidence needed to support identified Nonconformities should be gathered prior to the Closing Meeting but at a minimum, prior to exiting the hospital.

When a deficient practice (Nonconformity) is determined to have taken place prior to the survey and the organization states that it has corrected the deficient practice/issue, the survey team will consider the following:

- Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
- Has the organization implemented the corrective action(s)?
- Has the hospital taken a quality management approach to the corrective action to ensure monitoring, tracking and sustainability?
- The survey team will use their judgment to determine if any corrective action(s) taken by the organization prior to the survey is sufficient to correct the Nonconformity and to prevent the deficient practice from continuing or recurring. If the deficient practice is corrected **prior** to the survey, the survey team **will not cite** the Nonconformity.
- If a Nonconformity with any requirement is noted **during** the survey, even when the hospital corrects the Nonconformity during the survey, the Nonconformity shall be cited.

CLOSING MEETING

- The Lead Surveyor (Team Leader) is responsible for organization of the presentation of the closing meeting.
- The team determines who will present the findings.
- If the team feels it may encounter a problem during the closing, they should immediately contact the DNVHC office
- The facility determines which hospital staff will attend the closing meeting.
- The Lead Surveyor (Team Leader) will explain how the team will conduct the closing meeting and any associated ground rules.
- Ground rules will include waiting until the surveyor finishes discussing a given deficiency before accepting comments from facility staff.
- The identity of an individual patient or staff member must not be revealed in discussing survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference by which identity might be deduced
- The surveyor will present the findings of Noncompliance or Observation, explaining why the finding(s) is a violation. The surveyor will just present the facts.
- If immediate jeopardy is identified by the team, they will explain the significance and the need for immediate correction.
- The organization will have an opportunity to present new information after the closing meeting for consideration after the survey.
- The team will assure that all findings are discussed at the closing conference.
- If the closing conference was audio or video taped, the Lead Surveyor (Team Leader) must obtain a copy of the tape in its entirety before leaving the facility.

DISCONTINUATION OF THE CLOSING MEETING

It is DNVHC's policy to conduct a closing meeting at the conclusion of each survey. However, there are some situations that justify refusal to continue or to conduct a closing meeting. For example:

- If the provider is represented by counsel (all participants in the closing meeting should identify themselves), surveyors may refuse to conduct the closing meeting if the attorney tries to turn it into an evidentiary hearing; or
- If the organization leadership creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of a closing meeting, surveyors may refuse to conduct or continue the closing meeting. Under such circumstances, the Lead Surveyor (Team Leader) will stop the closing meeting and call the DNVHC offices immediately for further direction.

RECORDING THE CLOSING MEETING

If the organization wishes to audio tape the closing meeting, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyors should take one of the tapes at the conclusion of the meeting. Video taping is also permitted if it is not disruptive to the meeting, and a copy is provided to the Lead Surveyor (Team Leader) at the conclusion of the meeting. It is at the sole discretion of the surveyor(s) to determine if video taping is permitted.

POST-SURVEY ACTIVITIES

- A Preliminary Report shall be completed by the Survey Team and issued to the accredited organization.
- DNVHC will forward the final survey report to the organization within 10 days of the last date of the survey.

SURVEY FINDING DEFINITIONS: NIAHOSM

Nonconformity (NC)- (Category 1)

- Objective evidence exists that a requirement has not been addressed (intent), a practice differs from the defined system (implementation), or the system is not effective (effectiveness).
- The absence of one or more required system elements or a situation which raises significant doubt that the services will meet specified requirements.
- A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to requirement of the standard.
- A category 2 non-conformity that is persistent (or not corrected as agreed by the customer) shall be up-graded to category 1, OR a situation, that, on the basis of available objective evidence, would have the capability to cause patient harm or does not meet a standard of care.
- Condition Level Finding- A Condition Level Finding is a Category 1 Nonconformity in which the customer is determined to be completely or substantially out of compliance with the standard. Such finding is made on a case-by-case basis in DNV Healthcare Inc.'s sole discretion. A Condition Level Finding will be identified as a Category 1 Nonconformity- Condition Level Finding. All Condition Level Findings will require a follow-up survey prior to the next annual survey.
 - For organizations as new enrollees in the Medicare Program, all Category 1 Nonconformities must be closed prior to issuance of the accreditation certificate. If there are any Condition Level Category 1 Nonconformities identified, the customer will be required to complete a full re-survey prior to issuance of an accreditation certificate.

For all other, Category 1 nonconformities, a follow-up survey may be required prior to the next annual survey as specified in 3.5.1 (below)

Nonconformity (NC)- (Category 2)

A lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that services will meet requirements. Overall system requirement is defined, implemented and effective.

As applicable a finding as a Category 2 nonconformity may be:

- An isolated non-fulfillment of a standard requirement that is otherwise properly documented and implemented, or,
- Inconsistent practice compared to other areas of the customer, or,

- Significant enough to warrant the customer to take action to prevent future occurrence and/or has the potential for becoming a Category 1 nonconformity.

Opportunity for Improvement

An Opportunity for Improvement relates to an area and/or process of the customer that may meet the minimum requirement of the standard, but that could be improved.

An Opportunity for Improvement may be system- or performance-related and is normally addressed based on the surveyor's own experience, knowledge of an industry best practice within another unit/department of the customer.

Customer Follow-up Required for Nonconformities

- A Corrective Action Plan (CAP) must be delivered to DNV Healthcare Inc. within ten (10) calendar days from date of the written report. The CAP must:
 - Identify the root cause that led to the nonconformity;
 - Identify the actions taken to correct the nonconformity in the affected areas and/or processes;
 - Identify other areas and/or processes (if applicable) that have the potential to be affected by the same nonconformity;
 - Identify the process or system changes that will be made to ensure that the nonconformity does not recur;
 - Identify the timeframe for the implementation of the corrective action measure(s);
 - Identify the time of the person responsible for implementing the corrective action measure(s) and,
 - Identify the performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

DNV Healthcare Inc. follow-up with Customer for Nonconformities

DNV Healthcare Inc. will acknowledge receipt of the CAP and state any deficiencies and additional requirements with timelines for submission OR declare acceptance of the submitted documentation.

The customer is expected to implement corrective action measure(s) within sixty (60) days. When this is not feasible DNV Healthcare will consider and evaluate the circumstances involved and approve a suitable timeframe to enable the customer to implement the corrective action measure(s). Although such instances for extending the timeframe will be evaluated on a case-by-case basis, it would be a rare occurrence that the extended timeframe for implementation of corrective action measure(s) to exceed six (6) months.

For Category 1 Nonconformities, within sixty (60) days of DNV Healthcare Inc. acceptance, the customer shall submit performance measure(s) data, findings, results of internal reviews (internal audits), or other supporting documentation, including timelines to verify implementation of the corrective action measure(s). If a Category 1 Nonconformity results in a Condition Level Finding, a follow-up survey prior to the next annual survey will also be required to determine compliance with the specific Category 1 Nonconformity.

For Category 2 Nonconformities, if the corrective action plan(s) requirements are met, validation of effective implementation of the agreed corrective action plan will take place at the next annual survey.

DNV Healthcare Inc. will respond to the customer regarding acceptance of the submitted documentation and identify any deficiencies and additional requirements with time lines for submission.

Failure to comply with the requirements of the CAP regarding nonconformities may also result in a Condition Level Finding. A Condition Level Finding could result in Jeopardy Status for the customer as described in Follow-up and Special Surveys (ICP-12-5-i5) and Jeopardy Status, Withdrawal of Accreditation, Disputes and Appeals (ICP-12-6-i4).

DNV Healthcare Inc., in its sole discretion, shall determine the need for a follow-up survey when compliance and implementation cannot be reasonably determined through written documentation of objective evidence.

The scope and extent of the follow-up survey will be determined based upon the complexity of the nonconformity and one or more surveyors will be assigned to the follow-up survey. When possible, members of the survey team that conducted the survey when the nonconformity was issued will be assigned. When this is not feasible, DNV Healthcare Inc. will assign a surveyor that is familiar with the process and has the qualifications to validate compliance.

NOTE- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, all Category 1 nonconformities must be removed prior to the awarding of accreditation. In addition, if any Category 1 nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

NIAHOSM ACCREDITATION IN JEOPARDY (JEOPARDY STATUS)

NIAHOSM Accreditation in Jeopardy (Jeopardy Status) may be invoked based on the following:

- Customer fails to submit a required Corrective Action Plan and/or related documentation or if established reasonable timelines in a Corrective Action Plan are not met
- Customer fails to maintain the ISO quality management system or be certified to ISO 9001 within 2 years of initial DNV Healthcare Inc following the first NIAHOSM deemed survey.
- Customer violates terms of the signed accreditation agreement, including non-payment of fees or refusal of access.
 - Failure to respond adequately to nonconformities identified during the accreditation process.
 - Customer makes false public claims regarding its accreditation. (e.g., accreditation is used in a way that is unjustifiable or deceptive in advertising.)
 - Information from stakeholders that could affect the status of accreditation (e.g., non-compliance to regulatory/statutory requirements).
 - Individual is delivering patient care or providing services without a required valid license or certification or registration;
 - Preventable issues that pose Immediate Jeopardy (harm or injury to a patient); or,
 - Non-compliance with statutory and regulatory requirements of state and/or federal law.

The requirements that the Accredited Organization must meet to be removed from Jeopardy Status and the length of time an Accredited Organization may remain in Jeopardy Status before Accreditation and Certification are removed will be outlined for the Accredited Organization in the Jeopardy notification. Jeopardy Status notification will outline the length of time the Accredited Organization may remain in Jeopardy Status, but normally that timeframe will not exceed four (4) months. Any extension shall be based on a progressing Corrective Action Plan that has been validated by a Special Survey.

FINDINGS AND WRITTEN REPORT

- o DNV Healthcare Inc. shall provide final written report(s), NIAHOSM and/or ISO 9001, to the Applicant Organization within ten (10) days of the survey. The final written report(s) will contain all identified Nonconformities as well as Opportunities for Improvement relative to the NIAHOSM standards and/or ISO requirements that were identified by the team during the performance of the survey.
- o Following receipt of the final written report(s) the Applicant Organization will have ten (10) days from the date of the Survey report to appeal any Nonconformity findings relative to either NIAHOSM standards or ISO requirements.
- o The Applicant Organization will submit Corrective Action Plan(s) to address the nonconformities identified and return this to DNV Healthcare Inc. If the Corrective Action Plan(s) are approved, the report of nonconformities with the Corrective Action Plan(s) will be submitted to the Accreditation Committee.
- o Based on successful survey findings and/or Action Plan follow-up as described above, this will be presented to the Accreditation Committee for their decision regarding the accreditation status of the applicant organization. If approved, the Applicant Organization will receive a Three Year DNV Healthcare Inc. NIAHOSM Accreditation and, if appropriate, a Three Year Certification or Compliance for meeting the ISO 9001 Quality Management System requirements, subject to the approval of the Certification Body for ISO 9001.
- o In order to maintain accreditation, the organization will be subject to annual surveys for assessment of continual compliance with the NIAHOSM requirements and compliance with corrective action plan(s) from the prior survey.

APPEALS PROCEDURE

Appeals received by DNV Healthcare Inc. shall be:

- o Registered in a log to record the progress to completion;
- o Acknowledged by DNV Healthcare Inc. without undue delay; and,
- o Reviewed and answered.

The appeal is not bound to a particular form or content. However, the appeal shall be submitted in writing stating the basis of the appeal and the relief being requested. The appeal can be faxed, e-mailed or sent by US mail to:

Darrel J. Scott, Senior Vice President, Regulatory & Legal Affairs
DNV Healthcare Inc.
463 Ohio Pike, Suite 203
Cincinnati, Ohio 45255
Fax: (513) 947-1250
Email: Darrel.Scott@dnv.com

The appellant shall be informed of the right to:

- o Present its case in person
- o Appeal to the President of DNV Healthcare Inc. if the appellant does not accept the decision of the Executive Vice President, Accreditation.

The following applies for all appeals:

- o The decision reached by the Executive Vice President, Accreditation or President shall be communicated to the appellant in writing
- o If the appellant still remains dissatisfied with the decision of the Executive Vice President, Accreditation or President, the appellant is entitled to one (1) appeal to the Standards and Appeals Board.
- o Any appellant notice that it will pursue a remedy beyond DNV Healthcare Inc. shall be reported to DNV Corporate Legal Affairs through the Vice President, Regulatory Affairs.
- o The Executive Vice President of Accreditation and President, if appropriate, shall review the final outcome of all appeals to determine the need for any change in DNV Healthcare Inc. procedures.

FOLLOW-UP / SPECIAL SURVEY

A Follow-Up Survey will be performed when the following occur

- When compliance regarding a nonconformity has been issued, and cannot be reasonably determined to be corrected and implemented with contact with the organization written documentation of objective evidence;
- In all cases, when an applicant organization is undergoing an initial accreditation as a new enrollee in the Medicare program, if any nonconformity results in a Category 1 Nonconformity- Condition Level Finding, the applicant organization must correct the Condition Level Finding AND the applicant organization will be required to undergo another full hospital re-survey prior to the awarding of accreditation.

A Special Survey will be performed when the following occur

- Either in response to a patient or patient family complaint to DNV Healthcare Inc.;
- Media coverage of issues and the issue(s) cannot be resolved through DNV Healthcare Inc. evaluation of data findings, internal audits, or other documentation as requested by DNV Healthcare;
- CMS informs DNV Healthcare Inc. of a concern based on information they may have received from another source,; or,
- When a situation within the definition of Immediate Jeopardy is identified.

In those instances where the leadership of the organization is aware of the incident or nonconformity, DNV Healthcare Inc. encourages the organization to contact DNV Healthcare Inc. at the time of the event to discuss a process for resolution or when feasible to respond to the respective nonconformity. The Special Survey will focus on the issues and associated processes surrounding the incident or nonconformity. These Special Surveys will be unannounced.

Any Follow-Up or Special Survey will be done at the expense of the organization. The costs will be based on those in the basic DNV Healthcare Inc. fee schedule in effect at the time of the Follow-Up or Special Survey. DNV Healthcare Inc. will forward a written Report to the organization within ten (10) days, outlining the requirements, timelines, and required follow-up for any Corrective Action Plan(s).

NIAHOSM SURVEY REPORTS

DNVHC shall have a Lead Surveyor (Team Leader) evaluate all survey findings and provide a final report and any other appropriate information to the DNVHC Accreditation Committee. The DNVHC Accreditation Committee will make the final decision on granting or withholding DNVHC NIAHOSM Accreditation. The final accreditation decision will be sent to the Applicant/Accredited Organization upon the organization's completion of the correction action plan(s) within the applicable timeframes and acceptance of the plan(s) by DNVHC. The Applicant/Accredited Organization shall have one opportunity to appeal the DNVHC Accreditation Committee decision or any associated findings for a period of fifteen (15) days following the final decision date of the DNVHC Accreditation Committee. The DNVHC Accreditation Committee decision on the Applicant/Accredited Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

ISO 9001 CERTIFICATION/SURVEILLANCE AUDIT REPORTS

DNVHC shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on granting or withholding ISO 9001 Certification. The final Certification Status will be sent to the Organization within forty-five (45) days of the Survey. The Organization shall have the opportunity to appeal the Certification Body decision or any associated findings for a period of fifteen (15) days following the final decision date of the Certification Body. The Certification Body's decision on the Organization's appeal shall be final and no other appeal shall be permitted for the matters reviewed in the appeal.

Once certified to ISO 9001, the organization will undergo annual periodic audits to maintain compliance or Certification. DNV Healthcare Inc. shall evaluate all audit findings and provide a final report and any other appropriate information to the Certification Body. The Certification Body will make the final decision on continuing or determining the need to proceed with withdrawing ISO 9001 Certification if the audit findings warrant such action being taken. The organization will be notified of the decision of the Certification Body within forty-five (45) days. If a decision is made to proceed to withdraw the certification, the organization will be provided the appropriate information for remedying this and what subsequent actions that needs to be taken.

CHANGES IN ACCREDITATION REQUIREMENTS

DNVHC shall provide notice to DNVHC Accredited Organizations of any changes or additional requirements in the NIAHOSM Accreditation Program. The notice shall contain a description of the change(s) or additional requirement(s), the effective date(s) of the change(s) or additional requirement(s) and the action(s) required of DNVHC Accredited Organizations to meet the changes.

DNVHC Accredited and Compliant or Certified Organizations will have the opportunity to comment on proposed change(s) or additional requirement(s) for a period of no less than thirty (30) days prior to the DNVHC effective date of the change(s) or additional requirements. Any changes as required by CMS to be made to the NIAHOSM standards must be implemented immediately.

DNV HEALTHCARE INC. RESPONSE TO A COMPLAINT AGAINST AN APPLICANT OR ACCREDITED ORGANIZATION

DNVHC will respond to any written or verbal complaint received by DNVHC against an organization either accredited by DNVHC or scheduled for a survey to become accredited by DNVHC. A complaint may be received from the Centers for Medicare and Medicaid Services (CMS) or any other federal or state agency with oversight responsibility, a patient or patient family, payer, caregiver, or other interested party. Complaints will be prioritized as follows:

Immediate Jeopardy

- o This complaint category is identified by the hospital's Noncompliance with one or more of the NIAHO requirements that has caused, or is likely to cause, serious injury, harm, impairment, or death of a patient or is an immediate threat to life.
- o All Immediate Jeopardy complaints will result in an on-site Special Survey and investigation within two (2) working days of receipt of the information. A Special Survey for Immediate Jeopardy complaints will be unannounced. Determination of Immediate Jeopardy may be identified as a result of complaint submitted to DNVHC or identified during an on-site survey.

Operational (Response Required)

- o This complaint category is identified by the hospital's noncompliance with one or more of the NIAHOSM requirements that have caused physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s). A Special Survey is usually not required but may be initiated if it is needed to determine if there was patient harm. If a Special Survey is not conducted, the complaint and resolution would be reviewed at the next survey.
- o The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has caused harm of limited consequence and does not significantly impair the patient's mental, physical state for these types of complaints. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.

Operational (No Response Required)

- o This complaint category is identified when the hospital is in Noncompliance with one or more of the NIAHOSM requirements and has not resulted in any physical or mental discomfort to the complainant or whom he/she is acting on behalf of regarding the affected individual(s).
- o A Special Survey is usually not required but may be initiated if it is needed to determine to complexity and severity of the complaint.
- o The Vice-President for Regulatory and Legal Affairs will investigate the complaint and will not likely conduct a Special Survey if noncompliance has not been determined and has caused harm of limited consequence and/or does not significantly impair the patient's mental, physical state for these types of complaints.
- o The Vice-President for Regulatory and Legal Affairs will contact the organization and verify that the complaint has been addressed and resolved internally. However, the follow-up of actions taken by the Organization will be reviewed at the next survey.
- o No Action Required – If adequate information has been received about the complaint and the Vice-President for Regulatory and Legal Affairs has contacted the organization and determined that the complaint has been addressed and resolved internally, no further investigation is necessary.

INFORMATION SUPPLIED UPON REQUEST TO CMS OR STATE AGENCIES IN ACCORDANCE WITH DEEMING AUTHORITY OR OTHER REQUIREMENTS.

- o The following information will be supplied to CMS or any state agency that has regulatory oversight over the Applicant/Accredited Organization:
- o Complaint information that includes the complaint and selected action(s) taken. If the resolution required a Special Survey and/or a Corrective Action Plan, related documentation will be supplied, including the eventual outcome;
- o Notification of upcoming Surveys, including retrospective dates of unannounced Special Surveys;
- o Survey Reports from Surveys;
- o Corrective Action Plans and related documentation;
- o Notification of an Accredited Organization entering Jeopardy Status, with Corrective Action Plan and timelines for resolution;
- o Notification of removal of Accreditation and Certification following unsuccessful resolution of Jeopardy Status.

