

Comments on Standards NPRM—Joan Ash (Author) and Liz Johnson  
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In a report to ONC June 2011, HITPC identified certain “desired outcomes of improved usability” including improved safety and reduced cost, clinician frustration, training time, and cognitive load for clinical and non-clinical users alike.

The justification for the safety related foci states that the proposed changes were recommended in the November 2011 Institute of Medicine report on HIT safety. Two major changes are a requirement for documentation of user centered design use throughout development of any system and similar documentation indicating that standard quality criteria for software development were followed.

**For the UCD documentation requirement:**

Pros: solid principles exist and are well described for UCD; the list of 8 high priority areas of risk is excellent; this provides a focus on HIT safety for awareness and educational purposes; it makes the process transparent; it provides a good foundation for future requirements for usability; and it places a low burden on vendors.

Cons: it does place some burden on vendors; it leaves out other areas of high risk; there is no quality measure for either the UCD process or the documentation itself; and it may not go far enough in that safety specifications are not defined directly.

**For the documentation of the quality assurance for software requirement:\***

Pros: increases awareness for educational purposes; provides transparency; offers a good foundation; places a low burden on vendors.

Cons: places some burden on vendors; the document guiding developers is not yet available; no measure of the quality of the process or the documentation is required; it may not go far enough in that actual quality process steps are not required.

\*Consideration for 2014 Certification Standards

**Ability to generate a file for reporting EHR patient safety events to a PSO\***

Pros: would allow and encourage users to report these events; would allow aggregating reports across the country so good data could be collected.

Cons: the burden on vendors is unknown; the burden on users is unknown.

\*This functionality is being suggested for comment in the NPRM