

Intent to Process Provisional (ANS) American National Standards

AAMI Announcement of Intent to Process the following Provisional American National Standards ANS (PS) in accordance with Annex B of the ANSI Essential Requirements (www.ansi.org/essentialrequirements)

AAMI/HIT1000-1, Safety and effectiveness of health IT software and systems — Part 1: Fundamental concepts and principles

AAMI/HIT1000-2, Safety and effectiveness of health IT software and systems — Part 2: Application of quality systems principles and practice

AAMI/HIT1000-3, Safety and effectiveness of health IT software and systems — Part 3: Application of risk management

AAMI/HIT1000-4, Safety and effectiveness of health IT software and systems — Part 4: Application of human factors engineering

There is an urgent need for standards addressing fundamental principles of safety and effectiveness for Health IT software and systems. Authorities have recognized the specific need for standards on applying quality systems, risk management and human factors engineering in this domain.

AAMI has previously announced the development of these American National Standards, but their issuance as Provisional Standards is warranted due to the urgency of the need and to allow the standards to be implemented on a trial basis so that feedback from users in the field can be considered and incorporated as they are advanced for full American National Standards Status.

The intent is to complete the development and issue these documents as Provisional Standards over the next 6 to 9 months.

For more information about the standards or how to participate in the work, please contact Joe Lewelling at jlewelling@aami.org.