

Central Fabrication Accreditation PRE-APPLICATION

checklist



Thank you for choosing
ABC's Central Fabrication
Accreditation program.
We've created this checklist
to help you prepare for
the accreditation process.
Be sure to review this list
before applying.

Use this handy
checklist, along
with the standards
and tips, for a thorough
understanding of the
program!



**American Board for Certification in Orthotics,
Prosthetics and Pedorthics, Inc.**

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Eligibility Criteria

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) List of Excluded Individuals/Entities
- meets 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 as well as 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 is able to 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 the 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 helpful tips to 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.



Onsite Survey Checklist

Organization (OG) The following items are required for your business and your surveyor will physically check your compliance. 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' activities are executed. (OG5)
- A mission statement for your business that is part of your policy manual, available in your facility and/or posted on your website. (OG6)
- A list of the individuals who perform leadership functions. (OG7)

- Documentation to show that you have complied with the applicable sections of the Americans with Disabilities Act (ADA). (OG8)
- 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 allows quick retrieval. (BR3)
- A method to meet the requirements of the Healthcare Insurance Portability and Accountability Act (HIPAA). (BR4)
- Ability to 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 by checking 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)



Scan the code to find out more about

ABC Central Fabrication Accreditation.

Human Resources (HR) Your surveyor will review the following human resource items:

- A policy explaining the 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) for which you provide services. (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)



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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 must have:

- A written safety management program that describes the procedures you have taken to reduce risk of injury. (SE1)
- Conducted and evaluated annual safety inspections and taken corrective actions as necessary. (SE2)
- Documentation that all employees receive safety management orientations. (SE3)
- Procedures for the appropriate cleaning of your facility and equipment. These procedures should include staff training, even if you use an outside cleaning service. (SE4)
- A process for training your staff on appropriate hazardous waste disposal procedures, including federal, state and local requirements. (SE5)
- An established Emergency Evacuation Plan for fires and emergency situations. (SE6)
- 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)
- A written evaluation of the effectiveness of your emergency evacuation drill. (SE8)
- A Disaster Preparedness Plan designed to manage the consequences of natural disasters. (SE9)

- Documentation that your staff has been trained to use any specialized emergency equipment on your premises, such as an Automatic External Defibrillator (AED). (SE10)
- A posted no smoking policy. (SE11)
- An implemented equipment management program that includes inventory and maintenance training for staff. (SE12)
- Documentation of the training you provided to appropriate staff on the safe use of equipment. (SE13)
- Equipment maintenance that includes an inventory of all equipment and a log to identify the maintenance of each item. (SE14)
- Written policies and procedures that address occupational exposure. (SE15)
- A current file of Safety Data Sheets (SDS). (SE16)
- A cross contamination risk policy that documents the proper handling of items that have come in contact with a patient. (SE17)
- 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 must be included in your plan.

- A written assurance program that examines and evaluates the quality of the services you provide. (QA1)
- 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 look at your customer satisfaction survey process. Be sure that:

- 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)



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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

The inspection of your lab area will include, but not be limited to assessing that:

- Your file of Safety Data Sheets is current (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 able 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 call us at 703-836-7114 or email cfab@abcop.org

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