Standard for the Integrated Clinical Environment (ICE)

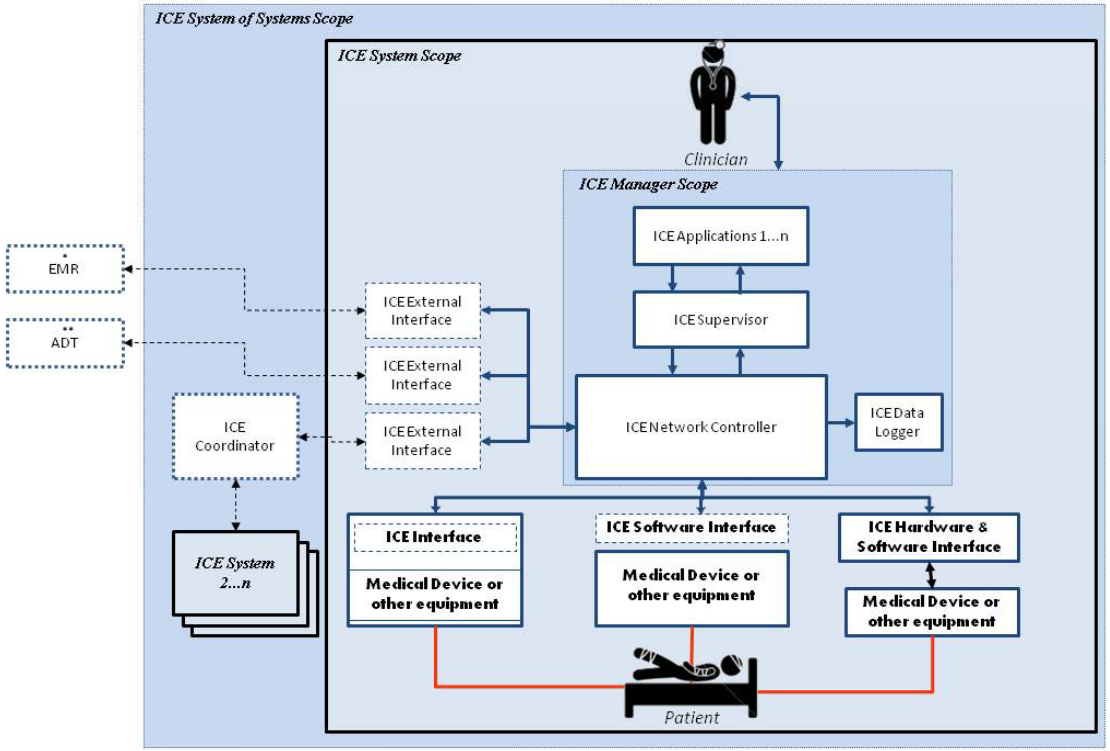
ASTM F2761-09: Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) Part 1: General requirements and conceptual model

The "Patient-Centric Integrated Clinical Environment" (ICE) standardization activity was initiated in 2006 by ASTM International, committee F29, based on foundational work performed by the MD PnP program and collaborators at interdisciplinary meetings convened to identify key capabilities of a patient-centric integrated clinical environment. These capabilities, such as comprehensive data acquisition for the EMR and the integration of devices to enable real-time decision support, safety interlocks, and closed-loop control, can be achieved through the functions described in a series of standards for the Integrated Clinical Environment.

The ICE standard specifies general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE), including:

- The characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single patient
- Requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices
- Requirements for design, verification, and validation processes of a model-based integration system for an Integrated Clinical Environment

ICE Functional Architecture



*Electronic Medical Record
** Admission/Discharge/Transfer

From ASTM F2761-09

ICE standardization activity is now under the auspices of ASTM Subcommittee F29.21, "Devices in the Integrated Clinical Environment," chaired by Dr. Julian Goldman. ICE Part I has been published as F2761-2009 and can be purchased from ASTM International at www.astm.org.