Accreditation Guidelines for

Healthcare Organizations and Office Based Surgeries

Version 6.1, July 2021

Contents

Foreword

This document describes the organization and processes that will be used by AACI to provide AACI accreditation of healthcare organizations/office surgeries. AACI currently has sets of requirements against which AACI can provide accreditation.

The Version 6 of the Accreditation Guidelines for Healthcare Organizations has been developed to communicate AACI procedures, to assist healthcare organizations in assessing their compliance with AACI Standards, and to provide tools and resources to help health care organizations improve.

REVISION HISTORY AND APPROVAL

Rev.	Nature of changes	Approval	Date
[Rev Number]	Original release.	Manual Approver Name	[Date of Issue]
2.1.	Fist revision	BW	March 2013
3.1.	Revised based on feedback from surveyors and local units	BW	October 2013
4.1.	Revision based on ISQua approvals for International Accreditation Standard	BW	May 2014
4.2.	Revision based on Clinical Excellence Certification Program	DM	May 2016
4.3.	Revision based on new ISO 9001:2015	DM	October 2016

4.4.	Revision based on new viusal indentity of AACI	DM	January 2017
4.5.	Revision made based on ISQua requirements for Accredited Organisations and ISO 17021	JB	September 2017
5.0	In the clause "3.9.3.1. Principles for on-site witness surveys", the Technical Director is replaced by experienced Surveyor Function Technical Director replaced by Certification Director	KP	November 2018
5.1.	Added section 8.1 Remote surveys	JB	March 2020
5.2.	Graphics added to front page Bibliography list updated	KP	September 2020
6.0.	QM-GOV-05 V1 replaced with OP-GEN-15 Management of impartiality Evolution of stanard and relevant de novo requirements to align with ISO/IEC 17021-1:2015	KP	January 2021
6.1.	Revision made based on 64B8-9.0092 Florida Administrative Code, Approval of Physician Office Accrediting Organizations. Accreditations logo replaced Accreditation Marks	JB	July 2021

1. INTRODUCTION

American Accreditation Commission International (AACI), is an independent accreditation body whose purpose is to develop meaningful and relevant standards for healthcare services.

AACI accreditation is a programme designed to support the development and continual improvement of healthcare quality and patient safety in healthcare organizations. It also addresses general safety for workers, patients, and other visitors within healthcare organizations. This document explains the AACI Accreditation process and is intended to guide healthcare and dental organizations that are either in the program or are considering entering it.
The AACI Accreditation Program integrates ISO 9001 Quality Management System requirements with the Centers for Medicare & Medicaid Conditions of Participation for Healthcare organizations (42 C.F.R. §482) (CoPs) and requirements of 64B8-9.0092 Florida Administrative Code, Approval of Physician Office Accrediting Organizations.

These Accreditation Guidelines are intended for healthcare organizations that are considering applying for AACI Accreditation as well as for those that are currently accredited by AACI under our accreditation program. When an organization has applied for but not yet been awarded AACI accreditation, it is referred to as an "Applicant Organization". When an organization is currently accredited by AACI, it is referred to as an "AACI Accredited Organization ".

2. GENERAL

Any healthcare or dental organization may apply for AACI accreditation/certification if it meets the following requirements:

- The organization is currently in operation as a healthcare provider organization in the country and licensed (if required),
- The organization has been providing health care services for at least six months before the on-site survey,
- The organization is legally constituted entity that primarily provides health care services,
- The organization is in compliance with applicable federal, state, and local laws and regulations, or, for organizations operating outside of the United States, all applicable laws and regulations.
- The organization assumes, or is willing to assume, responsibility for improving the quality of its care and services,
- The organization provides services addressed by AACI standards,
- Pays the appropriate fees in accordance with AACI policies.

3. ACCREDITATION STANDARDS

The AACI Accreditation Standards are used for accreditation process for healthcare and dental organizations and office based surgeries. They are based on available research, evidence, and experience as well as WHO publications and recommendations, International Standard organization guidelines (ISO), local and international legislative and regulatory requirements (USA based Medicare and Medicaid), and 64B8-9.0092 Florida Administrative Code, Approval of Physician Office Accrediting Organizations. The AACI Set of Standards include quality management requirements from ISO 9001:2015 and include requirements based on notices distributed under the CMS Conditions of Participation for Hospitals 42 C.F.R § 482 and State Operations Manual Regulations and Interpretive Guidelines for Hospitals, Federal and State law and regulations, and Rule 64B8-9.0092 Florida Administrative Code, Approval of Physician Office Accrediting Organizations.

(See link: https://www.cms.gov/Regulations-and Guidance/Legislation/CFCsAndCoPs/index.html)

Even though some of WHO recommendations may have been incorporated into CMS, AACI independently and consistently monitors, assesses and incorporates WHO recommendations. Additionally, AACI monitors other advisory groups noted herein to maintain a current accreditation standard. Periodic revision is also based upon updates of these notices as well as evidence-based outcomes or findings identified during the survey process, and information provided by nationally recognized professional organizations. The Accreditation Standards will undergo a major revision periodically according to the schedule identified below. During the process of revision input shall be sought from current customers, patient groups, AACI surveyors and healthcare group leaders and sales staff, and any other relevant external experts.

AACI shall continue to evolve our standard as interested parties specify improvements, corrections are required, and influencing conditions change. AACI welcomes your advice as well. Please submit written comments, suggestions, and remarks to AACI accordingly.

Please direct comments and suggestions to: info.usa@aacihealthcare.com

3.1. Transition Policy

The implementation of the Revised Accreditation Standard starts three (3) years after the standard is published. The existing certificates are valid until expiration but not later than three years after publication of new Version. Initial Accreditation according to the "old" Version of the Accreditation Standard is possible twelve months from the publication of the revised (new version) standard. AACI will inform all existing users about the transition dates fifteen day after new Version of the Standard is published.
For ISO 9001 certified clients the 18-month transition policy applies.

3.2. Revision of the Florida Office Surgery Standards

AACI shall send to the Board any change in its accreditation standards within 30 calendar days after making the change.

4. REGULATORY AND POLICY REFERENCE

- The Medicare Conditions of Participation for healthcare organizations are in 42 CFR Part 482
- Survey authority and compliance regulations can be found at 42 CFR Part 488 Subpart A
- 64B8-9.0092 Florida Administrative Code, Approval of Physician Office Accrediting Organizations
- The International Society for Quality in Health Care External Evaluation Association, Principles for the Development of Health and Social Care Standards, 5th Edition v1.0
- The AACI Accreditation Standard for Healthcare Organizations Requirements V5.0
- The AACI Accreditation Standard for Dental Organizations Requirements V2.0
- The ISO 9001:2015 (Quality Management System)
- ISO 14001:2015 (Environmental Management System)
- ISO/IEC 17021-1:2015 Conformity assessment
- ISO/IEC 17065:2012- Conformity assessment – Requirements for bodies certifying products, processes and services.

5. THE ACCREDITATION CYCLE

An accreditation award is valid for three years unless revoked by AACI. The award is retroactively effective on the first day after AACI completes the organization's survey or, when follow-up is required, completes any required focused surveys. At the end of the organization's three-year accreditation cycle, the organization must be re-evaluated to be eligible for renewal of its accreditation award. An AACI survey will consist of a survey for compliance with the international standards. Compliance to ISO 9001:2015 requirements may be done through AACI as part of the accreditation survey. Continuing AACI accreditation will require a successful annual survey that validates continuing compliance with AACI accreditation standards. Healthcare oorganization already certified to ISO 9001 and thus compliant with the international standard and that wish to move towards an integrated audit that can result in certificates of compliance for both International Accreditation and ISO 9001 Certification.

6. CONFLICT OF INTEREST AND MANAGING IMPARTIALITY

AACI shall not include members of the survey team that have assisted the Applicant Organization in preparation for the survey or otherwise served in the capacity as a consultant or as a former or current employee of the Applicant Organization within the last two years.
Our personnel shall not be assigned for surveys in customer organizations if they have, in any way been involved in consultancy activities, preparing or producing system documentation or giving any

specific instructions or advice on development or implementation of management system or are in any other way in a position of possible conflict of interest in client's organization. AACI shall not accredit any system on which internal survey or consultancy has been provided by its own personnel or in relation to any other consultancy organization which could present a threat to impartiality; shall not provide or outsource surveys to consultancy company. The services of accreditation shall not be offered together or in any connection with consultancy services. During the marketing and sales activities, accreditation activities shall not be marketed together or in connection with consultancy activities, thus implying that the accreditation would be faster, simpler or in any way better for the customer.

6.1. Impartiality statement

AACI management confirms full and total commitment to impartiality in providing Accreditation services within framework of relevant standards, regulations, and corporate documents. Acting in a manner that cannot be perceived as possible influencing on impartiality or business behavior. Only subcontractors that share AACI ethical values will be hired. Common expectation to all employees (including subcontractors) are defined and documented.

6.2. Statement of not providing consultancy services

AACI Management does not provide any consultancy services for the purpose of implementing or/and maintaining the accreditation of conformity. None of the services related to implementation, usage or maintenance of the system are provided. The Impartiality Committee, as an independent structure taking care that the accreditation services are done taking care of impartiality and ethics. The members of the Committee are independent representors of interest groups. The conflict of interest applies to all members of the Committee. The procedure defining the work of the Committee of Impartiality is OP-GEN-15 Management of impartiality. AACI profitability ensures long term independence and allows pursuit of continuous improvement and innovation, thus allowing the creation of competitive advantage for both our customers and us. Budgeting and resource planning, regular system reviews, revisions of independent bodies and risk evaluations well in advance of the activities ensure the proper risk care and coverage of liabilities.

6.3. Confidentiality

AACI requires and receives documentation and information, either verbally or documented (hard copies and/or electronic form), as part of the accreditation process from its customers, for use in the assignments, which shall be treated as confidential and not be made available to third parties other than accreditation bodies, unless agreed in writing by the customer. To safeguard confidentiality, following principles shall apply:

- All staff whether permanent or contractual shall sign the Confidentiality statement as a part of the hiring contract
- All members of the Committees shall sign a confidentiality agreement, to preserve the customer's secrets
- All subcontractors sign a Subcontractor agreement together with Confidentiality statement in which they oblige on confidentiality and impartiality.

AACI keeps confidential the following information received or developed during the accreditation process:

- The Survey report, unless the organization wishes to use its accreditation to fulfill government requirements (for example, for licensure). AACI will release additional information, up to and including the Survey Report required by law or agreement with a state or federal regulatory authority with the accredited organization's authorization,

- Information learned from the organization before, during, or following the accreditation survey, which is used to determine compliance with a specific accreditation standard,
- An organization's CAP prepared in response to a sentinel event or in response to other circumstances specified by AACI,
- All other material that may contribute to the accreditation decision (for example, surveyor notes)
- Written staff analyses and Accreditation Committee minutes and agenda materials,
- The identity of any individual who files a complaint about an accredited organization, unless AACI has the express permission of the submitter or unless required by law.

AACI will provide the following to the public:

- An accredited organization's status: that is, whether the organization is, was denied accreditation, or if accreditation was withdrawn by AACI and, upon request,
- The status of an organization noted on the AACI Web site as either Accredited (and date) or Accreditation Withdrawn (and date). The status of accreditation withdrawn will be posted on the AACI website for one year.

In submitting its F-002 Application for accreditation, the organization either provides or authorizes AACI to obtain official records and reports of public or publicly recognized licensing, examining, reviewing, or planning bodies. If AACI determines that an organization has supplied false, misleading, or incomplete information, AACI reserves the right to disclose information about the organization to obtain accurate or complete information.

7. CONTRACTING AND REQUIRED INFORMATION

The Accreditation process begins when the Applicant Organization submits a completed Application form (F-002). Upon receipt of the completed application form AACI will review the information and provide the organization with a proposal using a price policy that is based on the Applicant Organization's complexity and the services requested.
Once contracts have been signed then AACI will contact the Applicant Organization to agree on a date for the pre-assessment. Once the organization has confirmed in writing that the proposed dates are acceptable AACI will submit an organization the survey documentation sheet.

7.1. Information Accuracy and Truthfulness Policy

The organization must provide accurate and truthful information at all times in the accreditation process. Falsification is defined as fabrication, in whole or in part, of any information provided by an applicant or accredited organization to the AACI Accreditation Program. If the healthcare organization falsifies information relevant to the accreditation, either by commission or omission, its accreditation award will immediately be terminated, or, in the case of a new applicant, the healthcare organization will be ineligible for re-evaluation for one year.
Examples of fabrication can include altering the content of documents through redrafting, reformatting, or deleting content; knowing false information; or providing, hiding, and removing evidence during a survey.

After the organization has submitted an application form, AACI must be notified within 30 days of any change or at least 30 days before the scheduled survey date, if there is a change in the organization that modifies the information reported in the Survey Application. Also, between surveys, the organization must notify the AACI within 30 days when there are changes in the organizational structure, ownership, or services. Information that must be reported to the AACI includes the following:

- A change in organization name and/or ownership,
- Any change of the contact information by AACI - designated staff and/or leadership,
- Any personnel change of the AACI - designated staff and/or leadership,
- A significant increase or decrease in the volume of services,
- The addition of a new type of health service or acquisition,
- The deletion of an existing health service,
- A significantly altered building/physical plant.

7.2. Postponement Policy

An organization may postpone scheduled surveys when one or more accepted reasons for postponement occur.

7.2.1. Accepted Reasons for Postponement

- A natural disaster or another major unforeseen event occurs that totally or substantially disrupts operations,
- The organization is involved in a major strike, has ceased accepting patients, and is transferring patients to other facilities,
- Patients, the organization, or both are being moved to another building during the scheduled survey,
- AACI reserves the right to conduct an on-site survey if the organization continues to provide patient care services under such circumstances.

7.3. Cancellation Policy

A survey may be canceled by either party without penalty or damages when any of the following events make it impossible, illegal, or unreasonable to go forward:

- Acts of God,
- Wars,
- Terrorism,
- Government regulations,
- Disasters,
- Strikes,
- Civil disorders,
- Other emergencies of a similar nature.

Cancellation due to any of the reasons cited above must be communicated in writing as soon as practically possible. Further, AACI may follow the advice of relevant ministries concerned with evaluating political and military circumstances with regard to scheduling surveys.

7.4. Cancellation Fee

7.4.1. Organization-Initiated Cancellation.

If the organization cancels the survey 30 or fewer days prior to the first date of the survey for any reason or reasons other than those previously stated, AACI may require payment of one-half of the survey fees to recover costs AACI accreditation will incur.

7.4.2. AACI Initiated Cancellation

In the event that AACI cancels the survey for any reason or reasons other than those previously stated, the organization will not be charged.

7.5. Travel Costs Related to the Accreditation Survey

In addition to survey fees, the healthcare organization is responsible for paying all travel costs for the surveyors. This includes transportation (airfare, train, and car) and reasonable accommodations, including a set daily rate for meals and incidental expenses. This rate will not exceed the current rates set forth by the U.S. Department of State for international travel.

8. SURVEYS

All surveys are announced. AACI will provide organizations with advance notice of the upcoming survey (audit if applicable). The length of the accreditation 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 PE Specialist (initial and renewal surveys). The following activities apply whether the survey is for a combined ISO 9001 and AACI standards or just AACI standards. 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 (in case of ISO 9001 Initial audit STAGE 1),
- Organizational chart,
- Process map,
- A map/floor plan, indicating locations for patient care and treatment areas,
- Most recent ISO 9001 audit report (if applicable),
- Most recent accreditation survey report (if applicable).

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

- Quality Objectives
- Internal audit reports
- Management Reviews
- Control of Non-Conformity
- Corrections and Corrective Actions.

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 AACI and ISO 9001 standards and organization policies.
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.
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.

8.1. Remote Surveys

In emergency situations, or circumstances which do not allow onsite surveys, AACI will perform the survey by remote access to personnel interview and document review*. A remote survey will entail requisite validation of required compliance within Chapter 9 of this document. AACI will notify our clients of the preferred method of communication. In this situation we will conduct interviews, review

documents, and offer questions for understanding the current status of the healthcare organization. Our methods may include document access, AACI's Cloud tool, e-mail, and/or use of online cameras. AACI will provide our healthcare organizations with a survey schedule (OP-ACP-07) at least 2 weeks prior to the remote survey. AACI will conduct preliminary conversations with the healthcare organizational leadership to facilitate a smooth and effective process of administration. AACI will not ask for extensive material to be arbitrarily gathered for these surveys. We will however ask those in a position of leadership to have computer access to required documented information within their healthcare organization system. This survey will be categorized in line with AACI Accreditation Standard for Healthcare Organization/Office Surgery, i.e. Administrative, Clinical, and Physical Environmental/Life Safety. Extensive preparation for our survey is unnecessary and discourage. Our clients are expected to be prepared to discuss and document all outstanding non-conformances and your associated corrective action plans from the previous survey.

Upon conclusion of the survey, the lead surveyor will complete a survey report, documenting the findings of the surveyor team members. He/she will communicate these findings to Top Management. When nonconformities have been raised, AACI will require the healthcare organization to formulate a corrective action plan (CAP). This CAP shall provide for appropriate mitigation and methods to eliminate the nonconformance in question. This CAP shall meet the approval of AACI prior to initiation of that process. The established calendar deadlines for completion and approval and closure shall remain as described in Section 10. In the case of disagreement, AACI will accept evidence supporting the basis of said disagreement in accordance with OP-GEN-01 Complaints and Appeals handling Procedure. All other aspects of our operations remain unchanged and shall be performed as delineated herein.

9. ACCREDITATION PROCESS

The Accreditation process begins when the Applicant organization submits a signed contract to AACI (to AACI d.o.o. if ISO 9001 is requested). AACI 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 announced, the survey team and the dates will be shared with the Applicant Organization.

9.1. Initial Survey

9.1.1. Stage 1 (ISO 9001:2015 only)

If ISO 9001:2015 is included in accreditation process Initial audit Stage 1 shall be conducted. The Stage 1 shall provide an indication to the healthcare organisation whether relevant aspects of the ISO 9001:2015 standard have been addressed. Stage 1 is a service offered to customers prior to commencement of the certification process. The Stage 1 consists of a document review and site visit (can be done in parallel). Not all areas of the healthcare organisation that provide complex care need to be visited during the Stage 1.The Document Review and Initial Visit shall be performed:

- To audit and determine the customers readiness for Initial audit (stage 2);
- Evaluating the level of conformance of the customers management system processes and documentation with the standard(s);
- Evaluating the understanding and implementation of key requirements of the standard(s);
- To gain sufficient understanding related to the organization and their management system, services, processes, customers for proper planning of the stage 2 audit;
- To review the allocation of resources for stage 2 and agree with the customer on details of the stage 2 audit.

The Initial Visit shall also be used to:

- Ensure that the customer understands the Certification concept;
- Agree on the certification scope and possible exclusions;
- Identify if there are outsourced process relevant to the certification scope and determine how this affect the certification audit;
- Verify the correctness of key company info forming the basis for the project setup (e,g. Application Form, including confirmation of site specific information like location, processes, no. of employees, shifts etc.)

9.2. Survey Locations

Organizations that do not have off-campus provider-based locations or have a limited number shall have all departments, services, and locations (and that should be included in the scope statement) surveyed. Organizations that comprise of multiple provider-based locations will have the following surveyed:

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

The focus of the survey team visits will vary from department to department as well as between sites. This location/processes shall be surveyed every survey (applicable to accreditation process only):

- Surgery,
- Anesthesia,
- Emergency room,
- Infection prevention and control,
- Medical records,
- Intensive Care Unit.

Contracted patient care activities or patient services (such as dietary services, treatment services, diagnostic services, etc.) located on the organization campuses or organization-provider based locations shall be surveyed as part of the organization for compliance with appropriate requirements.

9.3. Surveyors (Auditors for ISO 9001:2015)

AACI surveyors are internationally based representing managers and surveyors from senior positions within the health care industry. AACI is accredited by IEEA for the Surveyor Training Program. All AACI surveyors have been trained according to accredited training program. In addition all surveyors are qualify to deliver ISO 9001:2015 audits.

9.3.1. Survey team

The team consists of at the minimum three surveyors, chosen by AACI one of whom is appointed as the team leader. Clients are provided with the F-022 AACI Surveyor Approval Form and surveyor biographies. The organization is requested to formally accept the survey team but if there is an objection to a selected surveyor, or a conflict of interest, the AACI should be informed of reasons for the objection within **five (5)** working days of receiving the information. AACI will review the reasons

for the objection and make the final decision to remove the surveyor from the team. AACI shall decide on the composition and size of the survey team, but this will depend on a number of factors that include:

- 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 history of serious deficiencies or complaints.

Survey teams shall be composed to match the requirements and challenges of the healthcare organization but will normally include a Clinical Surveyor, a PE Specialist, and a Governance Surveyor. PE surveyor must be in team at least on initial and renewal surveys but is usually not required during periodical surveys.
All the surveyors will be qualified as auditors for ISO 9001 and typically one surveyor will have knowledge of the local language, culture and legal and regulatory framework under which healthcare organization operates.

9.3.2. Lead Surveyor (Team Leader)

The survey is conducted under the leadership of a Lead Surveyor (Team Leader) that has been designated by AACI. The Lead Surveyor is responsible for assuring that all survey activities are completed within the specified time frames and according to AAC's policies. Responsibilities of the Lead Surveyor include:

- Preparation and communication of the survey plan to the healthcare organization
- Chairing the opening and closing meetings
- Communicating with healthcare organization leadership regarding survey progress and initial findings
- Evaluating team progress and adjusting survey plans as needed
- Coordination and preparation of the survey report and submission of report to AACI.

9.3.3. Surveyor requirements for surveyor of office surgery in the State of Florida

Accreditation surveyors shall meet the following qualifications in accordance with 64B8-9.0092:

a) The surveyor must be an ABMS board certified physician with two (2) years' experience performing office surgery, or
b) A Florida Health Care Risk Manager licensed through AHCA with two (2) years' experience serving as a risk manager in a surgical facility, or
c) An ABMS board certified anesthesiologist with two (2) years' experience administering anesthesia in a surgical facility.

9.4. Survey Agenda

A minimum of 2 weeks prior to the start of the survey an agenda shall be prepared, and this shall be sent to the healthcare organization for review and comment. The agenda shall ensure that compliance against the entire AACI standard can be assessed and that all departments, services, and locations are visited.

Where possible it will have particular focus on areas or activities where there may be greatest risk in terms of patient safety or quality of care based on the experience of the Lead Surveyor, discussions with the organization, previous survey results and any history of complaints or other investigations.

If ISO 9001:2015 is included in the accreditation process the survey agenda shall indicate ISO 9001:2015 requirements or cross-reference links.

9.5. 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 healthcare organization representative upon entering the building.
The Lead Surveyor (Team Leader) will announce to the Managing Director or Executive in charge or organization contact, that a survey is being conducted. If the Managing Director (or executive in charge) is not onsite or available, the Lead Surveyor will ask that they are notified that a survey is being conducted.

9.6. Opening meeting

This will be led by the Lead Surveyor and will address the following issues:

- Introduction of survey team,
- Confirmation of survey objectives, scope, and criteria,
- Review of the survey plan,
- Agreement of meeting times and attendees,
- Clarification of method of reporting.

Participants at the opening meeting are typically executive and medical staff leadership and board members and others that will be directly involved in the survey activities. The opening meeting should take no more than 30 minutes depending on the questions raised by the healthcare organization.

9.7. Interviews and building visits

The survey will include a series of activities that will include:

- Review of previous survey results and implementation of associated corrective action plans,
- Interviews with leadership, management staff, and physicians,
- Interviews with patients,
- Building tour (4-8 hours, dependent on applicant organization size),
- Interviews with individuals who oversee core processes (e.g., patient safety, infection control, etc.),
- Human Resources interview to verify compliance with staff requirements,
- Medical Staff credentialing session to verify compliance with Medical Staff requirements,
- Additional document review if deemed necessary by survey findings.

9.8. Patient sample size and selection

A sample of patients will be selected that reflects as well as possible the patient population and the services provided. The surveyors will perform the selection following a review of the patient lists as well as inspection of various patient logs. The majority of patients that are selected will be in the organization during the survey (i.e., open records) such that surveyors have the possibility 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 investigations, 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) and in most cases it will be sufficient to see a number equivalent to 10% of the ADC in an organization with an ADC of 200 or more. For smaller organizations, the sample will not be fewer than 10 inpatient records.

If a complaint or known non-conformance 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.

Patient sample size for the Office Surgery shall be a minimum of 10% of the average weekly surgical cases. In no case shall it be less than 10 patient records.

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

9.10. 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. Records of all interviews will be maintained by the surveyors.

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.

9.11. Closing meeting

- The Lead Surveyor 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 AACI office,
- The facility determines which healthcare organization staff will attend the closing meeting,
- The Lead Surveyor 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 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 organization must understand and accept all findings presented,
- The team will assure that all findings are discussed at the closing conference.

9.12. Discontinuation of closing meeting

It is AACI'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 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 will stop the closing meeting and call the AACI office immediately for further direction.

10. POST-SURVEY ACTIVITIES

A Report shall be completed by the Survey Team and issued to the organization. AACI will forward the final survey report to the organization within **ten (10)** working days of the last date of the survey.

10.1. Survey finding definitions and criteria

Nonconformities will be sited when 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 Nonconformities will be split into three categories: Critical, Major and Minor.

10.1.1. Non-Conformities: Critical

Critical nonconformity is interpreted as a situation in which the health and safety of individual(s) are at risk. A situation in which the healthcare provider's noncompliance with one or more requirements of the AACI standard has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual. These guidelines are for use in determining if circumstances pose a Critical NC to an individual's health and safety.
The goal of the survey process is to ensure the provision of quality care to all individuals receiving care or services. The identification and removal of Critical NC, either psychological or physical, are essential to prevent serious harm, injury, impairment, or death for individuals.

- Only **ONE INDIVIDUAL** needs to be at risk. Identification of **Critical NC** for one individual will prevent risk to other individuals in similar situations,
- Serious harm, injury, impairment, or death does **NOT** have to occur before considering **Critical NC,**
- The high potential for these outcomes to occur in the very near future also constitutes **Critical NC,**
- Individuals must not be subjected to abuse by **anyone** including, but not limited to, entity staff, other patient, consultants or volunteers, family members or visitors,
- Serious harm can result from both abuse and neglect,
- Psychological harm is as serious as physical harm,

- When a surveyor has established through investigation that a cognitively impaired individual harmed an individual receiving care and services from the entity due to the entity's failure to provide care and services to avoid physical harm, mental anguish, or mental illness, this should be considered neglect,
- Any time a team cites abuse or neglect, it should consider **Critical NC** ,
- A situation that on the basis of available objective evidence may directly lead to unacceptable risk of patient harm or does not meet minimum standards of care.

10.1.2. Non-Conformities: Major

An NC will be categorised as Major when there is either:

- An 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 minor non-conformities indicating inadequate implementation or effectiveness of the system relevant to a requirement of the standard,
- A category minor non-conformity that is persistent (or not corrected as agreed by the healthcare organization) shall be upgraded to category major.

10.1.3. Non-Conformities: Minor

NC will be categorised as minor when the healthcare organization has 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.

10.2. Scoring System

AACI applies the scoring system defined in the electronic reporting system iAuditor. When applying a scoring, use the following system to determine the level of compliance:

- **NC Critical = -1 points (RED)**
- **NC Major= 0 point (ORANGE)**
- **NC Minor = 1 (YELLOW)**
- **Conform= 2 points (GREEN)**

This is evident from the Survey report. For an organisation to achieve AACI accreditation, an overall compliance rate of **70%** of the maximum score must be achieved.

10.3. Customer Corrective action plan (CAP) required for Nonconformities

Following receipt of the written report and CAP, the organization shall prepare a Corrective Action Plan (CAP) to address the nonconformities. Non-conformities shall be responded to by the healthcare organization within maximum **thirty (30)** days following the last date of the survey
The organization is expected to implement corrective action measure(s) as stated below. When this is not feasible AACI 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.
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 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 person responsible for implementing the corrective action measure(s),
- Identify the performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

Scoring system shall not apply to ISO 9001:2015 certification.

10.3.1. Closing NC Critical

The risk related to the Critical NC must be mitigated within **seven (7) days**. The final resolution must be completed within **thirty (30) days**. The organization 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).
A follow-up survey prior to the next annual survey will be required. 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, AACI will assign a surveyor that is familiar with the process and has the qualifications to validate compliance. Critical NC shall not apply to ISO 9001:2015 certification.

10.3.2. Closing NC Major

Within **sixty (60)** days of CAP acceptance, the organization 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). In order to close Major NC, a desk follow-up survey prior to the next annual survey may be required.

10.3.3. Closing NC Minor

If the CAP requirements are met, validation of effective implementation of the agreed corrective action plan will take place at the next annual survey.

10.4. Follow up

AACI will respond to the customer regarding acceptance of the submitted documentation and identify any deficiencies and additional requirements with timelines for submission. AACI, 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.
In all cases, when an applicant organization is undergoing an initial accreditation as a new enrolee in the AACI accreditation, all Critical and Major nonconformities must be removed prior to the awarding of accreditation. Failure to comply with the requirements of the CAP regarding nonconformities may also result in withdrawal of accreditation, disputes and appeals.

10.5. Findings and written report

For applicant organization there is no requirement for a CAP to be submitted to AACI following pre-assessment. However, they are required to submit a CAP to AACI for technical review within **thirty (30)** days of receiving the survey report for the initial survey.
All other organizations that have already achieved accreditation and that have had NC raised during a survey are required to submit a CAP within **thirty (30)** days of receiving the survey report.

The CAP will be reviewed by technical staff for completeness and to ensure that the actions are appropriate, sufficient, and timely.
Within 10 working days of receiving the CAP AACI will either inform the organization that it has been approved by the technical review or it will be returned with requests for additional action or information and with timelines attached. For organizations that have Critical or Major NCs raised then the requirements for addressing the different categories of Critical or Major NCs will depend on whether they are an applicant organization or an organization that already holds AACI accreditation.
Following receipt of the written report(s) the applicant organization will have **thirty calendar (30)** days from the date of the survey report to appeal any nonconformity findings relative to either AACI standards.
The applicant organization will submit CAP to address the nonconformities identified and return this to AACI. If the CAP(s) are approved, the report of nonconformities with the CAP(s) will be submitted to the Accreditation Committee.
Based on successful survey findings and/or CAP 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 AACI accreditation. To maintain accreditation, the organization will be subject to annual surveys for assessment of continual compliance with the AACI standard requirements and compliance with corrective action plan(s) from the prior survey.

10.5.1. Reporting to the Florida Board of Medicine

Upon receiving the appropriate authorization from the accredited entity, AACI shall provide a copy of any accreditation report to the Board office within 30 days of completion of the survey process. AACI shall provide copies of all corrective action plans to that authority within 30 days of receipt from the physician office. Additionally, AACI shall report any adverse events found in the survey process.
If AACI finds indications at any time during accreditation activities that conditions in the surgical office pose a potential threat to patients, AACI will immediately report the situation to the Department.

11. THE ACCREDITATION AWARD

To gain accreditation, organizations must demonstrate acceptable compliance with all standards and achieve a minimal numerical score (70%) on these standards as identified in the decision rules. In addition, all NC Critical and NC Major must be closed, and evidence provided. For NC Minor, organization must provide CAP. Once CAP is approved, the documents are submitted to the AACI Accreditation Committee for approval. The AACI Accreditation Committee makes accreditation decisions based on the findings of the survey. An organization can receive one of the following two accreditation decisions:

- Accredited or
- Accreditation Denied.

These accreditation decisions are based on whether the organization meets the decision rules. Accredited organizations receive an approved survey report, letter and certificate. The report indicates the level of compliance with AACI standards achieved by the organization.

11.1. Certificate of Accreditation

Organization that achieves the status of being accredited will be recognised by the issuance of an Accreditation Certificate (Picture 1).
The Accreditation Certificate shall be issued only after a successful initial or re-accreditation process that will be judged by:

- Approval of the survey report by AACI technical review,
- Approval of the organization CAP by AACI technical review,
- Closure of all NC Critical and NC Major,
- All NC Minors have been adequately addressed in the CAP.

The AACI accreditation is valid for three years and in order to maintain accreditation the organization will be subject to annual surveys for assessment of continual compliance with the AACI requirements.

Picture 1.

12. USE OF ACCREDITATION/CERTIFICATION AWARD LOGO

AACI accredited organizations may use the AACI accreditation award logo on letters, documents and other promotional material including the organization websites. Organizations shall be careful not to make or permit misleading statements regarding its Accreditation. The logo shall never be shown as larger than organization's own logo. The logo shall always be shown in its entirety. AACI will provide the accreditation award logos with instructions for use and display to all accredited clients.
The appropriate use of the accreditation logo shall be verified during the annual survey. It may also be checked periodically at the client's website. If a survey reveals that the accreditation logo is not displayed according to the established instruction, AACI shall issue a major nonconformity and require

the healthcare organization to take a corrective action. Evidence of the implementation of the approved corrective action shall be confirmed before removal of the nonconformance.

13. RE-ACCREDITATION PROCESS

The AACI sends the organization an information and F-002 Application form **three (3)** months before the organization's triennial accreditation due date. The organization is responsible for completing and returning the F-002 by a specified date. AACI then schedules the survey. Every effort is made to schedule the triennial survey to occur at the approximate conclusion of the previous three-year accreditation cycle. An organization's previous accreditation status may remain in effect up to **three (3)** months after the subsequent full accreditation survey to accomplish any required follow-up. If, during the period of accreditation, AACI receives information that the organization is substantially out of compliance with current accreditation standards, AACI will determine the need to re-survey the organization and/or render a new accreditation decision.

14. MAINTAINING ACCREDITATION AND PERIODICAL SURVEYS

AACI will continue to monitor accredited organizations for compliance with all the relevant AACI standards on an ongoing basis throughout the annual accreditation surveys. The focus of the survey team visits will vary from department to department as well as between sites. During planning the Periodic survey, the AACI makes sure that the following locations/processes are included in survey agenda:

- Surgery,
- Anesthesia,
- Emergency room,
- Infection Control and Prevention,
- Medical Records,
- Intensive Care Unit.

Other focused area to be included in the survey agenda document are those where critical or major nonconformities have been raised during the previous survey. Before starting the periodic survey, survey team must verify the objective evidence of implementation of minor nonconformities and close them. Evidence of closing must be indicated in the previous survey report.

15. SUSPENSION OR WITHDRAWAL OF ACCREDITATION

Where the organization operates outside of the agreed conditions of the AACI requirements there are two stages of consequences:

- A time limited invalidation (suspension) or
- A permanent invalidation (withdrawal).

15.1. Suspension

AACI may initiate suspension in cases where:

- AACI becomes aware through surveys, external investigations, complaints or other activities, that the provision of care or other services by the organization poses an extreme, immediate and unacceptable risk to the safety of patients, staff or visitors
- The organization fails to submit a required CAP within **thirty (30)** working days of receiving a survey report
- Objective evidence is not made available to AACI, within the timelines given in the approved CAP, that the corrective actions described in the CAP have been fully implemented
- Periodic surveys and re-accreditation surveys are not allowed to be conducted according to required frequency or as scheduled
- The organization violates terms of the signed accreditation agreement, including non-payment of fees or refusal of access
- AACI judges that the organization has made false public claims regarding its AACI (e.g., accreditation is used in a way that is unjustifiable or deceptive in advertising.)
- Information from stakeholders that could affect the status of AACI accreditation (e.g., non-compliance to regulatory/statutory requirements).

AACI may also choose to only give the organization a warning that suspension is being considered, but when AACI decides that suspension of AACI accreditation is appropriate the organization will be informed in writing. This letter will describe the situation that has led to suspension as well as the requirements and timelines that must be met to have AACI accreditation reinstated. The healthcare organization will have **ten (10)** working days from receiving the notification letter to respond or to appeal the decision.
During suspension both the organization and AACI shall inform enquirers that this is the case and use of all advertising matter containing a reference to AACI accreditation are prohibited during time of suspension. AACI accreditation shall not be suspended for a period longer than **six (6)** months.
Verification that the requirements have been met may require additional on-site surveys that will be charged to the healthcare organization based on the rates and costs used in the original contract.

15.2. Withdrawal

AACI accreditation will be withdrawn from the healthcare organization if:

- The customer does not meet the conditions of suspension and
- A suspension is not considered to be an adequate action.

Any decision to withdraw a certificate shall be communicated through a formal letter. The organization shall be required to terminate any use of the Accreditation mark and any reference to AACI accreditation and return accreditation certificate and copies to AACI. The healthcare organization will be informed of its right to appeal.

16. COMPLAINT ABOUT AACI ACCREDITED/CERTIFIED ORGANIZATION

The AACI evaluates and reviews complaints, concerns, and inquiries related to accredited organizations, as received from a variety of sources.
These complaints may be submitted by patients, families, and healthcare practitioners, by governmental agencies, or through information from the media. The term complaint therefore covers a broad spectrum of information received by AACI. Upon AACI review of a complaint, a number of actions may result. These include recording the information for trending purposes and possible action

in the future, obtaining the involved health care organization's response to the complaint, and conducting a for-cause survey. If AACI determines that the organization should respond to the complaint, the organization will be so notified.
The request for a response will be e-mailed to the organization's President/CEO (as stated below) with the following information:

- The complaint itself,
- A summary of the complaint if the complainant requested anonymity.

If an organization is required to respond to the complaint, it is required to do so usually within **thirty (30)** days of being notified. For more serious issues, the organization may be required to respond to the complaint within **five (5)** working days of being notified. When a response in a short time frame is required, the organization will be so notified.
Once a response is received, it is evaluated for compliance with AACI accreditation and or ISO/IEC 17021-1:2015 standards, as and if applicable. If additional information is required, the organization will be notified. When the organization's response is complete and has been accepted, a letter indicating acceptance is e-mailed to the Managing Director, and the case is considered closed.
AACI requires accredited organization to communicate to organization employees, visitors, and patients that when complaints are not resolved to their satisfaction, individuals may choose to report their complaints to the AACI.
AACI policies are not allowing organizations from taking retaliatory action against employees who submit complaints to the AACI and prohibit the AACI from disclosing to a complainant whether a complaint is substantiated.

16.1. Third Party Complaints

Complaints brought to AACI regarding accredited and or certified organizations shall be handled by a competent individual appointed by the CEO who shall evaluate the severity and priority of the complaint so that appropriate and timely action may be initiated.
The appointed investigator will initiate the investigative process by reviewing the complaint with the complainant. Generally, the complainant will be addressed to the organization depending of the complaint in question.. Complaints about nonrecurring events that occurred more than twelve (12) months prior to the initiation of a complaint will not require an investigation. However, based on severity, an investigation may be initiated to determine current compliance based upon concerns identified when the complaint was made.

17. APPEALS PROCEDURE

Appeals received by AACI shall be:

- Registered in a log to record the progress to completion
- Acknowledged by AACI without undue delay and
- 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 e-mailed or sent by mail to:

John D. Bell MD, President
AACI America LLC
658 E Sunset Dr.
Hendersonville, NC 28791
United States of America

Kresimir A. Paliska, CEO
AACI America LLC
658 E Sunset Dr.
Hendersonville, NC 28791
United States of America

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NOTE *This list contains the major sources of reference and guidance material. Many other related documents served in this purpose. Please direct any questions regarding these topics to our International Standard Advisory Committee if assistance is required.*