

# CENTRAL FABRICATION ACCREDITATION GUIDE

Getting Started  
Standards  
Resources and Tools



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Thank you for considering ABC for your central fabrication accreditation. The following information will give you everything you need to know to understand and meet the requirements of the standards to ensure that your facility is ready for accreditation. This program seeks to recognize those central fabrication operations that promote best business practices and provide quality items/devices to practitioners in the O&P profession. Are you the best at what you do? Prove it with ABC accreditation!



## Who We Are

The American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) is an independent, nonprofit, standard-setting organization for the accreditation of orthotic, prosthetic and pedorthic practices and the certification of practitioners in these professions. ABC is governed by a voluntary board of directors composed of orthotic, prosthetic and pedorthic health care professionals and consumers. In coordination with the board, ABC's accreditation policies are administered by the Facility Accreditation Committee.

ABC's mission is to establish and promote the highest standards of organizational and clinical performance in the delivery of orthotic, prosthetic and pedorthic services.



# CENTRAL FABRICATION ACCREDITATION AT A GLANCE

A BC's Central Fabrication Accreditation program is a stand-alone accreditation designed for facilities that are **not** providing patient care but are fabricating orthotic devices and prostheses for other professionals. Your business must have on staff a board certified or licensed orthotist, prosthetist, pedorthist, technician and/or assistant in the discipline(s) of the services the business provides.

ABC developed its central fabrication accreditation program based on recommendations from central fabrication business owners and

clinical practitioners. Due to changes in the orthotic and prosthetic field, many patient care facilities have moved toward using a central fabrication facility to fabricate orthotic, prosthetic and/or pedorthic items/devices for their patients. Although these facilities do not provide direct patient care, they play an important role in the provision of orthotic and prosthetic patient care.

**Accreditation is a privilege, not a right.** ABC has the legal authority to award accreditation and may withhold, suspend or revoke accreditation if your facility violates ABC's policies, rules and regulations. Once you submit a signed application for accreditation, you agree to abide by the ABC *Code of Professional Responsibility* and the published accreditation standards.



# ELIGIBILITY CRITERIA

The following criteria will help you determine if you are eligible for Central Fabrication Accreditation.

Your organization must:

- Be located within the United States, one of its territories or possessions
- Be a formally organized and legally established business that provides onsite custom fabrication of orthotic, prosthetic and/or pedorthic items/devices for external patient care providers
- Be licensed according to applicable state and federal laws and regulations, and maintain all current legal authorization, permits and zoning requirements to operate

- Have a physical location and operate in an appropriate central fabrication setting. The decision of what is an appropriate central fabrication setting is solely within ABC's discretion
- Have a full-time employee onsite who maintains a nationally recognized certification as an orthotist, prosthetist, pedorthist, technician or assistant in the discipline(s) of the services the business provides
- Any individual who has ownership interest must not appear on the Office of Inspector General (OIG) exclusion list.  
In addition, your organization will:
  - Comply with the ABC *Code of Professional Responsibility*
  - Agree to the terms and conditions in the application materials
  - Not falsify or misrepresent your accreditation status.



# APPLICATION INFORMATION

Once your facility has met the eligibility criteria and meets the standards, you are ready to submit your application and the required documents. **We recommend that you do not submit your application until you are ready for your onsite survey.**

Please complete the application and include the application fee. An incomplete application or missing documentation will delay the accreditation process.

You'll need to submit the following:

- Central Fabrication Accreditation application
- Application and survey fee (non-refundable)
- Copies of all non-ABC certifications and professional staff licenses—it is NOT necessary to submit copies of any ABC credentialed staff certificates
- Legal documentation of your business's ownership (e.g. Articles of Incorporation)

If necessary, ABC may require additional information. All information and application materials are confidential and only used by ABC and its survey contractors or as required by law. All submissions are handled in accordance with HIPAA regulations.

You will receive an email confirmation once your application has been received and both an email and written confirmation once ABC determines that your application is complete.

## Incomplete Applications

If your application is incomplete, ABC will send a request for additional materials via certified mail to the primary contact listed on your application. All requested materials must be received by ABC by the deadline indicated in the letter. If your application is still incomplete by the deadline, your application will be denied.

If your application is denied, you must reapply with a new application as well as application and survey fees. Incomplete applications will be processed after all required documents and/or fees are received. Any delay in completing your application could result in a delay of your accreditation.

## Falsification of Your Application

If ABC discovers that you provided false or misleading information on your application, any or all of the following actions may be taken:

- Denial of the application
- Denial of reapplication for accreditation
- Revocation of any existing ABC credentials from individuals who were found to be responsible for the falsification of the accreditation application
- Referral of the incident to ABC's Professional Discipline Committee
- Possible legal action



# ACCREDITATION SURVEY PROCESS

A BC's goal is to make the accreditation process as easy and uncomplicated as possible. The following information will help you understand the process and what you can expect from your onsite survey.

## Preparing for Your Survey

Before submitting your application, make sure your facility is compliant with the central fabrication accreditation standards and prepared for the onsite survey. We offer a variety of accreditation tools on our website, [ABCop.org](http://ABCop.org)

Additional resources to help you prepare can be found in the Resources and Links section of this publication.

It is your responsibility to ensure that you are in compliance with ABC standards at all times. In the event that we revise any of the standards, we will establish a time frame for accredited facilities to achieve compliance.

## Scheduling Your Survey

ABC assumes that once you have submitted an application, your facility is ready and available for the onsite survey. Your surveyor will contact you to schedule your survey. Our surveyors are in the field with multiple surveys and your flexibility in scheduling your survey will expedite the process.

Surveyors will schedule their visit during your business hours, which must be indicated on your application. If there are essential personnel,

such as an office administrator or owner, whose schedule varies from your regular business hours, please provide that information with your application.

If you or anyone acting on your behalf denies the surveyor access to the facility and/or any essential paperwork or if your facility is closed during the agreed upon survey time, your survey will be terminated. You will need to begin the process again by reapplying with a new application and submitting the appropriate application and survey fees.

## Hold Request Policy

You do have an option to place your application on hold if your facility is not ready for the survey or if you or your key staff are unavailable for more than two consecutive weeks. In these circumstances, we recommend that you remove your facility from the survey queue. Simply send us written notification at least 30 business days in advance that you wish to place your application on hold. Requests submitted in less than 30 days will be denied. We recommend that you include any hold requests when you submit your application. Requests must include: your facility name and address, the amount of time you wish to hold your application, and name and contact information of the authorizing individual.

When you are ready to reactivate your application, please notify us in writing. If we are not notified that you are ready to reactive your application within six months of the date your initial application was received, your application will be deactivated and you will need to resubmit all application materials, including the appropriate fees.





# THE ONSITE SURVEY

ABC prides itself on being the premier accrediting body in the orthotic, prosthetic and pedorthic professions and feels that our survey process and team of surveyors are the best. We believe the best central fabrication businesses will achieve this accreditation as a demonstration of their dedication to best business practices and the provision of quality items/devices.

## Surveyors

ABC employs a team of trained and qualified surveyors who will conduct your survey. Their role is to review the information presented and clarify, observe and verify the data that supports your compliance with the applicable standards.

During your onsite survey, your surveyor will discuss with your facility representative any area where standards are not fully met and he or she will provide best practice suggestions to help your facility achieve optimum performance. ABC surveyors are trained to be minimally intrusive throughout the survey in order to reduce interruptions to your business operations.

All surveyors must disclose to ABC any potential conflict of interest with you or your facility before they are assigned to conduct your survey. You may also notify ABC of a potential conflict of interest with any of our surveyors by submitting a letter with your application or by emailing ABC staff. Any surveyor with a confirmed conflict will not conduct your survey.

Surveyors are unavailable once your onsite survey is completed. ABC will not provide the surveyor's personal contact information, including address, phone number or email. If you wish to send correspondence to your surveyor, please email [accreditation@abcp.org](mailto:accreditation@abcp.org).

## Survey Types

### INITIAL SURVEY

An initial onsite accreditation survey will be used to determine if you have met the accreditation standards. We recommend that you use the Pre-Application Checklist provided in this publication to help ensure that you are prepared for the survey.

### RESURVEY

If your facility experiences significant changes, such as a location move or change of ownership, you will be required to undergo a resurvey.

Resurveys will also be required if the surveyor is denied access to the facility. To begin the resurvey process, you must submit a new application along with the appropriate fees.



## VERIFICATION SURVEY

If any deficiencies were found during your survey, you may be required to submit a Corrective Action Plan (CAP) outlining how you corrected these deficiencies. A verification survey is sometimes required to ensure that the corrections detailed in your CAP have been implemented. During this survey, the surveyor will confirm that any deficiencies from your initial survey have been rectified and that any items documented in your corrective action plan have been completed. ABC will inform you in writing if we require a verification survey. You will be responsible for any fees associated with a verification survey.

## QUALITY CONTROL SURVEY

On occasion, ABC will randomly conduct a quality control survey to determine consistency among ABC accredited locations and evaluate surveyor performance. We appreciate your cooperation if this occurs at your facility. In addition, we reserve the right to conduct a quality control survey to determine ongoing compliance with ABC standards. These surveys are random and unannounced and may be initiated in response to complaints. There is no charge to the facility for quality control surveys.

## Survey Structure

When your surveyor arrives at your facility, he or she will identify that they are from ABC and will present you with their photo identification badge. Make sure the individual's badge is valid and from ABC. If not, do not allow the individual into your facility and call ABC.

**Initial Interview:** You'll have a brief interview with your surveyor.

You can expect the surveyor to:

- Discuss the purpose of the survey and go over the schedule
- Answer any questions you may have about the survey process
- Determine the general layout of the facility

**The Survey:** To verify that you have met the requirements of ABC's Central Fabrication Standards, your surveyor will look at and focus on the following items and areas:

- Your business's Policies and Procedures Manual
- Personnel files
- Accounting and bookkeeping records
- Contracts with vendors
- Fire and emergency evacuation plans
- Customer satisfaction surveys and survey analysis
- Information on fabrication turnaround times
- Employee interviews

By applying for accreditation, you authorize ABC and its surveyors access to all records (including personnel, financial management, risk management, operational review, quality assurance and quality improvement) necessary to determine your facility's degree of compliance with the ABC standards. Your surveyor will also conduct staff interviews and may examine other areas as they relate to the standards. ABC and its surveyors comply with all HIPAA, privacy and confidentiality requirements.

**Closing Interview:** After your survey has been completed, your surveyor will brief you on their findings and make any suggestions for overall improvement. During the closing interview please keep in mind:

- You will have plenty of opportunity to clarify or submit any information that may not have been available during the survey.
- Your surveyor may have suggestions that could help you comply with the standards; this is your chance to talk to the surveyor one on one. Be sure to take notes.
- Your surveyor does not know whether you passed the survey and is not permitted to discuss your results.
- All significant recommendations and deficiencies will be discussed with you. A final survey report will be sent to you from ABC.

## After the Survey

### RESULTS

Surveyors submit their initial reports to ABC. All results are validated and finalized by ABC Facility Accreditation staff. Finalized results will be mailed to you two to four weeks after your survey. Any questions regarding accreditation status should be directed to ABC.

Your survey report and decision letter will indicate if you are **Compliant**, **Partially Compliant** or **Non-Compliant** with each standard. Standards where you were found to be Partially Compliant or Non-Compliant will include comments to assist you in taking corrective action to meet the standard. If deficiencies are found, you may need to submit a Corrective Action Plan (CAP.) If your facility meets all of the accreditation criteria, ABC will award you accreditation.



# ACCREDITATION DECISIONS

## Full Approval

ABC Central Fabrication Accreditation is awarded when all accreditation criteria are met and no major deficiencies are found. If your facility is granted full approval, you will receive a letter and a certificate for your five-year accreditation.

## Corrective Action Plan

If your surveyor finds deficiencies during the survey and/or if your facility's overall score is just below the passing range, your facility may be given the opportunity to submit a Corrective Action Plan (CAP). A CAP is a document that you submit to ABC that demonstrates the steps you have taken to address your facility's compliance with the standards that were in question during your onsite survey. Supporting documentation should accompany each missed standard in order to adequately demonstrate your facility's compliance. CAPs are reviewed and approved on a case-by-case basis; submitting a CAP does not guarantee that you will be awarded accreditation. There is no cost to submit a CAP and they may be mailed, emailed or faxed. Documentation items submitted to ABC with your CAP will not be returned.

If you are required to submit a CAP, it is due within 60 days of the CAP request letter date. ABC will notify you by mail and email. Failure to submit your CAP by the deadline will result in denial. It takes approximately eight weeks for the CAP review process.

If we find that your CAP does not adequately demonstrate your compliance with the missed standards, we will inform you in writing and any additional materials will be due by the deadline stated in the correspondence.

## Denial

Your facility may be denied accreditation for multiple reasons. The most common causes of accreditation denial are:

- You were non-compliant with a number of standards resulting in an overall score below the passing range
- Your Corrective Action Plan did not adequately address the issues or you failed to submit a CAP by the deadline
- Your surveyor was denied facility and/or documentation access
- Your facility was closed or otherwise unavailable during the scheduled onsite survey

If your facility is denied accreditation, we encourage you to reapply and be resurveyed once you are confident that you are in compliance with the standards. When you are ready to reapply, please submit a new application along with the appropriate fees.

## Accreditation Effective Dates

Your accreditation effective date will be either:

- The first day following the onsite survey, if your facility passes the survey on the first review, or
- The first day after approval of your Corrective Action Plan

## Accreditation Decision Appeals

If your facility is denied accreditation you may formally appeal the decision.

### APPEALS PROCESS

You have 15 days from the receipt of your survey report to submit a written appeal to the Facility Accreditation Committee. Your appeal must be sent by certified mail return receipt requested or by verifiable overnight express mail service to:

ABC

Attn: Facility Accreditation

330 John Carlyle St.

Suite 210

Alexandria, VA 22314

Email: [accreditation@abcop.org](mailto:accreditation@abcop.org).

Your appeal must include the necessary evidence or relevant documentation supporting the basis of your appeal. If you do not appeal the decision within the 15-day time period, the accreditation decision is final.

You will receive notification of the committee's decision on your appeal within 60 days of its receipt by ABC. If you are not satisfied with the decision, you may submit a second appeal to the ABC Board of Directors by sending another written appeal via certified mail return receipt requested or by verifiable overnight express mail service within 15 days of receipt of the committee's decision. You will be notified of the board's decision within 60 days of receipt of your appeal. The board of director's decision is final.



# ACCREDITATION FEES

**A**ccreditation fees are set by the ABC Board of Directors and reviewed annually. ABC reserves the right to adjust accreditation fees and establish the effective date of change. All accreditation related fees (application, survey, annual fees, certificate reprint, etc.) are non-negotiable and non-refundable. Current accreditation fees are available on the ABC website.

## Application and Survey Fees

All fees must be submitted with your application. The fees associated with the application include application processing and the onsite survey. A facility will only be added to the survey queue once payment has been received and the application is complete.

## Annual Fees

All ABC accredited facilities are required to pay an Annual Fee in order to maintain their accreditation. Your on-going accreditation status is dependent on the timely receipt of this fee. Annual renewal notices are sent to the address on record in September of each year and are due on December 1st. Failure to submit your annual fee may result in any or all of the following:

- Removal from ABC's online directory
- Our inability to verify your facility's accreditation with interested parties
- Revocation of facility accreditation

## Certificate Reprint Fees

If you wish to obtain an additional accreditation certificate, you must login to the facility's MYABC account to submit request and pay the associated fee. Your facility must be in good standing in order to process your request.



## MAINTAINING ACCREDITATION

**A**ccreditation requires that you continue to comply with the ABC standards, abide by all policies and procedures and submit your annual fee on time. You must notify ABC of any and all changes with your facility within 30 days of the effective changes. Failure to fulfill any of these requirements may result in the revocation of your accreditation.

If ABC revises the standards, time frames for compliance will be established and communicated to all accredited facilities.

### Personnel Changes

You are responsible for notifying ABC of employment status changes of all certified and licensed personnel in writing within 30 days of the change. In the event that a personnel change leaves your facility without a qualifying professional, you have six months to replace them and notify ABC of the new personnel. Failure to do so will result in loss of accreditation.

### Changing Corporate Structure

If your corporate structure changes, you must submit a letter detailing the change and the effective date along with legal documentation (i.e. new business license, Articles of Incorporation). If you are changing ownership in addition to corporate structure, please see Ownership Changes.

## Closing or Selling Your Facility

You must notify ABC in writing if you close or sell your facility; notification must be sent within 30 days of the sale or closure. You must also surrender your original ABC accreditation certificate. If you decide to reopen your facility at a later date, you must begin the accreditation process again with a new application and all applicable fees.

## Ownership Changes

### ADDING OWNERS TO EXISTING OWNERSHIP

If you are bringing on an additional owner to your business, you must submit a letter detailing the change and the effective date along with legal documentation (i.e. Articles of Incorporation). A resurvey is not required as long as an existing owner remains.

### REMOVING AN OWNER FROM EXISTING OWNERSHIP

If you are removing an owner from the existing ownership, you will need to submit a detailed letter notifying us of the change and the effective date. We will also need copies of the legal documentation (i.e. sale of shares evidence, Articles of Incorporation). A resurvey is not required as long as an existing owner remains.

## COMPLETE CHANGE OF OWNERSHIP

ABC Central Fabrication Accreditation is not transferrable between two different owners. If no existing owners are remaining at the facility, new ownership must submit a new application with a detailed letter, legal documentation of the sale and application fees. The facility will undergo a new onsite survey.

## Lawsuits and Disciplinary Actions

You must notify ABC if there are pending lawsuits and/or disciplinary actions against any staff members or your business. You must submit a detailed written statement that includes the following:

- Description of the lawsuit
- Outcome of any charge(s) that were filed against the individual/facility (e.g. verdict)
- Any penalty/sentence associated with charges that have been filed
- When the sentence was or will be completed
- Official court documentation

If the documents are not available, indicate the jurisdiction in which the charge(s), conviction or plea occurred and why the documents are not available.

## Complaints Against Accredited Facilities

ABC will investigate any and all complaints involving an ABC accredited facility that appears to be out of compliance with the accreditation standards. ABC requires that you provide ABC's telephone number to your customers for the purpose of reporting a complaint.

ABC will notify the appropriate regulatory authority if an alleged complaint involves:

- Professional misconduct
- Noncompliance with state or federal laws

You will be informed of all allegations and provided with copies of all complaint-related materials.

If a review of the complaint determines that there is immediate risk to employees or customers, ABC will notify the appropriate governmental and investigative agencies. If the situation does not pose immediate risk, the complaint will be investigated by ABC in accordance with the *Code of Professional Responsibility and Rules & Procedures*.

Accredited facilities must abide by the *Code* and depending upon the nature of the complaint, the following actions may be taken:

- Request your cooperation in resolving the complaint
- Request that you respond to the complaint within an identified time frame
- Request information on the corrective action taken



ABC will review all the information collected about the complaint, including any information gathered in a re-survey. If the investigation reveals the complaint or allegations are valid and employees or customers are at risk, accreditation may be revoked or suspended. You may appeal the committee's decision by following the appeals process.

Thank you for considering ABC's Central Fabrication Accreditation for your business. We hope that this information provides you with the information you need to determine how this program benefits your business. The goal of this program is to recognize those central fabrication businesses that meet the ABC standards for best business practices and the provision of quality items/devices to practitioners in the O&P profession. If you are the best at what you do, now is your opportunity to prove it with ABC accreditation!



# ACCREDITATION STANDARDS AND COMPLIANCE TIPS

**A** BC accreditation standards represent baseline expectations of your facility's physical environment and the functions of fabrication. Accreditation decisions are based on the degree of compliance with the standards. Compliance is assessed as appropriate to the size of your facility and services provided. However, all facilities are evaluated on the same set of standards.

The standards for central fabrication facilities are grouped into the following eight categories:

**Organization (OG):** legal status and legitimacy of the business and the establishment of internal policies and procedures.

**Business Records (BR):** policies and procedures related to business operations.

**Record Keeping (RK):** policies and procedures related to customer orders and fabrication records.

**Human Resources (HR):** policies and procedures for personnel qualifications and human resource management.

**Warranty and Recalls (WR):** policies and procedures related to warranties, item/device failures and product recalls.

**Safety and Equipment (SE):** facility safety, safety management and occupational exposure risks.

**Quality Assurance (QA):** tracking and evaluating organizational strengths and weaknesses and implementing improvements to business operations.

**Customer Satisfaction (CS):** employing satisfaction surveys to identify and implement improvements to business operations.

## Organization (OG)

The Organization Standards address the legal status and legitimacy of the business and the establishment of internal policies and procedures. To be fully compliant with the standards in this section, the business must be able to demonstrate how the requirements are met. The business must provide documentation that it is legally constituted where it is located and provide full disclosure of all ownership information.

A written policy manual must be available that outlines the ongoing operating procedures and that the business has adopted a mission statement. In addition, all licenses, certificates and permits must be appropriately displayed.

## OG1

**The business documents that it is a legally constituted entity in the state(s) in which it is located and is authorized to provide the services for which it is seeking accreditation.**

### TIP–Legally Constituted Entity

You must provide legal documentation of proof of ownership. Examples of this are your Articles of Incorporation (Corporation) or Articles of Organization (LLCs).

You must have available for the onsite survey all applicable business licenses and necessary permits from federal, state and local governments. Since licensing and permit requirements vary among jurisdictions, it is critical that you follow the specific requirements for your jurisdiction.

## OG2

**The business shall disclose its ownership and control information.**

### TIP–Ownership Disclosure

You must identify all of the business owners. You can do this with corporate records and/or your corporate tax records.

## OG3

**The business complies with all applicable federal, state and local laws.**

### TIP–Federal, State and Local Laws

You will need to show proof of compliance. Examples may include, but are not limited to:

- OSHA Regulations
- Fire safety/inspection codes
- Building and occupancy permits

## OG4

**All licenses, certificates and permits to operate the business must be current and available for review.**

### TIP–Licenses, Certificates and Permits

The following documents must be displayed as required by your locality. All documents must be current. Examples may include, but are not limited to:

- Business license from your city or county
- Zoning or occupancy permit
- Sales tax license
- Fire department permit
- Registration with the FDA, if applicable

## OG5

**The business has a written policies and procedures manual that is available to and adhered to by the staff.**

### TIP–Policies and Procedures

You must have documented policies and procedures that describe how your business activities are performed. You must inform and make available to your staff these policies and procedures. You can do this with staff meetings and/or by providing your staff with electronic access or hard copies of the policies and procedures. When you change or add to the policies you need to inform your staff and have documentation of staff notice.

## OG6

**The business has adopted a mission statement that includes a description of the services provided and its goals and objectives.**

### TIP–Mission Statement

Your mission statement could be part of your policy manual, available in your facility and/or posted on your website.

## OG7

**The business shall have one or more individuals with authority, responsibility and accountability, who perform leadership functions.**

### TIP–Business Leadership

These individuals have the authority to direct key aspects of the business. They could be identified on organizational charts or with written job descriptions.

## OG8

**The business makes reasonable accommodations for its employees and is compliant with the Americans with Disabilities Act (ADA).**

### TIP–Accommodations for Employees

Examples are:

- Ramps, entrances and exits must be appropriate for the business
- Staff using wheelchairs, walkers, crutches or other mobility aids must be able to access the facility
- Restrooms must be accessible to your staff
- Doorway width must be appropriate for your staff

## OG9

**The buildings and grounds are appropriate to the nature of the services provided.**

### TIP–Buildings and Grounds

Your premises must meet all local zoning regulations. The business must comply with state and local health and fire codes and occupancy classifications for this location. There must be adequate space to safely conduct business.

## OG10

**The business has specific laboratory area(s) consistent with the services offered.**

### TIP–Laboratory Space

You must have a laboratory area appropriate for fabricating, adjusting, repairing and modifying.

## Business Records (BR)

The Business Records Standards address the establishment of policies and procedures related to business operations. You must have in place written policies that address your standard operating procedures and how you manage revenues and expenses on an ongoing basis. Your policies must include how records are backed-up and how those records are recovered in a disaster. You must also demonstrate that appropriate measures have been taken to secure all records and permit prompt retrieval of information.

### BR1

**The business establishes and documents written policies and procedures that address business operations.**

#### TIP—Business Operations

Your policies and procedures must be available to staff. Examples may include, but are not limited to, standard operating procedures and employee handbooks.

### BR2

**The business manages revenues and expenses on an ongoing basis according to generally accepted accounting principles.**

#### TIP—Managing Revenues and Expenses

The following are examples of compliance:

- Your operating budget meets the needs of your business operations
- You manage revenues and expenses on an ongoing basis
- You use either a cash or accrual-based accounting practice for your business
- Your records or financial accounts allow you to identify which specific items/devices were provided to specific customers

### BR3

**Business records are secure and permit prompt retrieval of information.**

#### TIP—Information Access

You must have a secure and quickly accessible system for retrieving account, customer and purchasing information.

## BR4

**The business complies with the appropriate provisions and requirements of the Healthcare Insurance Portability and Accountability Act (HIPAA).**

### TIP -- HIPAA

You should be knowledgeable of the many sections of HIPAA and its applicability to your business.

Examples of compliance include:

- Business Associate Agreements (BAA) are in place
- HIPAA Privacy Rules in place
- HIPAA Security Regulations are in place, as applicable
- Customer records are stored appropriately
- Access to Protected Health Information (PHI) is properly restricted
- Computer and other system passwords are in place

## BR5

**Customer and production records are reasonably protected from all risks and appropriate measures are taken to maintain backups of customer data.**

### TIP–Record Protection

You must have written policies in place protecting your records from all risks such as theft, fire and/or natural disasters. Your policies must include how you successfully and efficiently back-up your records and how you would recover those records in the event of a disaster or theft.

## Record Keeping (RK)

The Record Keeping Standards address the establishment of policies and procedures related to customer orders and fabrication records. You should have documented policies and procedures that address the creation, maintenance and storage of records. Each record should consistently include detailed descriptions of the item/device, turnaround times, delivery dates and communication with the customer. You are required to maintain a tracking system that links items/devices to the customer.

## RK1

**The business establishes written policies and procedures that address the creation, maintenance and storage of customer orders and fabrication records.**

### TIP–Fabrication Records

Your procedures may include, but are not limited to, explanation of how:

- Job or work orders are created
- Records are entered into the tracking system
- Records are updated during the fabrication process
- Records are securely stored

## RK2

**The business shall maintain documentation that includes customer communications for each item/device.**

### **TIP**–Customer Communications

Any communications with your customer including change orders or specification clarifications must be documented. These communications may include phone calls, faxes or emails.

## RK3

**The business maintains records that include detailed descriptions of the item/device fabricated and the components incorporated.**

### **TIP**–Detailed Documentation

The detailed descriptions may include, but are not limited to:

- Work orders
- Type of device
- Materials used
- Components used
- Fabrication timeframes

## RK4

**The business shall maintain a tracking system that links custom fabricated items/devices to the customer.**

### **TIP**–Tracking System

Your system could be comprised of a tracking database, spreadsheet, log or other documentation and may include applicable model and serial numbers.

## RK5

**The business informs the customer of the expected time frame for the fabrication and delivery of requested items/devices and notifies the customer of delays as applicable.**

### **TIP**–Expected Time Frame

Examples of compliance may include, but are not limited to:

- Published turnaround times
- Arranged delivery dates
- Documented communication with customer

## RK6

**Prior to delivery, the business documents that the item/device meets the specifications of the component manufacturer's guidelines and/or customer's requests.**

### **TIP**–Compliance with Manufacturer's Guidelines

Examples of documentation include, but are not limited to:

- Quality assurance forms that include the manufacturer's guidelines
- Final inspection checklist prior to shipping item/device



## Human Resources (HR)

The Human Resources Standards address policies and procedures for personnel qualifications and human resource management. You must have written policies that describe staff qualifications and provide documentation of participation in orientation and training. All licenses and certifications must be verified and documented in the employee's personnel file or another file specifically for this purpose.

You must conduct and document staff reviews that provide individuals with feedback on their job performance.

### HR1

**The business establishes written policies and procedures for personnel qualifications and training, including 1) detailed job descriptions; 2) required certifications and/or licenses as applicable; 3) required experience; and 4) continuing education requirements.**

#### **TIP**–Personnel Qualifications

You must have policies and procedures in place that describe the qualifications and employment requirements of your staff. Documentation may be located in personnel files, human resources records, training records and/or staff meeting minutes.

### HR2

**The facility must have a full time staff member onsite who is credentialed as an orthotist, prosthetist, pedorthist, technician or assistant by a nationally recognized orthotic, prosthetic or pedorthic certifying board in the discipline of the services it provides to assist in the determination of the design specifications.**

#### **TIP**–Full time Credentialed Staff Member

A full time credentialed staff member is onsite the majority of the business' operating hours.

### HR3

**The business provides appropriate orientation and training programs to familiarize all personnel with its facilities and procedures. Appropriate reference materials and educational information are available to all personnel.**

#### **TIP**–Staff Orientation and Training

You must provide orientation and training to familiarize your staff with your facility and all procedures. You need to document staff participation in this orientation or training as well as all ongoing and remedial training programs. The orientation or training materials must be available to all staff.

Documentation may include, but is not limited to:

- Employee handbook
- Safety orientation
- Signed and dated list of program participants and a copy of the agenda for the orientation or training session

## HR4

**The business verifies all required professional licenses and/or certifications, at least annually.**

### **TIP**–Licenses and Certifications

All of the licenses and certifications held by all staff need to be verified every year. You can do this by contacting the issuing agency (licensure or certification board) and requesting verification that the individuals' credentials are still valid. This can be done via phone, email or by checking the agency's website. Once acquired, the verification should be documented in the employee's personnel file or another file specifically for this purpose. You should document the date and method by which the verification was received.

## HR5

**The business conducts performance reviews of its staff, at least annually.**

### **TIP**–Performance Reviews

During your performance reviews you must provide the individual with feedback on their competencies and areas for improvement, if needed. These reviews must be documented in their personnel file or another file specifically maintained for this purpose.

## Warranty and Recall (WR)

The Warranty and Recall Standards address written policies and procedures related to warranties, item/device failures and product recalls. You must have written policies to identify incidents such as failures and product recalls. These policies must include the ability to identify and notify all customers affected by a recall. You must also have procedures for the disclosure of request information related to an item/device failure. You must document and disclose the addition of any used components and that items/devices were obtained without fraud or deceit.

## WR1

**The business has established written policies and procedures that address item/device failures and product recalls.**

### **TIP**–Failures and Recalls

You must have a policy in place for investigating and documenting incidents such as failures and product recalls. The investigation documents should include all relevant information, your conclusions and whether or not you will be making changes to protocols or procedures because of the incident.

## WR2

**The business has established written policies and procedures related to the disclosure of information requested as part of an investigation by the customer involving item/device failure.**

### TIP–Information Requests

In the event that a customer reports an item/device failure, your written policy will detail your response and follow up actions.

## WR3

**The business has written policies and procedures to collect data related to item/device failures and to respond to product recalls.**

### TIP–Collecting Data

Data can be compiled from customer feedback and recorded in a complaint log, failure log or other tracking system. Data may also be obtained from customer work orders, complaints, visual defects or employee feedback. Your policy needs to include how you will identify and notify all customers affected by the recall.

## WR4

**The business provides its customers with warranty information on items/devices that it fabricates.**

### TIP–Warranty Information

This information can be provided in a variety of methods such as on your website or warranty cards included with the shipped item or device. Warranty information includes both your warranty of the services provided and the manufacturer's warranty for components included in the item/device.

## WR5

**The business shall verify that its supplied items were obtained without fraud or deceit.**

### TIP–Verification of Purchase

You must have documentation that shows items were purchased from a known, reputable source. This can be documented through purchase orders, invoices or packing slips.

## WR6

**The business shall document and disclose to the customer the incorporation of any used components, not supplied by the customer, on items/devices that it fabricates.**

### TIP–Disclosure of Used Components

Disclosure may be through labeling on the item/device or direct communication with the customer. You need to document any instance of fabrication with used components.

## Safety and Equipment (SE)

The Safety and Equipment Standards address facility safety, safety management and occupational exposure risks. The standards require you to administer a written safety management program that provides a physical environment free of hazards as well as procedures that reduce the risk of injury to employees.

You must also have a disaster preparedness plan designed to manage the consequences of natural disasters, long term power outages, fires and other emergencies. Staff must be trained to carry out duties and responsibilities specified in the contingency plans.

You are required to administer an equipment management program that is designed to assure safe equipment performance that is supported by preventive maintenance programs.

### SE1

**The business administers a written safety management program that is designed to provide a physical environment free of hazards and to manage staff activities to reduce the risk of injury.**

#### TIP–Safety Management

You need to have written policies and procedures that reduce the risk of injury to employees. A copy of this plan needs to be in your policy manual and available to all staff. Examples may include, but are not limited to:

- Appropriate use and storage of hazardous materials
- Proper use and maintenance of equipment
- Training and orientation on facility safety

### SE2

**The business conducts and evaluates the results of safety inspections of the facility. These inspections must be performed and documented at least annually.**

#### TIP–Safety Inspections

Document each of your facility safety inspections and include documentation of any deficiencies and corrective actions taken as a result of the inspection.

Examples of documentation may include, but are not limited to:

- Staff meeting minutes
- Equipment logs
- Safety inspection checklists
- Safety consultant reports

### SE3

**The business conducts and documents safety management training for all staff, at least annually.**

#### TIP–Safety Management Training

Your safety management training should include:

- General safety procedures
- Safety plans
- Emergency preparedness
- Emergency plans
- Special hazards related to assigned duties
- Safety practices
- Explanation of any changes since last training

Documentation of safety management training may include, but is not limited to:

- Staff meeting minutes
- Sign-in sheets

## SE4

**The business establishes and maintains procedures for cleaning the facility and equipment.**

### **TIP**–Facility and Equipment Cleaning

You need to have processes in place to ensure that your facility and equipment are adequately cleaned. Staff training should include procedures for the appropriate cleaning of the facility and equipment, even if you use an outside cleaning service.

## SE5

**The business has established written policies and procedures and complies with all appropriate hazardous waste disposal procedures.**

### **TIP**–Hazardous Waste Disposal

You need a process that ensures and documents that your staff is trained and consistently follows appropriate hazardous waste disposal procedures. This process should include federal, state and local disposal requirements.

## SE6

**The business has established an emergency evacuation plan that addresses appropriate staff response to fires or other emergencies and provides appropriate education and training to all staff. Based upon occupancy classification, the plan includes provisions for appropriate fire alarm and fire suppression systems.**

### **TIP**–Facility Emergency Evacuation Plan

Your plan needs to include evacuation routes, as well as the duties of specific staff, in the event of an emergency. These duties should include identifying who is responsible for calling fire and other emergency personnel and who is responsible for checking that all staff have safely evacuated the premises and assembled in a previously designated area.

You also need to document that your staff has been trained on the emergency evacuation plan with sign-in sheets, program agendas or staff meeting minutes.

## SE7

**The business conducts an emergency evacuation drill in accordance with the evacuation plan, at least annually.**

### **TIP**–Emergency Evacuation Drill

Your emergency evacuation drill must include all staff members. If you have more than one shift, you must conduct a drill for each shift. Your drill also needs to include testing of the fire suppression and/or alarm systems, if applicable.

## SE8

**Written evaluations of the effectiveness of the emergency evacuation drill are prepared and results of the evaluation are documented.**

### TIP–Drill Evaluation

After you’ve conducted the drill, write an evaluation of its effectiveness. Your evaluation might include items such as timeliness of evacuation, confirmation that all staff exited the premises, all staff gathered at the pre-determined meeting location and the all clear procedures for returning to the facility were followed. The written evaluation should be kept in your emergency preparation files.

## SE9

**The business has created a disaster preparedness plan designed to manage the consequences of natural disasters or other events that affect its ability to service its customers.**

### TIP–Disaster Preparedness

Fires are not the only emergency for which you need to be prepared. Other events such as natural disasters (i.e., flood, tornado, hurricane or wind storm) or widespread and lengthy power outages could also disrupt your ability to serve your customers.

Provide documentation that you have a plan to manage the consequences of such a disaster or interruption. This might include a process for data backup and/or restoration in order to continue operations in the event of a disaster, or contracts and/or agreements with other businesses to help you maintain service to your customers.

## SE10

**When the business elects to maintain specialized emergency equipment, such as an Automatic External Defibrillator (AED), personnel are trained in the proper use of that equipment.**

### TIP–Specialized Emergency Equipment

If you have any specialized emergency equipment on your premises, you must provide documentation that your staff has been trained in its use. Documentation could be in the form of sign-in sheets, program agendas or course certificates.

## SE11

**The business has established written policies and procedures that prohibit smoking within its facility.**

### TIP–No Smoking Policy

Your facility must be a non-smoking environment. A copy of your no smoking policy needs to be in your policy manual, which is available to all staff as well as included in staff orientation. The policy also needs to be posted in a location visible to all staff.

## SE12

**The business has implemented an equipment management program for all serviceable equipment that promotes its safe use by staff.**

### **TIP**–Equipment Management Program

Your equipment management program must include, but is not limited to:

- An inventory of all equipment
- Staff training on the appropriate use of equipment
- A plan for the appropriate maintenance of equipment

## SE13

**The business has documented training for appropriate staff on the safe use of equipment.**

### **TIP**–Equipment Safety

You must have documentation that your equipment safety training program trains staff in the safe use of all equipment and items. Documentation may include, but is not limited to:

- Staff meeting minutes
- Training log
- Agenda for staff safety training

## SE14

**The equipment management program includes documented maintenance of each piece of equipment.**

### **TIP**–Equipment Maintenance

Your equipment management program (referenced in SE12) must include an inventory of all equipment and a log to identify the maintenance of each item. Your staff needs to be trained on the program and the maintenance requirements.

## SE15

**The business has established and adheres to written policies and procedures that address occupational exposure.**

### **TIP**–Occupational Exposure

Occupational exposure is defined as the exposure to potentially harmful chemical, physical or biological agents that occurs as a result of one's occupation. You must have documentation that these policies are consistently followed by staff.

Examples may include, but are not limited to, policies that address items such as:

- Contaminated patient cast impressions
- Injury in the workplace
- Blood borne pathogens
- Chemical handling
- Noise abatement



## SE16

**The business maintains a current file of Safety Data Sheets (SDS). All appropriate staff are trained on the potential risks and dangers of materials used in the facility.**

### **TIP**–Safety Data Sheet

You collect, maintain and update all pertinent Safety Data Sheets. All staff must have access to the SDS file and be knowledgeable of its contents.

## SE17

**The business has written policies and procedures that address cross-contamination risks.**

### **TIP**–Cross-Contamination

You need a policy that documents the proper handling of items that have come in contact with a patient such as cast impressions, positive models and/or devices returned for repair. Your procedures should include universal precautions and cross contamination policies. Staff must be trained on the policy. A copy needs to be in your policy manual and must be available to all staff.

## SE18

**The business adopts written policies and procedures that address the use of Personal Protective Equipment (PPE) for all appropriate staff.**

### **TIP**- Personal Protective Equipment

You must require the use of PPE items as per OSHA regulations or as you deem additionally necessary for the services you provide.

These policies may include items such as:

- Hearing protection
- Protective eyewear
- Dust masks
- Respirators
- Gloves and lab coats
- Other protective clothing

## Quality Assurance (QA)

The Quality Assurance Standards address how an organization tracks and evaluates organizational strengths and weaknesses and implements improvements to the business operations. You must dedicate adequate resources to create and administer a quality assurance program designed to monitor and evaluate services, pursue opportunities to improve those services and resolve any identified problems.

### QA1

**There is a written quality assurance program, which is an ongoing process to monitor and evaluate the quality of the services provided.**

#### TIP–Quality Assurance Program

As part of your written program, you must monitor and evaluate the quality of your services, pursue opportunities to improve those services and resolve any identified problems. The effectiveness of the action you take must be documented and assessed.

### QA2

**The business collects and measures data to evaluate the frequency of fabrication errors.**

#### TIP–Fabrication Errors

You need to collect fabrication error data and analyze trends such as the use of incorrect materials or components, training deficiencies and/or waste loss. This analysis needs to be written and maintained in an appropriate file.

### QA3

**The business collects and measures data to evaluate the frequency of shipping and billing errors.**

#### TIP–Shipping and Billing Errors

By collecting and analyzing shipping and billing error data, you will be able to recognize trends and make corrections. This analysis needs to be written and maintained in an appropriate file.

### QA4

**The business seeks and documents input from employees when assessing the quality of its operations.**

#### TIP–Staff Input on Quality Business Operations

This input can be sought through staff meetings, surveys and/or interviews. All resulting input needs to be documented and maintained in an appropriate file.

### QA5

**When an opportunity to improve is identified, corrective/preventative action is taken and documented.**

#### TIP–Corrective/Preventative Action

After collecting information that leads to an opportunity for improvement, the next step should be to implement and document changes to your methods and procedures.

## Customer Satisfaction (CS)

The Customer Satisfaction Standards address the use of satisfaction surveys to identify and implement improvements to business operations. Customer satisfaction surveys are a powerful tool for performance feedback. Information collected should include questions addressing satisfaction with the quality of services and resolution of complaints. After collecting this information, the data must be reviewed and analyzed. If your review identifies changes needed to your operations, these changes should be documented.

### CS1

**The quality assurance program (see QA1) includes the establishment and implementation of a customer satisfaction survey.**

#### TIP—Customer Satisfaction Survey

If you do not have your own customer satisfaction survey, many national associations and other groups have them as free resources or for purchase. These can be adapted for use in your facility. Your survey could be mailed with the item/device, emailed to the customer following delivery or mailed separately. You might consider an incentive of some kind to encourage customer participation.

### CS2

**The customer survey includes, but is not limited to, questions addressing satisfaction with the quality of services, resolution of complaints and timeliness of response to the customer.**

#### TIP—Elements of Customer Satisfaction Survey

Your survey needs to focus on the customer's satisfaction with:

- Quality of your services, such as meeting the customer's expectations, ease of working with your staff and meeting delivery time expectations
- Resolution of complaints, such as timeliness of resolution, effectiveness of solutions offered and satisfaction with outcome
- Response time to customer's questions and concerns, such as ease of contact, responsiveness to inquiries and resolution of the issue

### CS3

**Results of the customer satisfaction surveys are documented and evaluated, at least annually.**

#### TIP—Customer Satisfaction Survey Review

Document your survey review to identify areas for improvement in service, quality or responsiveness. Your review can be documented with notes, a report or minutes of a meeting. If your review identifies changes needed to your program, the changes you make should also be documented.



## RESOURCES AND LINKS

A BC has identified several useful links from relevant organizations to help guide you with the compliance of ABC's Central Fabrication Accreditation Standards.

Americans with Disabilities Act (ADA)

Occupational Safety and Health Association (OSHA)

Federal Emergency Management Agency (FEMA)

Centers for Disease Control and Prevention (CDC)

Health Insurance Portability and Accountability Act (HIPAA)

Safety Data Sheets (SDS)  
US Department of Labor

Workplace Safety & Health Topics  
*Centers for Disease Control and Prevention*

General O&P Business Information  
*American Orthotic & Prosthetic Association (AOPA)*

# Central Fabrication Accreditation Checklists



## PRE-APPLICATION

Thank you for choosing ABC's Central Fabrication Accreditation program. To help ensure that you are ready for the accreditation process, ABC has created the following checklist. We recommend that you review these items in order to be prepared for the application and onsite survey process.

This checklist does not replace the need to have a thorough understanding of the Central Fabrication Accreditation Standards.

Before you apply, make sure your business:

- ☐ is located within the United States, one of its territories or possessions
- ☐ is a formally organized and legally established business that provides onsite custom fabrication of orthotic, prosthetic and/or pedorthic items/devices for external patient care providers
- ☐ is licensed according to applicable state and federal laws and regulations, and maintains all current legal authorization, permits and zoning requirements to operate
- ☐ has a physical location and operates in an appropriate central fabrication setting
- ☐ has a full time employee onsite who maintains a nationally recognized certification as an orthotist, prosthetist, pedorthist, technician or assistant in the discipline(s) of the services the business provides
- ☐ has no individual with ownership interest on the Office of Inspector General (OIG) exclusion list
- ☐ has met the *Central Fabrication Accreditation Standards*
- ☐ has a minimum of 10 customer records
- ☐ has designated at least one individual to be in charge of accreditation and compliance and that you have also assigned a back up contact
- ☐ is compliant with the Americans with Disabilities Act (ADA), Occupational Safety & Health Administration (OSHA) regulations, Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules and US Department of Labor Safety Data Sheets (SDS)
- ☐ is able to disclose the full listing of ownership (any individuals or parties holding more than 5% of controlling interest) or provide the list of your board of directors or trustees



# ONSITE SURVEY

Once you are confident that you have met the eligibility criteria, it's time to prepare for your onsite survey. The following information will help you prepare your records and facility for your surveyor.

The checklist is organized by standard to help you reference each item in the Central Fabrication Accreditation Standards.

This is not a complete list and is not intended to replace your thorough knowledge and understanding of the standards. Now would be a good time to re-read the standards and make sure that you are familiar with what your survey will encompass. This checklist is intended to highlight some of the areas that tend to be overlooked during preparation for the accreditation process.



## ORGANIZATION (OG)

The following items are **required** for your business and your surveyor will physically check that you are in compliance with the following. You should have all necessary documents organized and available for the surveyor to review.

- ☐ Articles of Incorporation, or other documents establishing legal formation of the company such as your business license (if applicable.) (OG1)
- ☐ Current Certificates of Occupancy and Inspection, as required by your state or local regulations. Examples may include, but are not limited to a business license from your city or county, zoning or occupancy permit, sales tax license, fire department permit or registration with the FDA, if applicable. (OG4)

- ☐ A written Policies and Procedures Manual that illustrates how your business's activities are executed. (OG5)
- ☐ You have a mission statement for your business and it is part of your policy manual as well as available in your facility and/or posted on your website. (OG6)
- ☐ You have documentation of your business leadership roles. (OG7)
- ☐ There is documentation that you have complied with the applicable sections of the Americans with Disabilities Act (ADA). (OG8)
- ☐ Business has a dedicated laboratory consistent with services offered. (OG10)



## BUSINESS RECORDS (BR)

The Business Records Standards address the establishment of policies and procedures related to business operations:

- ☐ Policies and procedures on business operations that are available to staff. Examples may include, but are not limited to, standard operating procedures and employee handbooks. (BR1)
- ☐ Accounting Policies (operating budgets, revenue and expense tracking, other documents that show your ability to manage the financial aspects of the business). (BR2)
- ☐ A written plan that demonstrates the actions you have taken to secure your records and also allows for quick retrieval. (BR3)
- ☐ A method to meet the requirements of the Healthcare Insurance Portability and Accountability Act (HIPAA). (BR4)
- ☐ You can demonstrate that your records will not be jeopardized due to disasters and that you have a back-up plan to recover records. (BR5)

## RECORD KEEPING (RK)

Your surveyor will look to validate that you have appropriate record keeping. They will check to



make sure you have the following:

- ☐ A written policy that explains your procedure for creation, storage and maintenance of records, including, but not limited to, how job or work orders are created, records are entered into the tracking system, records are updated during the fabrication process and how records are securely stored. (RK1)
- ☐ Records that include all communications with customers, such as change orders. (RK2)
- ☐ Records that include detailed descriptions of the item/device fabricated and the components incorporated. The detailed descriptions may include, but are not limited to, work orders, type of device, materials used, components used and fabrication timeframes. (RK3)
- ☐ Documentation proving that you have a system to track devices that were provided to customers. (RK4)
- ☐ A procedure for providing the customer with an expected time frame for delivery of requested items/devices. (RK5)
- ☐ Documentation that each item/device meets the manufacturer's guidelines or other specifications prior to delivery. (RK6)



## HUMAN RESOURCES (HR)

Your surveyor will review the following human resource items:

- ☐ Your policy explaining the requirements and personnel qualifications for your employees, including detailed job descriptions, required certifications and/or licenses as applicable, required experience and continuing education requirements. (HR1)
- ☐ Proof that your business is staffed with a certified individual in the discipline(s) that you provide services during your hours of operation. (HR2)
- ☐ Documentation that you have provided orientation and training to your staff on all of your facility procedures. (HR3)
- ☐ Verification that your staff's credentials and state licenses are checked annually to ensure that they are current and in good standing. (HR4)
- ☐ Documentation that you conduct an annual review of each staff member's job performance. (HR5)



## WARRANTY AND RECALL (WR)

Your surveyor will check to make sure policies and procedures are in place that cover the following:

- ☐ Item/device failures and product recalls. (WR1)
- ☐ Your response in the event that a customer reports an item/device failure. (WR2)



- ☐ Data collection procedures related to item/device failures and how you respond to product recalls. Data may be collected from the following: customer work orders, complaints, visual defects or employee feedback. Your policy needs to include how you will identify and notify all customers affected by the recall. (WR3)

You will also need to show the surveyor that your business has policies in place to provide your customers with the following information:

- ☐ Warranties and care instructions for items/devices. (WR4)
- ☐ Proof that all items from outside sources were obtained without fraud or deceit. (WR5)
- ☐ Disclosure in the event that any used components, not supplied by the customer, are incorporated in any items/devices. This may be through labeling on the item/device or direct communication with the customer. (WR6)



## **SAFETY & EQUIPMENT (SE)**

You will need to make sure that you are in compliance with the following items related to the safety of your employees and equipment.

- ☐ You have a written safety management program that describes the procedures you have taken to reduce risk of injury. (SE1)
- ☐ Your annual safety inspections have been conducted, evaluated and any necessary corrective actions were taken. (SE2)
- ☐ Documentation that all employees receive safety management orientations. (SE3)
- ☐ You have a procedure in place for the appropriate cleaning of your facility and equipment. These procedures should include staff training, even if you use an outside cleaning service. (SE4)
- ☐ You have a process for training your staff on appropriate hazardous waste disposal procedures, including federal, state and local requirements. (SE5)
- ☐ You have an established Emergency Evacuation Plan for fires and emergency situations. (SE6)
- ☐ You have conducted an emergency evacuation drill for all staff members, including those working different shifts. Fire suppression and/or alarm systems testing was included, if applicable. (SE7)
- ☐ You have a written evaluation of the effectiveness of your emergency evacuation drill. (SE8)
- ☐ Your Disaster Preparedness Plan is designed to manage the consequences of natural disasters. (SE9)
- ☐ If you have any specialized emergency equipment on your premises, such as an Automatic External Defibrillator (AED), you must provide documentation that your staff has been trained in its use. (SE10)
- ☐ Your facility's no smoking policy is posted. (SE11)
- ☐ You have implemented an equipment management program that includes inventory and maintenance training for staff. (SE12)
- ☐ You have documentation of the training you provided to appropriate staff on the safe use of equipment. (SE13)

- ☐ Your equipment maintenance includes an inventory of all equipment and a log to identify the maintenance of each item. (SE14)
- ☐ Your written policies and procedures address occupational exposure. (SE15)
- ☐ You maintain a current file of Safety Data Sheets (SDS). (SE16)
- ☐ Your cross contamination risk policy documents the proper handling of items that have come in contact with a patient. (SE17)
- ☐ You have a written policy that addresses the use of Personal Protective Equipment (PPE). (SE18)



## QUALITY ASSURANCE (QA)

Every business must have an effective quality assurance plan. The following items should be included in your plan.

- ☐ A written assurance program that examines and evaluates the quality of the services you provide. (QA1)
- ☐ You have a method to collect, record and measure data in order to identify fabrication errors. (QA2)
- ☐ Written analyses of shipping and billing error trends that you use to make corrections to your processes and procedures. This analysis needs to be written and maintained in an appropriate file. (QA3)
- ☐ Documentation that you have employee participation when assessing the qualities of your business operations. (QA4)
- ☐ Corrective/preventative actions are documented when identified. (QA5)



## CUSTOMER SATISFACTION (CS)

Your surveyor will be looking for your customer satisfaction survey process.

- ☐ You have created and implemented a customer satisfaction survey that includes, but is not limited to, questions addressing satisfaction with the quality of services, resolution of complaints and timeliness of response to the customer. (CS1 & CS2)
- ☐ All returned surveys have been documented, evaluated and the outcomes are reviewed at least annually. (CS3)



## OTHER REMINDERS

### Outside your Facility

Take a close look at your building entrance—look for the following:

- ☐ Handicapped spaces in your parking lot are clearly indicated.
- ☐ Hours of operation are posted and visible from the exterior of the building.

### Inside your Facility

Make sure that the following documents are posted and easily accessible:

- ☐ Business License
- ☐ Sales and Use Tax permit (when required)
- ☐ Each Individual's Certification and/or License
- ☐ Emergency Numbers
- ☐ Automatic External Defibrillator (AED), if applicable and other medical emergency instructions
- ☐ Fire Evacuation Maps

## Laboratory Area

In your lab area your inspection will include, but is not limited to, the following:

- ☐ Current file of Safety Data Sheets (SDS)
- ☐ Personal Protective Equipment (PPE) is in use for all appropriate staff
- ☐ Fire exit instructions are clear, concise and visible
- ☐ Your equipment is properly maintained
- ☐ Your no smoking policy is posted in a visible area



### WHAT YOU CAN EXPECT FROM THE ONSITE SURVEY

Your survey will be scheduled with you in advance. Upon arrival, your surveyor will identify that they are from ABC and will present you with their photo identification badge.

## Initial Interview

First, you'll have a brief interview with your surveyor.

You can expect the surveyor to:

- Discuss the purpose of the survey and go over the schedule
- Answer any questions you may have about the survey process
- Determine the general layout of the facility

## What your Surveyor Will Do

To verify that you have met the requirements of ABC's Central Fabrication Standards, your surveyor will look at and focus on the following items and areas:

- Your business's Policies and Procedures Manual
- Personnel files
- Accounting and bookkeeping records
- Contracts with vendors
- Fire and emergency evacuation plans
- Customer satisfaction surveys and survey analysis
- Information on device delivery times
- Employee interviews

## Closing Interviews

After your survey has been completed, your surveyor will brief you on their findings and make any suggestions for overall improvement.

- You will have plenty of opportunity to clarify or submit any information that may not have been available during the survey.
- Your surveyor may have suggestions that could help you comply with the standards; this is your chance to talk to the surveyor one on one. Please take notes as this is a great opportunity to discuss your survey findings with the surveyor.
- Your surveyor does not know whether you passed the survey or not and is not permitted to discuss your specific results.

All significant recommendations and deficiencies will be discussed with you. The final Survey Report will be sent to you from ABC.

For additional information about the Central Fabrication Accreditation program, please don't hesitate to email [accreditation@abcop.org](mailto:accreditation@abcop.org)



**Thank you for choosing  
ABC for your accreditation  
program!**



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