UP TO EXCELLENT STANDARDS!

Dr Fergal Mc Caffery is the Leader of the Medical Device Software Engineering Competency Group in Lero and Director of the Regulated Software Research Centre (RSRC) at Dundalk Institute of Technology (DkIT). The RSRC has a strong commitment to the development and evolution of international standards, in relation to both generic software engineering and medical device software development. Over the past year, this commitment has led to the development of many new standardised international technical reports

Although time consuming to develop, the publication of each of these standards represents an important contribution to the international standards community. It is through standards such as these that the role of IT in medical IT networks and medical devices is safer, more secure and more efficient. As an example, the publication of IEC/TR 80002-3 provides a process reference model for the general medical device software process lifecycle standard, IEC 62304. This enables the evaluation of the capability of software producers with respect to IEC 62304, thus supporting the difficult task of unifying generic software engineering best practice with medical device software specific best practice. Specifically in this case, the IEC/TR 80002-3 process reference model will enable the consistent assessment of software process capability in line with the ISO/IEC 15504 standard (to be replaced by the ISO/IEC 33000 series). This is potentially a very important step forward for medical device software development, where there is presently an acknowledged difficulty in consistent assessment of software process capability.

Another area with a recognised difficulty relates to the ever increasing numbers of medical devices that are available for connection into medical IT networks, even within a single hospital. With hundreds and even thousands of individual devices now connected to IT networks, the task of connecting devices has become much more complex. Guidance such as is found in IEC/TR 80001-2-7 provides a framework for evaluating the risk of attaching a new medical device to a new or existing network, thus reducing the impact of service delivery on the network as a whole.

The RSRC often take the lead on the development of new standards authoring texts entirely. Getting a standard or technical report published can be a lengthy process, involving the engagement of many dozens of national representatives, and finally presenting and representing the texts such that a successful international voting outcome can be reached. However, once published, the standards and technical reports can play a vital role in the establishment of better organisation and practice in the day to day technology challenges faced by the medical device and healthcare sectors.

It is the ambition of the RSRC to continue to work closely with the international standards community to develop and evolve new techniques for advancing the effectiveness of IT in the medical device and healthcare sectors. This important role raises the profile of Ireland in the international standards development space. It demonstrates our excellence in the area of publishing standards, therefore supporting the case for continued investment in Ireland, as an international centre of excellence, in the software development and medical device software arenas.


lero
THE IRISH SOFTWARE
RESEARCH CENTRE