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This technical information report (TIR) provides additional guidance to augment the ANSI/AAMI/ISO 11135 series. Topics covered in this TIR are sterilization equipment, considerations for preconditioning, calculations for relative humidity, calculations of ethylene oxide concentration, and flammability

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AAMI Water Quality for Medical Device Reprocessing Working Group This technical information report (TIR) was developed by the AAMI Water Quality for Medical Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee.

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The TIR explains how to map the IEC 62304 activities described in sections 5.x with the levels of agile methods. A diagram in the TIR sums-up the mapping. This diagram is probably the best way to begin with agile methods in a regulated environment. Discipline. As agile coaches say, agile methods need discipline.

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He is a senior member of ASQ, corporate AAMI member (serving on several AAMI committees) and a RAPS member. Mark has spent the last several years as an active member of ISO Technical Committee 210 (TC210), Working Group 1 (WG1) working on the revision of ISO 13485 that was published on March 1, 2016, was the project co-lead for the guidebook on ...

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