

MedAccredSM

Administered by PRI



What you need to know about MedAccred



PERFORMANCE REVIEW INSTITUTE

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MedAccred is an industry managed supplier quality accreditation program focusing on critical manufacturing processes whose goal is to improve the quality and consistency of medical devices. The MedAccred Program is managed by PRI, the Performance Review Institute, a not-for-profit organization. MedAccred has been modeled on the highly regarded Nadcap program that provides accreditation of critical process suppliers in the aerospace industry.

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MedAccred Overview

In today's world of global manufacturing, manufacturers are increasingly dependent on outsourcing, making supply chain oversight challenging and costly. Like other rapidly expanding, high volume industries defined by safety and quality, the Medical Device Industry demands the highest level of assurance for Supplier critical processes.

MedAccred is a cost-effective, industry-managed oversight program of providers of critical manufacturing processes to the medical device industry that reduces risk to patient safety and assures product quality by addressing many of the challenges posed by today's global, multi-tiered supply chain.

Why has MedAccred been created?

Issues affecting product quality and patient safety are faced by all sectors of the Medical Device Industry and are well documented.

Below are examples of supplier quality issues affecting the medical device industry:

- Increased number of recalls attributed to Supplier quality issues
- Globalization of the supply chain and enhanced interest in outsourcing has increased the challenges of providing effective oversight
- Purchasing control has consistently been one of the top ten most frequently cited FDA 483 observations for Medical Device quality system violations
- Purchasing controls have been the target of several enforcement actions (warning letters, consent decrees)

To prevent product failures, critical processes must be identified and evaluated to determine their impact on finished devices, and to ensure they meet quality requirements, industry standards and the requirements and specifications of the original equipment manufacturer (OEM).

Through MedAccred, the medical device industry has joined forces to develop a program that:

- Establishes stringent industry-consensus audit criteria that incorporate robust industry standards and OEM requirements
- Replaces the need for routine Supplier audits conducted by many OEMs with one comprehensive audit program that has been developed and managed by industry participants and seasoned subject matter experts (SME) using a consensus approach to decision-making
- Generates in-depth, robust, technically superior, critical process audits by SMEs
- Drives Supplier quality improvements throughout the industry
- Reduces costs through improved standardization and the need for redundant audits at suppliers of critical processes
- Provides improved oversight of the critical process providers in the supply chain for OEMs and reduces the need for individual critical process audits at these suppliers

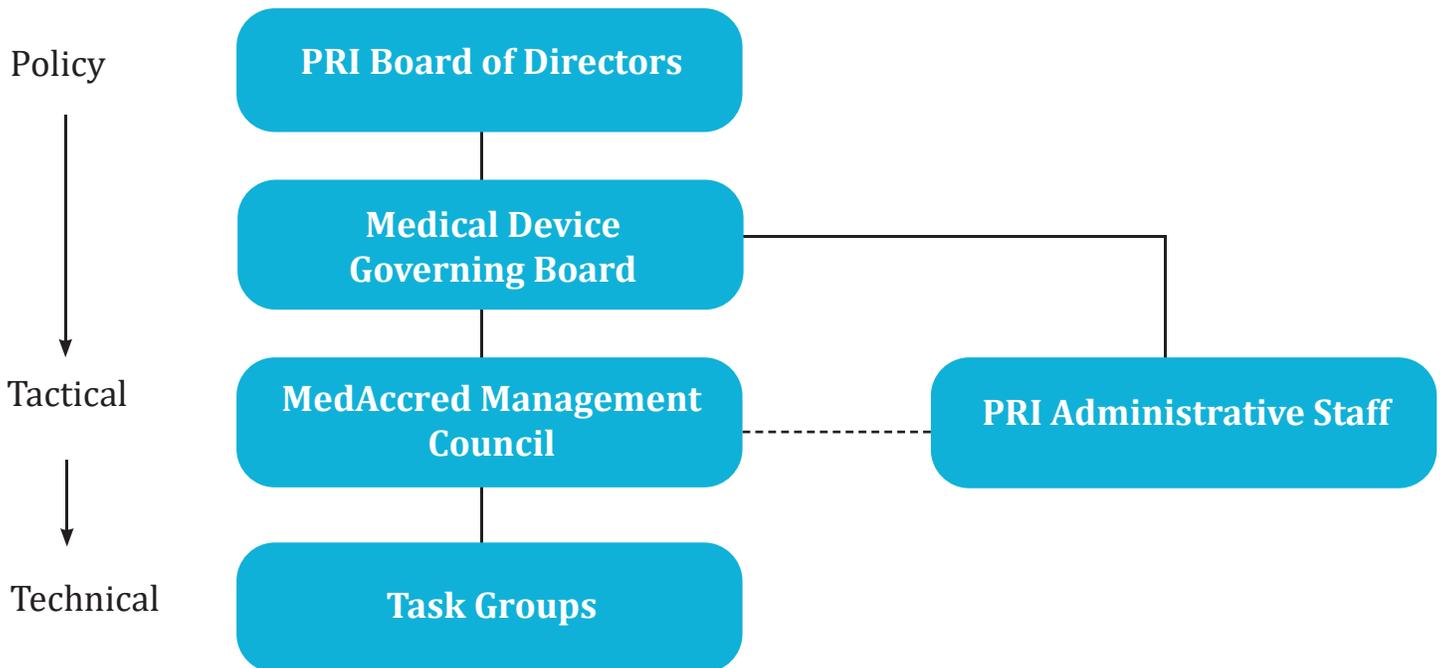
How does one participate in the MedAccred program?

One may actively participate in the MedAccred program at three different levels, either as a member of the Medical Device Governing Board (responsible for making policy decisions), MedAccred Management Council (managing the program operations) or by sharing your technical expertise by participating on one of the various Task Groups. MedAccred members generally fall within the following defined categories:

Subscriber: A Manufacturer or Specification Developer of a finished medical device who subscribes to the MedAccred information and accreditation services which is subject to a Subscriber Agreement and; is accountable for conformance to critical manufacturing process specifications and; receives a product or service from a Supplier. Subscribers shall be granted Subscriber Voting/Alternate Voting Membership on the Task Group to which they subscribe in addition to the MMC.

Supplier: A company which performs/provides a critical manufacturing process and/or service and; is subject to a Supplier Agreement and; is currently/will have, one or more critical manufacturing processes accredited by MedAccred. Suppliers may be granted Supplier Voting/Alternate Voting Membership in Task Groups.

MedAccred Organization Structure



MedAccred Benefits

Benefits for OEM Subscribers:

- Establishes stringent industry consensus audit criteria based on industry standards and specific OEM requirements that ensure quality and compliance of devices
- Provides greater visibility of the supply chain at all levels of the supply chain including sub-tier providers that provide critical processes to subscribing OEMs, consistent with regulatory requirements
- Reduces product recalls by having greater confidence in the quality of critical processes and reduced risk of exposure to lower-quality suppliers
- Provides early warning notification to OEMs of potential critical process capability issues observed during audits
- Frees up OEM resources to focus on supplier development opportunities and/or problem area resolution
- Improves flow down of OEM requirements to sub-tier suppliers
- Provides an efficient supplier selection process by identifying potential suppliers that are accredited by MedAccred
- Facilitates global supply chain visibility through an online listing of quality critical process providers (Qualified Supplier Listing - QSL)
- Supports subscribing OEM supplier risk management strategies
- Shared pool of trained, recognized and approved SMEs supporting the subscribing OEMs

Benefits for Suppliers:

- Provides consistent/standardized critical process audits accepted by the medical device industry resulting in need for fewer redundant onsite audits by multiple OEMs
- Enhances the quality of the products and services provided
- Establishes industry expectations about the quality and consistency of products and services provided
- Achieving MedAccred accreditation should result in increased client base and improve opportunities across the medical device industry
- Provides medical device industry-accepted and consistent technical requirements leading to process discipline, greater operational efficiency and continuous improvement resulting in higher quality and lower overall cost.
- Helps suppliers develop a structured approach to special processes and products
- Opportunity to provide input in development of audit criteria and the accreditation program

Critical Processes, Products and Systems Currently Audited by MedAccred

Cable and Wire Harness	Contact Julia Markardt, Staff Engineer T: +1 724 772 8649 E: jmarkardt@p-r-i.org
Heat Treating Metal Systems (Carbon & Alloy Steel / Tool Steel / Stainless Steel / pH Steel/ Cast Iron / Aluminum Alloys / Titanium Alloys / Heat Resisting Alloys / Other Nonferrous Metals) Heat Treating Processes (Normalizing / Annealing / Hardening & Tempering / Solution & Aging / Carburizing / Nitriding / Stress Relieving) Heat Treating Equipment (Furnace / Pyrometry / Instrumentation / Atmospheric Control/Quench Systems/Refrigeration) Brazing (Vacuum Brazing / Atmosphere Brazing)	Contact Marcel Cuperman, Senior Staff Engineer T: +1 724 772 8678 E: mcuperman@p-r-i.org
Plastics Injection Molding Extrusion Molding	Contact Justin McCabe, Senior Specialist Business Development T: +1 724 772 8693 E: jmccabe@p-r-i.org
Printed Circuit Board Assembly	Contact Julia Markardt, Staff Engineer T: +1 724 772 8649 E: jmarkardt@p-r-i.org
MedAccred Quality Systems	Contact Susan Frailey, Staff Engineer T: +1 618 615 4478 E: sfrailey@p-r-i.org
Sterilization Radiation (Gamma & E-Beam) Ethyleneoxide	Contact Mark Aubele, Senior Program Manager T: +1 724 772 8654 E: maubele@p-r-i.org
Welding Electron Beam Welding Fusion Welding (i.e. GTAW, PAW etc) Laser Welding	Contact Ian Simpson, Associate Program Manager T: +44 (0) 1332 869 272 E: isimpson@p-r-i.org

Lessons to be learned from the aerospace industry

This is an extract from an article by Bob Hill, President, Solar Atmospheres of Western PA which was first published by Today's Medical Developments in May 2014. Solar Atmospheres also works in aerospace and holds Nadcap accreditation.

Heat treatment standards are stricter in the aerospace industry than in the medical industry where lives are on the line. This doesn't make sense and something is being done about it.

Recently, I was asked to give a vacuum heat-treating presentation to a group of design engineers at a large medical device company. The lead engineer asked if I would help educate his team on this subject primarily because they had just experienced a major failure caused by improper heat treatment.

After learning more about the failure, it became evident that the medical device engineers in that room could learn a great deal from the aerospace industry, especially regarding knowledge of aerospace materials and secondary aerospace processes. It also became apparent that an industry-managed oversight program addressing the technical competency required in special processing was necessary in order for medical device companies to improve design and manufacture of future medical devices.

Nadcap (formerly National Aerospace and Defense Contractors Accreditation Program) is the organization in the aerospace industry that helps establish strict industry, prime contractor, and regulatory standards and enforces compliance with those standards. Nadcap's mission is to improve supply chain quality and conformity within the aerospace industry.

In today's world of global manufacturing, organizations increasingly find they must rely on effective supply chains or networks of specialized suppliers in order to compete. Supply chains and their management have grown and become increasingly complex over the years. With that growth comes many internal challenges. Suppliers conform to technical quality standards is one of the most important.

To that end, we are glad to hear of the establishment of MedAccred by the same organization that manages Nadcap, the Performance Review Institute in Pittsburgh, Pa. Solar Atmospheres of Western PA has been involved from the very early stages and any reputable heat treater desiring to process medical parts should sit up and take notice. We believe this type of certification is healthy for the industry and we wholeheartedly support the effort.

For medical device manufacturers, I suggest a more thorough understanding of heat-treat standards and the MedAccred program. This type of standardization will be helpful to the manufacturer, vendors, and end users.

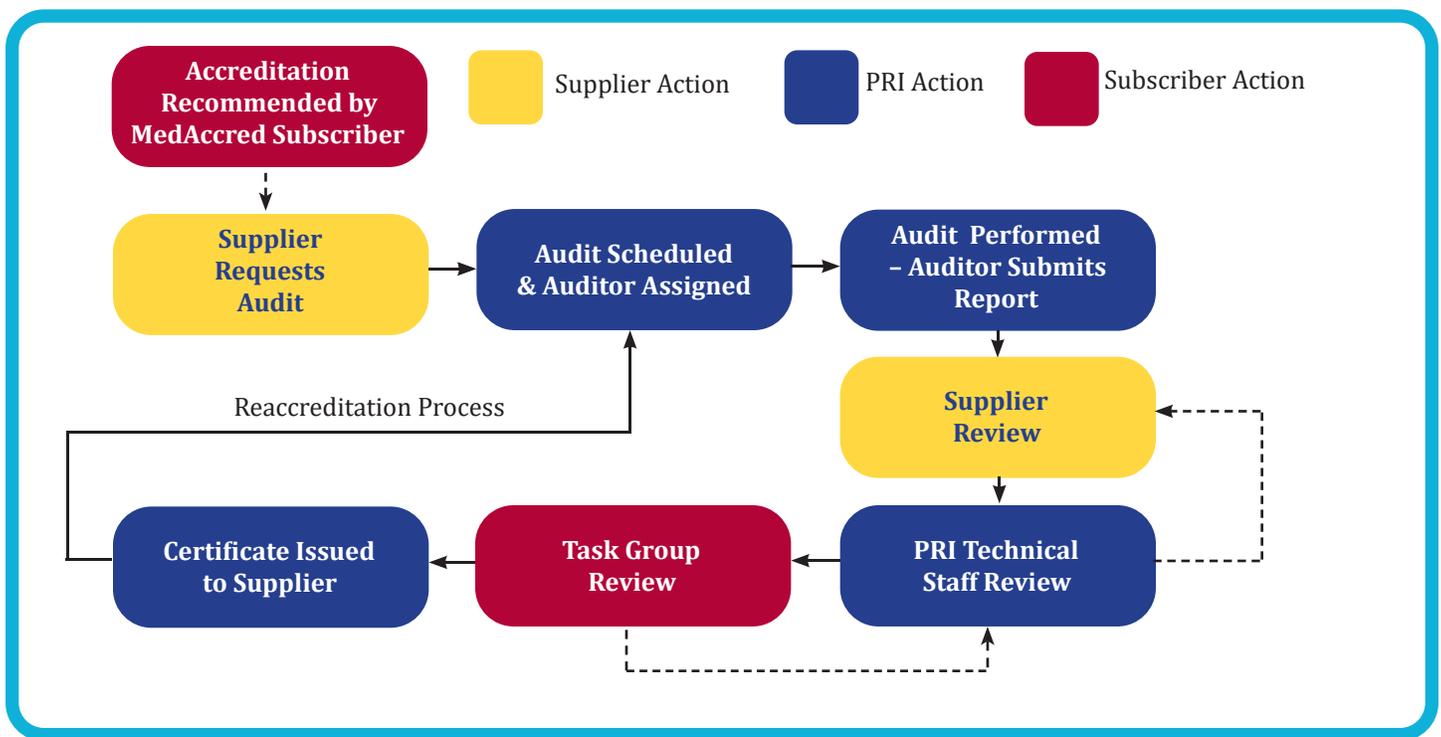
Who administers MedAccred?

The MedAccred program is administered by Performance Review Institute, the same not-for-profit organization that has administered the Nadcap program, for 25 years, for the global Aerospace industry. Nadcap has been extraordinarily successful for the major aerospace companies involved and their suppliers who have gained Nadcap accreditation. Many achieve technically superior quality levels and report a range of benefits from reduced scrap and rework to increased sales, productivity and customer satisfaction. The long-term goal for the MedAccred program is to replicate this success for the medical device manufacturing industry.

MedAccred Audit Flowchart

The MedAccred audit and accreditation process typically begins with a notification from a customer (an OEM subscriber to the program) to the Supplier that they should attain accreditation, although some suppliers may choose to pursue MedAccred accreditation without prompting.

The Supplier contacts the Performance Review Institute to request the audit, which is scheduled according to the timeframe and content expectations of the Supplier and the customer. An appropriately qualified auditor is assigned. MedAccred auditors are subject matter experts with extensive experience in their field and are contracted after a rigorous selection process with input and approval from OEM subscribers.



After the audit, a report is submitted electronically via eAuditNet, the proprietary audit software program used by MedAccred. The Supplier has an opportunity to respond to any non-conformances identified in the report, and those responses, are evaluated and reviewed by the relevant Performance Review Institute Staff Engineer.

When the Staff Engineer is satisfied that the root cause of all non-conformances has been identified and sustaining corrective action has been implemented, the entire report is submitted to the critical process Task Group. This body of MedAccred subscribers, who are also experts in the critical process, verify the conclusion of the Staff Engineer and approve the audit for accreditation.

At any stage, the Staff Engineer or Task Group may request more information before progressing the audit to the next stage.

MedAccred Reaccreditation

MedAccred accreditation is an ongoing activity. Once initial accreditation has been issued, the next audit is usually automatically scheduled. Once the audit has been scheduled, notification is sent via email to the Supplier and the assigned auditor. Suppliers should check as soon as possible if the scheduled dates are not suitable and contact the Performance Review Institute if they need to be changed.

Initial accreditation is based on a twelve-month cycle. However, the actual period of initial accreditation depends on audit performance. For example: if the initial audit takes place on 1 January 2013, the expiry date of the accreditation will be 30 April 2014 - regardless of when accreditation is actually granted.

eAuditNet Overview

eAuditNet is a web-based system that maintains everything relating to MedAccred audits. The biggest benefit of eAuditNet is the reduction in operating costs for the industry:

- eAuditNet eliminates paperwork
- eAuditNet facilitates real-time interaction, regardless of location or time - it is available 24 hours per day, 365 days per year
- All stakeholders share responsibility in the knowledge that eAuditNet provides the structure to function efficiently and effectively

Suppliers use eAuditNet extensively: from requesting a quote for an audit to scheduling an audit; from carrying out thorough audit preparation to responding effectively to non-conformances after the audit in order to gain accreditation promptly.

eAuditNet houses many useful documents to help you navigate the MedAccred process: User Guides, Tutorials, and other helpful Supplier documents. Just complete the free registration at www.eAuditNet.com and go to the Documents application under Resources.

In addition, eAuditNet also contains the online Qualified Suppliers List (QSL), which is a searchable database of certified MedAccred Suppliers. Procurement can use the QSL to research and contact MedAccred accredited potential Suppliers.

Is Your eAuditNet Profile Up To Date?

Please keep your contact details up-to-date on eAuditNet to ensure you receive important information regarding your audit. Please notify Performance Review Institute of any changes.

Frequently Asked Questions

Q: Should my company get MedAccred accreditation?

This is a key question and it's really one that must be resolved between you and your customer/s. Most Suppliers pursue MedAccred accreditation because it has been recommended by their customer/s, although some make the decision independently. It is up to you to balance the needs of your customer/s and your business with the demands of the MedAccred audit.

Q: If my company decides to become MedAccred accredited, what do we do next?

The first step is to contact Performance Review Institute Scheduling staff to request the audit. They will give you access to eAuditNet so you can access the relevant audit checklists and associated reference material to help in your audit preparation. They will also provide you with a quote detailing the audit duration and cost.

It is recommended that you conduct a self-audit using the MedAccred audit checklist/s. Where any non-conformances are found, the root cause(s) should be identified and addressed via sustaining corrective action. When you feel you are prepared - or you are confident in the timeline you have established for your audit preparation - please contact the Performance Review Institute to arrange the initial audit.

Q: How long does MedAccred accreditation last?

Initial accreditation lasts for twelve months, with the opportunity to extend that to eighteen months based on audit performance, after three audits.

Q: Are the rules governing the MedAccred audit process published anywhere?

Yes, the rules governing MedAccred are detailed in PD1300, which is available on www.eAuditNet.com under Resources >Documents >Procedures and Forms >Program Documents.

Q: Are there are any opportunities to have training in preparation for a MedAccred audit?

Yes, PRI offers training courses to medical device industry critical process suppliers through the eQuaLearn Program. These courses are used as tools to improve personnel quality and critical process manufacturing capabilities. Courses are held around the world in multiple languages by instructors who are industry experts with hands-on technical experience.

Course content can be customized to meet individual company needs and is available in a range of formats from public sessions, to onsite sessions customized for delivery at company facilities, and webinars. Current course offerings include quality related courses which provide an understanding of key quality principles such as: Root Cause Corrective Action – MedAccred style, Internal Auditing, Statistical Process Control and Problem Solving Tools. There are also MedAccred Audit Preparation courses that provide in-depth training on specific technical areas, such as Pyrometry - Heat Treating.

Getting Started

For most companies and individuals new to the MedAccred process, or who want to learn more about it, the Scheduling department is the first point of contact. The staff listed below can answer all your general questions and identify the right person for you to talk to when you have technical questions.



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Access eAuditNet as soon as you can for useful guidance in the Resources section and to download the audit checklists.

Tips from PRI Staff Engineers



The audit is a comprehensive assessment for compliance to customer requirements - make sure you understand your customers' expectations and ask questions if you are unsure.



Conduct a self-audit using the MedAccred audit checklists before scheduling the audit - this will help you work out how much you need to do before the auditor arrives.



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