March 7, 2011

National Institute of Standards and Technology USA Department of Commerce SOS_RF@NIST.gov

Subject: GE Healthcare Comments

Standardization Feedback for Sub-Committee on Standards

Federal Register notice – Request for information [75 FR 76397 (Dec. 8, 2010)]

GE Healthcare provides these comments in response to the Request for Information published in the *Federal Register* on December 8, 2010 (75 FR 76397).

GE Healthcare appreciates the opportunity to provide input on important issue of federal agency participation in aligning Health Information Technology to be consistent with national priorities, the National Technology Transfer and Advancement Act, the OMB Circular A-119 and the American Recovery and Reinvestment Act. GE Healthcare encourages NIST and other involved regulatory federal agencies to more strongly coordinate their activities while continuing to endorse the use of consensus-based standards. In this regard, we urge NIST to consider the observations regarding federal coordination of and involvement with standards development contained in the comments for this Request for Information submitted by the HIMSS Electronic Health Record Association.

The participation of NIST scientists and experts in the application of connectivity standards for medical device data has benefited that process and the use of standards. For example, the NIST ITL SSD has worked closely with the members of the IEEE 11073 and IHE Patient Care Devices communities. By providing test tooling in a transparent and consensus-based approach, NIST's participation enhances the value of existing standards such as ISO/IEEE 11073 and promotes vendor adoption of that standard. This activity also promotes international standards that can be used in multiple markets.

The last section of our comments focuses on the exemplary collaboration between the NIST ITL Software and Systems Division (SSD) Interoperability Group and the Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD) domain.

NIST ITL SSD and IHE Patient Care Devices Domain

Our comments refer to the following group within NIST:

National Institute of Standards and Technology (NIST) Information Technology Laboratory (ITL) Software and Systems Division (SSD) Interoperability Group

and specifically to the NIST IHE-PCD HL7 V2 Test Effort, led by John Garguilo and Lisa Carnahan:

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The NIST ITL SSD Interoperability Group has worked closely with the Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD) domain to develop test tools and databases that support rigorous conformance testing of HL7 V2.6 messages that convey near real-time medical device data to and from a hospital EMR using the IHE PCD Device Enterprise Communication (DEC) Technical Framework.

The NIST tooling has played an essential role in the IHE PCD effort, since it has been used for Pre-Connectathon, Virtual-Connectathon and Connectathon testing for the past several years. The NIST tooling integrates the widely used HL7 Messaging Workbench with the ISO/IEEE 11073 Medical Device Communications nomenclature and domain information model to provide a rigorous yet easy-to-use testing framework that is now a foundational part of our testing.

NIST has also developed the *Rosetta Terminology Mapping Management System* (RTMMS) that provides a repository of harmonized medical device terms plus associated co-constraints (e.g. units-of-measure, enumerated values, measurement sites, etc.) and is currently used by all vendors participating in the IHE PCD domain.

The NIST test tools and the RTMMS provide an HL7 V2.6 message testing framework facilitate *comprehensive and rigorous message validation*. Participation of NIST further legitimizes the use of open standards for sending medical device date to the EMR in a 'plug-and-play' manner that will benefit our industry, our customers and ultimately the patients we serve.

NIST IHE-PCD HL7 V2 Test Effort Specific Recommendation

The NIST IHE PCD HL7 V2 test effort is a major project that requires a *long-term commitment* by NIST as well as the vendors and standards organizations. Developing and updating the underlying IEEE and HL7 standards can take several years, followed by a multi-year deployment by vendors. Thus, funding period for NIST work in this area should be extended to at least ten years to ensure the availability of state-of-the-art test tools and supporting databases. The longer funding period will encourage vendors and other standards organizations to participate in making the NIST tooling the cornerstone of their testing methodology, to the benefit of all.

Respectfully submitted,

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