NIAHO® Accreditation Program
Accreditation Process
Revision 18

DNV GL Healthcare USA, Inc.
400 Techne Center Drive, Suite 100
Milford, Ohio 45150
Phone 513-947-8343 ● Fax 513-947-1250

DNV GL HEALTHCARE USA, INC.

NIAHO® ACCREDITATION PROGRAM

ACCREDITATION PROCESS

INTRODUCTION

The National Integrated Accreditation for Healthcare Organizations (NIAHO®) is a program offered by DNV GL Healthcare USA, Inc. (DNV GL) 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 NIAHO® Hospital Accreditation Program integrates ISO 9001 Quality Management System requirements with the Medicare Conditions of Participation for Hospitals (42 C.F.R. §482) or Critical Access Hospitals (42 C.F.R. §485), as applicable (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.

DNV GL has been approved by CMS for deeming authority to determine healthcare organizations in compliance with the Conditions of Participation for Hospitals and Critical Access Hospitals (CAHs) since September 26, 2008 and December 23, 2010, respectively.

This Accreditation Process addresses healthcare organizations that are either applying for DNV GL Healthcare USA, Inc. accreditation or are currently accredited by DNV GL. When a healthcare organization has applied for but not received DNV GL accreditation, it is referred to as an "Applicant Organization." When a healthcare organization is currently accredited by DNV GL, 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 NIAHO® accreditation requirements and compliance with or Certification to the ISO 9001 Quality Management System within three years of initial NIAHO® accreditation. **Compliance** to ISO 9001 requirements must be determined by DNV GL. **Certification** to ISO 9001 can be achieved either through DNV GL or by another Accredited Registrar as outlined in NIAHO® Requirement QM.1, SR 1-3.

Continuing NIAHO® accreditation will require a successful annual survey that validates continuing compliance with NIAHO® Requirements as well as continued ISO 9001 compliance or Certification following the ISO 9001 three-year implementation 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 NIAHO® Accreditation Survey.

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

Initial 3 Year Contract

- Year One: NIAHO® Accreditation Survey (including informal ISO 9001 education)
- Year Two: NIAHO® Annual Survey and ISO 9001 Pre-Assessment
- Year Three: NIAHO® Annual Survey and ISO 9001 Stage One Audit

Second 3-Year Contract

- Year One: NIAHO® Re-Accreditation Survey and ISO 9001 Stage 2 Audit
- Year Two: NIAHO® Annual Survey and ISO Periodic Audit
- Year Three: NIAHO® Annual Survey and ISO 9001 Periodic Audit

Third 3-Year and All Subsequent Contracts

- Year One: NIAHO® Re-Accreditation Survey and ISO 9001 Re-Certification (or compliance) audit
- Year Two: NIAHO® Annual Survey and ISO Periodic Audit
- Year Three: NIAHO® Annual Survey and ISO 9001 Periodic Audit

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 GL Healthcare (DNV GL) 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 NIAHO® Accreditation Requirements and Interpretive Guidelines, and CMS State Operations Manual (SOM) provide the policies and procedures regarding NIAHO® 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 NIAHO® Requirements and Interpretive Guidelines provide the basis for the ISO survey activities

Surveyors assess the organization's compliance with the NIAHO® Requirements 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. DNV GL will not provide hospitals with advance notice of the upcoming survey.

ACCREDITATION AND CERTIFICATION PROCESS

The Accreditation and Certification process begins when the Applicant Organization submits a completed DNV GL Healthcare USA, Inc. Accreditation Application, to include an ISO 9001 Certification Application if DNV GL is to be the ISO Registrar. Upon receipt of a completed Application, DNV GL 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 the Medicare Administrative Contractor (MAC). A survey may only be scheduled if the applicant organization has received their 855A enrollment completeness notification from the MAC.

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

DNV GL shall identify a survey team to conduct the on-site survey and confirm an acceptable date after which the survey may be conducted. As the survey is unannounced, the survey dates will NOT be shared with the Applicant Organization.

Following the initial on-site accreditation survey and all necessary post-survey activities, the next and all future surveys will follow at approximately one-year intervals, and will continue to be unannounced.

SURVEY TEAM SIZE AND COMPOSITION

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 and survey planning process. DNV GL decides the composition and size of the team. In general, a suggested survey team for a full survey 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 Physical Environment 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;
- Distance between main campus and off-site care locations
- Whether the facility has a historical pattern of serious deficiencies or complaints

Prior to the on-site survey, DNV GL 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, DNV GL will remove any surveyor and replace that individual with another surveyor free of any conflict of interest.

SURVEYOR QUALIFICATIONS

DNV GL Healthcare surveyors must successfully complete the following:

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

Additionally, the Physical Environment Specialists must successfully complete the following:

- NFPA (National Fire Protection Association) Life Safety Code training with an additional focus on hospital requirements, or equivalent experience.

SURVEY TEAM LEADER

The survey is conducted under the leadership of a Survey Team Leader, designated by DNV GL. The 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 DNV GL policies and procedures. Responsibilities of the 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 DNV GL

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.

SURVEY PLAN PREPARATION

DNV GL will 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 DNV GL to develop a preliminary survey plan. The type of organization information needed includes:

- Information from the organization profile, to be updated as changes occur, and annually at a minimum using the organization profile update on the DNV GL Healthcare customer website.

- 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).

Currently accredited organizations are required to maintain current profile information via the profile update on the DNV GL Healthcare customer website. The information contained within the Profile 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)

SURVEY TEAM OFF-SITE SURVEY PREPARATION

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

The 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 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.

The Team Leader will provide the organization contact with a survey agenda and list of documents and records to be reviewed during survey, requesting that these documents be

produced as soon as possible, but in any case no later than 3 hours after the request is made. This Document Request List will be available on the DNV GL Healthcare website and hospitals are encouraged to organize the requested documents in advance, or arrange for ready access by the surveyors. Surveyors may request other documents and records in the course of routine survey activities.

OPENING MEETING

The Team Leader will request a formal opening meeting, to include the organization primary contact, members of leadership, and other participants as determined by the organization. This opening meeting shall include:

- Explanation of the purpose, scope of the survey, and proposed schedule of survey activities
- Brief explanation of the survey process;
- Introduction of survey team members, 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
- Confirm the location (e.g., conference room) where the team may meet privately during the survey
- Make arrangements for surveyor meals and breaks
- Ensure a telephone and internet connection is available 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.

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, surveyors will 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 should be at least 10% of the ADC but no fewer than 30 inpatient records as sufficient to determine compliance in most instances (including surgical or other specialty hospitals).

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 requirements and 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.

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 will be surveyed as part of the organization for compliance with appropriate requirements.

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 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.

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 Team Leader'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.

SURVEY ACTIVITIES

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 using tracer methodology.

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 an 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. In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

INTERVIEWS

Surveyors will conduct formal and informal interviews throughout the survey to collect information, and to verify and validate information obtained through observations. 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 only 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 either written or 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.
- Surveyors will select 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 tested 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

SURVEYOR PLANNING MEETINGS

The survey team will meet periodically during the survey 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 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. Each 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 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.
- The Team Leader will gather surveyor notes and documentation for submission to DNV GL

CLOSING MEETING

The Team Leader will request and coordinate a formal closing meeting, to include the organization primary contact, members of leadership, and other participants as determined by the organization. This closing meeting will include:

- Review of the purpose, scope and objectives of the survey
- Opportunity for the organization to introduce leaders, closing meeting participants and attendees
- Introduction of survey team members and their respective roles
- Review of organization areas and locations surveyed, including confirmation that the survey is completed
- Review definitions of nonconformance categories
- Presentation of all non-conformances and observations made during survey, including reference to relevant standards and summary of evidence supporting the NC
- Presentation of results of Corrective Action Plan review from prior surveys
- Description of post survey activities and expectations for Corrective Action Planning
- Ensure all organization documents, records, and survey materials are returned and accounted for
- If the team feels it may encounter a problem during the closing, they should immediately contact the DNV GL office.
- If immediate jeopardy is identified by the team, they will explain the significance and the need for immediate correction.
- The team will assure that all findings are discussed at the closing conference.

DISCONTINUATION OF THE CLOSING MEETING

It is DNV GL'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 Team Leader will stop the closing meeting and call the DNV GL offices immediately for further direction.

RECORDING THE CLOSING MEETING

If the organization wishes to record audio and/or video of the closing meeting, it must provide a copy of the recording for the Team Leader at the conclusion of the meeting. The Team Leader will submit the recording to DNV GL with post survey documentation. Recording is permitted if it is not disruptive to the meeting, and a copy is provided to the Team Leader at the conclusion of the meeting. It is at the sole discretion of the surveyor(s) to determine if recording is permitted.

FINAL SURVEY REPORT AND CORRECTIVE ACTION PLAN SUBMISSION

The Team Leader will compile and submit a preliminary survey report to DNV GL, with findings corresponding to those presented at the closing meeting.

- DNV GL Healthcare USA, Inc. shall provide final written report(s) to the Organization within ten (10) business days of the last day of the survey. Business days exclude US national holidays, DNV GL recognized holidays, and special events during which the accreditation office may be closed, such as surveyor training meetings, the DNV GL Healthcare Symposium, and CMS Accreditation Organization meeting dates.
- The final written report will contain all identified Nonconformities relative to the NIAHO® requirements and/or ISO standards that were identified by the team during the performance of the survey.
- The Organization will have ten (10) calendar days from the date of the Final report to request clarification or challenge any Nonconformity findings relative to either NIAHO® requirements or ISO standards.
- The Organization will submit Corrective Action Plans to address the nonconformities identified within ten (10) calendar days to DNV GL Healthcare USA, Inc. If the Corrective Action Plans are approved, the report of nonconformities with the Corrective Action Plans will be submitted to the Accreditation Committee.
- 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 GL Healthcare USA, Inc. NIAHO® Accreditation and, if appropriate, a three year Certification of Compliance for meeting the ISO 9001 Quality Management System requirements, subject to the approval of the Certification Body for ISO 9001.
- In order to maintain accreditation, the organization will be subject to annual surveys for assessment of continual compliance with the NIAHO® requirements and compliance with corrective action plans from the prior survey.

ISO 9001 CERTIFICATION/SURVEILLANCE AUDIT REPORTS

DNV GL 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 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 GL Healthcare USA, 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. If a decision is made to withdraw the certification, the organization will be provided the appropriate information for remedying this and what subsequent actions are required.

SURVEY FINDING DEFINITIONS

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 the requirement.

- 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.

Nonconformity (NC)- (Category 1) Condition Level

- A Category 1 Nonconformity in which the customer is determined to be completely or substantially out of compliance with the requirement.
- Such finding is made on a case-by-case basis in DNV GL Healthcare USA, Inc.'s sole discretion.
- All Condition Level Findings will require an onsite follow-up survey no later than sixty (60) calendar days following the last date of the survey.
    - For organizations as new applicants in the Medicare Program, with Condition Level Category 1 Nonconformities identified, the organization will be required to complete a full re-survey prior to issuance of an accreditation certificate.

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.

- An isolated non-fulfillment of a requirement that is otherwise properly documented and implemented, or,

- Inconsistent practice compared to other areas of the organization, or,

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

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, or the organization obtains evidence of conformance post survey the Nonconformity shall be cited.

POST SURVEY ACTIVITIES

CORRECTIVE ACTION PLAN DEVELOPMENT AND SUBMISSION

A Corrective Action Plan (CAP) for all non-conformances must be submitted to DNV GL Healthcare USA, Inc. within ten (10) calendar days from date of the Final report. The CAP must:

- Identify the 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 including a staff training plan, as applicable;
- Identify the timeframe for the implementation of the corrective action measure(s) including specific dates of completion for corrections that have already been implemented before the CAP is submitted
- Identify the name 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
- Address all reported elements of the non-conformance and/or all individual Findings identified in the non-conformance.

CORRECTIVE ACTION PLAN REVIEW, IMPLEMENTATION AND FOLLOW-UP

DNV GL Healthcare USA, Inc. will acknowledge receipt of the CAP and request any clarifications or additional information requirements, with timelines for re-submission, OR declare acceptance of the submitted Corrective Action Plan. DNV GL's final approval of Corrective Action Plans for a survey requires complete submission of CAPs for all non-conformances on the report.

The customer is expected to implement corrective action plans within sixty (60) days. When this is not feasible DNV GL Healthcare will consider and evaluate the circumstances involved and approve a suitable timeframe to enable the customer to implement the corrective action plans. 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 plans to exceed six (6) months.

For Category 1 Nonconformities, within sixty (60) business days of DNV GL Healthcare USA, Inc. communication to the organization of the 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).

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.

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 GL Healthcare USA, 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.

CMS TIME-LIMITED WAIVERS

CMS has determined that all Life Safety Code® (LSC) non-conformances must be corrected within 60 calendar days of the last day of survey in which the finding was identified. If the organization concludes that it cannot correct LSC non-conformances within the required 60 day timeframe, the organization may request a Time-Limited Waiver by submitting a formal waiver request with the Corrective Action Plan.

DNV GL's collaborative review of a Time-Limited Waiver request is treated as a survey follow-up activity. The review may result in a recommendation to the CMS Regional Office that the waiver be granted, or may result in no recommendation. DNV GL processes Time-Limited Waiver requests for LSC non-conformances on behalf of CMS, however the CMS Regional Office has exclusive authority to grant Time-Limited Waivers.

CHALLENGE OF A NONCONFORMANCE

If the organization wishes to challenge a specific finding or nonconformance issued on the final report, the request for an additional review shall be submitted in writing. The challenge shall be submitted after receipt of the final report and as part of the corrective action plan (CAP) submission. The organization shall submit supporting evidence, including the details of the organization's internal review, to be reviewed as part of the DNV GL CAP review process. In line with the NIAHO® Accreditation Process consistent with the expectations of CMS, all nonconformances identified during the survey will be cited when supporting information is not presented to the surveyor to verify compliance during the on-site survey.

FOLLOW-UP / SPECIAL SURVEY

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

- When a nonconformity has been issued, and compliance cannot be reasonably determined to be corrected and implemented through review of 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.
- All Condition Level Findings not involving Immediate Jeopardy will require a follow-up survey within sixty (60) calendar days of the last day of the survey in which the nonconformance was identified.

A Special Survey may be performed when the following occur

- Either in response to a patient or patient family complaint to DNV GL Healthcare USA, Inc.;
- Media coverage of issues and the issue(s) cannot be resolved through DNV GL Healthcare USA, Inc. evaluation of data findings, internal audits, or other documentation as requested by DNV GL Healthcare;
- CMS informs DNV GL Healthcare USA, 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 GL Healthcare USA, Inc. encourages the organization to contact DNV GL Healthcare USA, 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 GL Healthcare USA, Inc. fee schedule in effect at the time of the Follow-Up or Special Survey. DNV GL Healthcare USA, Inc. will forward a written Report to the organization within ten (10) business days, outlining the requirements, timelines, and required follow-up for any Corrective Action Plan(s).

NIAHO® ACCREDITATION IN JEOPARDY (JEOPARDY STATUS)

NIAHO® 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 3 years of initial DNV GL Healthcare following the first NIAHO® 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.

APPEALS PROCEDURE FOR ADVERSE ACCREDITATION DETERMINATIONS

Appeals of any accreditation decision received by DNV GL Healthcare USA, Inc. shall be:

- Registered in a log to record the progress to completion;
- Acknowledged by DNV GL Healthcare USA, Inc. without undue delay; and,
- Reviewed and answered in a timely manner by the Executive Vice President.

The appeal is not bound to a particular form or content. However, the appeal of an accreditation decision shall be submitted in writing to the Executive Vice President no later than five (5) business days after receiving an accreditation decision. The appeal shall state 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, Executive Vice President
DNV GL Healthcare USA, Inc.
400 Techne Center Drive, Suite 100
Milford, Ohio 45150
Fax: (513) 947-1250
Email: Darrel.Scott@dnvgl.com

The following applies for all appeals of accreditation decisions:

For an appeal to receive consideration, the relevant issues must be raised before DNV GL Healthcare USA, Inc.'s acceptance of the appellant's corrective action plan, as described in the CHALLENGE OF A NONCONFORMANCE section above.

- The decision reached by the Executive Vice President shall be communicated to the appellant in writing.
- If the appellant still remains dissatisfied with the decision of the Executive Vice President, the appellant is entitled to one (1) appeal to the President.
- Any appeal to the President must be in writing and received by DNV GL Healthcare USA, Inc. within ten (10) business days of receipt of decision of the Executive Vice President.
- Any appellant notice that it will pursue a remedy beyond DNV GL Healthcare USA, Inc. shall be reported to DNV GL Group Legal.
- The Executive Vice President and President, if appropriate, shall review the final outcome of all appeals to determine the need for any change in DNV GL Healthcare USA, Inc. procedures.

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

DNV GL will respond to any written or verbal complaint received by DNV GL against an organization either accredited by DNV GL or scheduled for a survey to become accredited by DNV GL. 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

- 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.
- 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 DNV GL or identified during an on-site survey.

Operational (Response Required)

- This complaint category is identified by the hospital's noncompliance with one or more of the NIAHO® 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.
- DNV GL 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)

- This complaint category is identified when the hospital is in Noncompliance with one or more of the NIAHO® 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).
- A Special Survey is usually not required but may be initiated if it is needed to determine to complexity and severity of the complaint.
- DNV GL 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.
- DNV GL 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.
- No Action Required – If adequate information has been received about the complaint and DNV GL has determined that the complaint has been addressed and resolved internally, no further investigation is necessary.

CHANGES IN ACCREDITATION REQUIREMENTS

DNV GL shall provide notice to DNV GL Accredited Organizations of any changes or additional requirements in the NIAHO® 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 DNV GL Accredited Organizations to meet the changes.

DNV GL 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 DNV GL effective date of the change(s) or additional requirements. Any changes as required by CMS to be made to the NIAHO® requirements must be implemented immediately.

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

The following information will be supplied to CMS or any state agency that has regulatory oversight over the Applicant/Accredited Organization:

- 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;
- Notification of upcoming Surveys, including retrospective dates of unannounced Special Surveys;
- Survey Reports from Surveys;
- Corrective Action Plans and related documentation;
- Notification of an Accredited Organization entering Jeopardy Status, with Corrective Action Plan and timelines for resolution;

- Notification of removal of Accreditation and Certification following unsuccessful resolution of Jeopardy Status.