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January 13, 2017

To whom it may concern:

In response to the Request for Information on Identification of New Capabilities Needed by the Hollings Manufacturing Extension Partnership Program, I would like to provide input that I believe would aid small and medium-sized manufacturers who make up the medical device, instrument, and supply industry in the United States. I believe these recommendations would aid medical device manufacturers in the areas of critical manufacturing capabilities; supply chain requirements and optimization; potential business services; and other services that would improve their ability to supply in the competitive global marketplace.

There is a need for U.S. medical device manufacturers, including medical instrument and supply manufacturers, and their supply chains to increase their critical process capability and maturity in order to acquire new business and not be shut out for years to come due to strong global competition. According to IBISWorld, the U.S. medical device, instrument, and supply industry has over 17,000 businesses and generates an annual revenue of over $130 billion. Since 2012, the marketplace has become more competitive globally and Medical Device exports have dropped while imports have increased. In Medical Instruments and Supply, exports have remained flat while imports have increased. Future projections continue this trend.

In 2010 cross industry benchmarking by a major medical device OEM identified potential benefits in product quality and improved patient safety by using medical device suppliers that undergo critical process accreditation similar to what is required in the aerospace Nadcap program. Leading global companies in the medical device industry developed the MedAccred program in concert with Performance Review Institute, the not-for-profit that administers the Nadcap program. MedAccred is an industry driven critical process accreditation program for the medical device industry supply chain to improve product quality and enhance patient safety. The MedAccred program awarded its first accreditation in 2015 and in 2016 continued with a number of supplier accreditations, including accreditations in U.S., China, Mexico, and throughout Europe.

Several large medical device OEMs plan to require MedAccred Accreditation to help determine their future business awards for new products. Due to the rigorous FDA approval process, once business is awarded, an OEM tends to keep business with the approved supplier. Therefore, suppliers who delay pursuing and achieving MedAccred Accreditation will face a significant disadvantage in the marketplace. Suppliers around the globe are beginning to achieve MedAccred Accreditation, placing any supplier who does not have MedAccred Accreditation at a significant disadvantage. It is vital that U.S. medical device suppliers become MedAccred accredited in order to not be shut out of new business opportunities.

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The NIST MEP system is in a unique position to be able to support the U.S. medical device supply base with training of critical process supplier personnel, preparation for MedAccred Accreditation, resolution of MedAccred audit findings, and continued critical process validation support, positioning the supply base to be stronger and more competitive in both the U.S. and global marketplaces.

Additional members of the Medical Device Industry including medical instrument and supply manufacturers, and their supply chains are in the process of drafting submissions but will not be submitted before the deadline.

Sincerely,

Joseph G. Pinto
Chief Operating Officer and Executive Vice President

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