UL and AAMI to Develop Interoperability Standards

Underwriters Laboratories

With the goal of improving patient safety and healthcare efficiency, AAMI and UL (Underwriters Laboratories) are joining forces to develop a suite of standards on medical device interoperability-one of the biggest challenges facing the modern healthcare community.

The collaboration is a first for AAMI and UL, and comes at a time when many healthcare facilities and manufacturers are grappling with how to achieve interoperability. In its broadest terms, interoperability has the potential to improve patient care by enabling clinicians to work with integrated systems of diagnostic and therapeutic devices and sharing data with electronic health records (EHRs), thus providing enhanced clinical-decision support safely and effectively.

"Interoperability is a huge space still under development," said AAMI President Mary Logan. "It will take multidisciplinary commitment and collaboration to achieve meaningful management of the space and the issue."

That is why AAMI and UL have signed a memorandum of understanding to develop the suite of consensus-based standards, which will be drafted to help manufacturers design safer interoperable products and aid healthcare facilities in implementation.

"This suite of standards is not intended to replace or supplant existing interoperability implementation standards or profiles," said Dr. Terenzio Facchinetti, Business Development Manager for UL Life and Health Business Unit. "This family of standards instead aims to map existing implementation practices into a risk management framework and to address further safety issues where applicable."

AAMI, a globally recognized standards development organization, and UL, a prominent testing, certification, and standards development organization, are well suited for the task, said Carol Herman, AAMI senior vice president for standards policy and programs.

"What makes this particular collaboration between AAMI and UL unique is that we each have deep experience with medical devices, and yet the two organizations bring different expertise to the table, so that the sum truly will be greater than the parts," Herman said.

UL, which writes standards on products such as video cameras and tests new medical devices for manufacturers, believes safety is paramount to success in the emerging interoperability market.

"The medical device interoperability sector is a new development with extraordinary

expectations. Its success is linked to the quality and the safety of the products and their interoperability. This agreement will support the achievement of these targets," Robert Williams II, Vice President of standards, and Anil Patel, Vice President of the Life and Health Business Unit at UL, said in a joint statement.

For more information on the development of interoperability standards, contact AAMI's Carol Herman at cherman@aami.org [1] and UL's Terenzio Facchinetti at Terenzio.Facchinetti@ul.com [2].

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[1] mailto:cherman@aami.org
[2] mailto:Terenzio.Facchinetti@ul.com