January 13, 2017

To Whom It May Concern at the National Institute of Standards and Technology

Subject: MEP Competitive Awards Program RFI Responses

This note is in response to a request for information pertaining to

1. **Critical manufacturing technologies;**
2. **Supply chain requirements;**
3. **Potential business services, including information services; and**
4. **Other technologies or services that would enhance global competition.**

In today's world of global manufacturing, supply chain oversight is challenging and costly. Like other rapidly expanding, high volume industries defined by safety and quality, the Medical Device and Instrument Industry demands the highest level of assurance for supplier critical processes. MedAccred is an industry managed accreditation program for critical process manufacturing operations throughout the medical device and instrument supply chain. MedAccred has been modeled on the highly regarded **National Aerospace and Defense Contractors Accreditation Program (Nadcap)** that provides accreditation of critical process suppliers in the aerospace industry.

Participants in the MedAccred program consist of medical device and instrument OEMs, contract manufacturers and suppliers who work together to develop industry-wide audit criteria and provide accreditation of critical manufacturing process suppliers to improve product quality. The MedAccred program is administered on behalf of the medical device industry by the Performance Review Institute (PRI) http://p-r-i.org/ , a not-for-profit affiliate of SAE International, which also administers the Nadcap program. As the Accrediting body, it is a conflict of interest for PRI to assist companies in audit preparation. The Performance Review Institute believes that MEP Centers are a good fit for helping prepare suppliers for the MedAccred Accreditation audit. Due to the in-depth process knowledge level required in each critical process category, a regional approach of MEP support may be the best solution.

Recently, interest in the program to move to industry self-accreditation has received high level attention at the Food and Drug Administration, Office of Compliance. They are preparing to fully support this initiative as FDA seeks to reduce the public sector load on site based compliance monitoring.

Supply Chain Requirements

The need is to assist the supply chain of this $135 billion industry consisting of over 17,000 businesses with exports of over $35 billion annually (source: IBISWORLD) to establish the technology platforms, process capabilities and resident skills to achieve external accreditation of critical manufacturing technologies. Cost to change the supply chain base is high; accreditation is recognized as a barrier to supply base disruption, a requirement for entry and also allows companies to better secure their supplier and customer relationships. Exports have historically also been strong, as the US has been the global center for Innovation for this industry. However, overseas competition is aggressively pursuing this business due to profitability, as well as taking advantage of detrimental domestic tax policies (2.3% federal excise tax) that reduce US supply chain competitiveness. Therefore, foreign based companies are aggressively pursuing accreditation as part of their strategy to capture share in the USA. A significant loss of domestic share in the markets are forecast, without a substantial change in US supplier competitiveness. Clearly, domestic supply chains offer significant advantages in terms of lead time, innovation and on time performance. MedAccred enables those companies to also provide a preeminent position regarding quality of product supplied, a major factor contributing to total cost of ownership and supplier selection.

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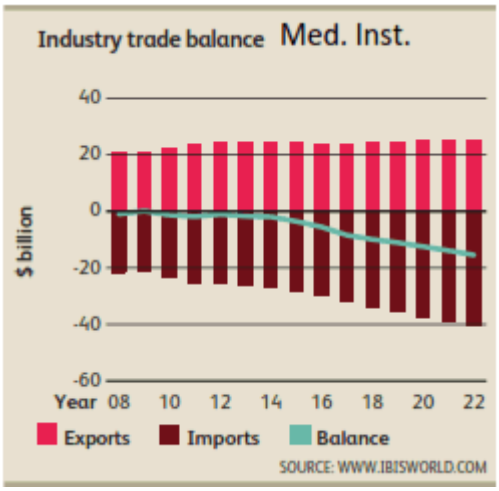

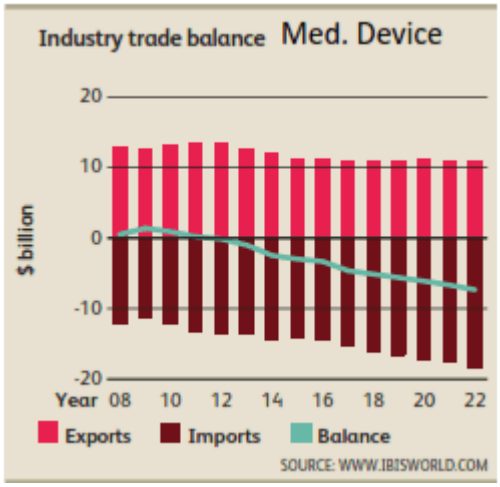

Critical Manufacturing Technologies

Similar to Nadcap, critical manufacturing process technologies have been identified for accreditation.

Active MedAccred Critical Process Technologies include:

Cable & Wire Harness
Printed Board
Printed Circuit Board Assemblies
Heat Treating
Pyrometry
Metallography and Micro-indentation Hardness
Hardness & Conductivity Testing
Plastics – Extrusion
Blown Film
Co-Extrusion
Film
Over-Jacketing
Ram Extrusion
Sheet
Tubing/Profile
Plastics - Injection Molding
Compression Molding
Injection Blow Molding
Insert Molding
Micro Molding
Over-molding
Transfer Molding
Sterilization
Ethylene oxide
Radiation (Gamma & E-Beam)
Welding
Fusion Welding
Laser Welding
Resistance Welding
Welding Operator Qualification

In order to prevent output deficiencies, **critical processes** must be validated in order to prove that they are fit for purpose, satisfy regulatory requirements and reduce patient and business risk. A critical process compliance audit

differs significantly from an audit for general quality or for compliance to an ISO standard. Where other industry standards look at general quality across an entire facility, MedAccred zeros in on very specific processes (e.g. heat treatment, welding, and sterilization) and brings in experts in those fields to ensure suppliers know exactly what they are doing, and operating in a way that meets industry, customer and regulatory requirements. Similar to the development of quality management systems such as ISO, critical process accreditation requires subject matter experts to guide companies in meeting the requirements established for a particular critical process.

Potential Business Services

The MEP system including GENEDGE already serves this market with about 5% penetration, but not in this manner. The market and the domestic economy would be well served by establishing an MEP supply chain of technical subject matter experts to assist companies in preparing for accreditation. The service offering would include assessment of current state and technical assistance to develop a **Compliant Critical Process Technology within a supplier manufacturing business.** The implementation would be critical process specific, and prepare the supplier to successfully undergo an accreditation audit and maintain that accreditation.

MEP system medical device and instrument clients are portrayed in the following exhibit:

Enhancing Global Competitiveness for Domestic Supply Chains

As MedAccred quickly accelerates in the market due to the 1) direction of the industry, 2) the support of the FDA and 3) individual company mandates to comply, the timing for an initiative to enhance US Medical Device and Instrument supply chains could not be better. This is an opportunity for the MEP system to enhance the competitiveness of a critical US industry and better position the industry to thrive in a domestic and global market. GENEDGE has expressions of interest to participate in a regional model from the following MEP centers / sub-recipients. The intent would be to develop a business services set of offerings and a MEP supply chain service center to support MedAccred process accreditation across the entire US.

Centers Expressing Interest in MedAccred Services Delivery

GENEDGE (Lead)
NC State IES
Georgia Tech Enterprise Innovation Institute
Florida Makes
TMAC
CMTC
Purdue University MEP
Enterprise Minnesota
Wisconsin Center for Mfg. & Productivity
Michigan Manufacturing Technology Center
Catalyst Connection
MassMEP
NJMEP

We greatly appreciate your interest in considering this innovative opportunity to enhance a significant manufacturing industry supply chain in the United States.

Best Regards,

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