Real-Time Consensus Knowledge Sharing through 'Nuggets'

Previous articles for this department have focused on new standards and updates to existing standards and have been good at keeping people up to date with changes that might affect them. However, this article is going to step back a bit and discuss some of the challenges and a possible solution to real-time knowledge sharing—through the communication of quickly developed information “nuggets.”

Traditionally, we have two methods for delivering consensus knowledge: standards and technical information reports (TIRs). Standards deliver a set of requirements and are developed by consensus, where different stakeholders, including competitors and regulators, come to agreement on their expectations around a particular process or product. We also create TIRs as a way to capture consensus knowledge. A TIR provides guidance—not requirements—on a particular topic and can be developed faster than standards. Recognizing that things change over time, standards and TIRs are periodically reviewed and new projects are started when updates are needed.

Standards and TIRs take several years to create because their scope often is very broad and considerable time is needed to develop content, review, resolve comments, and iterate until sufficient consensus is achieved. The lag between when the knowledge is available and when it can be published is considerable.

Our world is moving much faster and is a lot more complex than it was in the past. As with any change, some early adopters have learned things the hard way and are willing to share their experiences and advice with others. However, we don't have an appropriate communication mechanism for these bits of knowledge. This undocumented knowledge base grows incrementally, one small piece at a time.

What if we have a real-time method to share this consensus knowledge? John Murray, expert regulatory review scientist at the Food and Drug Administration’s Center for Devices and Radiological Health and co-chair of the AAMI Software and Information Technology (SWIT) committee, recognized a need for information “nuggets” that can be shared with the broader community.

These nuggets would be much shorter than a standard or TIR and could be developed quickly by a small team. Their scope would be very focused on a particular, bite-sized topic, and would share the experiences of the team with the broader community. A collection of these nuggets could eventually trigger the development of a new or updated standard or TIR, but their primary goal would be to disseminate better healthcare, and individuals exist who are willing to share their experiences and advice with others. However, we don't have an appropriate communication mechanism for these bits of knowledge. This undocumented knowledge base grows incrementally, one small piece at a time.

The communication of “nuggets” would be a means of quickly disseminating information related to emerging technologies that can be leveraged to provide better healthcare.
information as quickly as possible. Sharing these timely insights with the device community would mean that not everyone is required to start from scratch or “reinvent the wheel.”

During recent SWIT committee discussions about potentially updating AAMI TIR36:2007, *Validation of software for regulated processes,* it was suggested that this document should be updated to address cloud services—something that many companies are dealing with currently but simply wasn’t an issue when TIR36 was initially created. The SWIT team supported the update, but also thought that a paper on cloud services would be an interesting nugget-article—possibly for publication right here in Bi&T.

Three volunteers (John Murray; Mike Attili, owner of the consulting firm Amaxo Inc.; and myself) offered to create an article on “things to consider when adopting cloud services.” We endeavored to complete the article within three months and for it to be no more than 10 pages. We also identified some volunteers to review and advise us on developing the paper.

We are definitely learning as we go. As we develop the article, new ideas come up. We debate whether the new topic should be included in the nugget, if the nugget should be larger and spread over two consecutive articles (e.g., parts 1 and 2), or if it would be better to have a series of nuggets, where each article stands alone but cloud services remain the common theme.

Hopefully, this work on nuggets also will help jump-start the update to TIR36, and we could potentially reuse or repurpose some of the content originally developed for the article(s). In agile software development, there is the concept of a “backlog” listing of features that are waiting to be implemented. We think that a similar mechanism can work for real-time content generation and knowledge sharing. We want to write more nuggets—we think that a strong need exists for information sharing that doesn’t fit within the traditional standard or TIR paradigm.

Although the SWIT committee has a few ideas for potential nuggets, we’d appreciate any thoughts you, the reader of this article, might have. What gaps do you see? What emerging topics would be helped by a short article and might eventually evolve into a TIR or a standard? Wil Vargas, a director of standards at AAMI, has graciously volunteered to collect these suggestions; he can be reached at wvargas@aami.org.

**Reference**