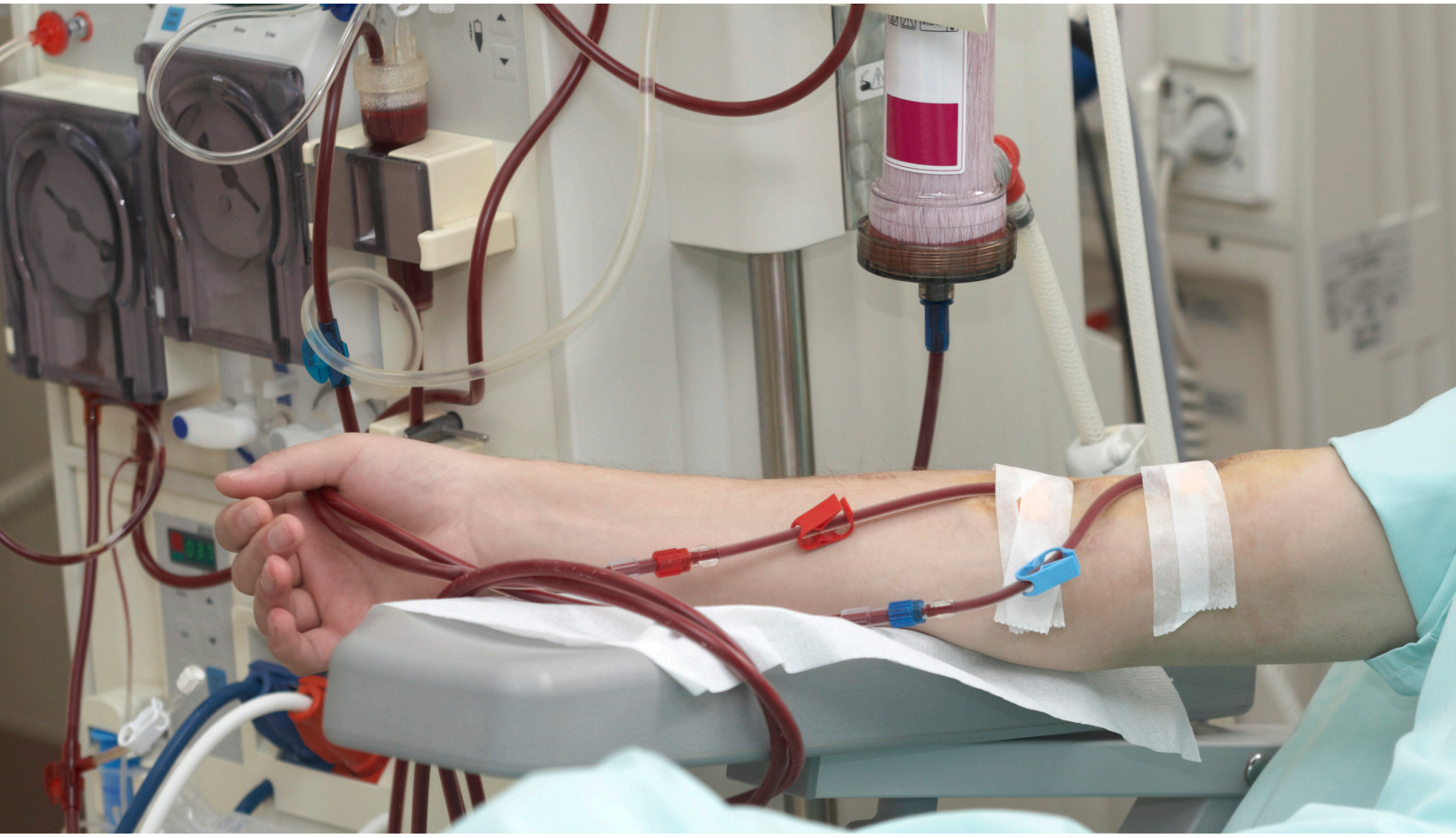
COMPARISON OF IEC 62366-1:2015 AND IEC 62366:2007+AMD1:2014 - THE MAJOR DIFFERENCES

EXECUTIVE SUMMARY

The publication of the internationally harmonized usability standards IEC 62366-1:2015[1] and IEC TR 62366-2:2016[2] replaces the prior edition of the usability standard, IEC 62366:2007+AMD1:2014[3] . The new IEC 62366-1 describes a contemporary usability engineering process that is somewhat streamlined compared to the previously prescribed one. The new standard strengthens links to ISO 14971:2007[4] and the risk management methods related to safety-related aspects of medical device user interfaces. While we are unable to share direct excerpts of the documents due to copyright limitations, the following provides a clause by clause explanation of the changes.



[1] IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices

[2] IEC TR 62366-2:2016 Medical devices - Part 2: Guidance on the application of usability engineering to medical devices

[3] IEC 62366:2007+AMD1:2014 Medical devices - Application of usability engineering to medical devices

[4] ISO 14971:2007 Medical devices - Application of risk management to medical devices

Clause 1: Scope

The standard calls for the root cause analysis of use errors with increased rigor and with a focus on severity of any potential harm(s) that the errors could cause. As such, the focus subtly shifted from meeting discrete acceptance criteria to reaching the point that a manufacturer is confident that the level of residual risk is acceptable.

Clause 2: Normative references

The changes are largely editorial in nature and are intended to clarify how referenced standards are applied. The only normatively referenced standard is ISO 14971:2007, which remains unchanged from the preceding standard.

Clause 3: Terms and definitions

Several definitions have been added, modified, or deleted from the preceding standard's set. For example, the definition of primary operating functions now includes only those functions related to safety, removing reference to frequently used functions. In effect, this change might eliminate the need to test certain primary operating functions (as defined in the prior edition) that are not safety-related. As such, individual definitions must be reviewed in detail.

Clause 4: Principles

This clause clarifies the linkage between IEC 62366-1 and both ISO 13485[5] and ISO 14971. For example, IEC 62366-1 now states:

> *"Where a documented product realization PROCESS exists, such as that described in Clause 7 of ISO 13485:2003..., it shall incorporate the appropriate parts of or reference the USABILITY ENGINEERING PROCESS"; and also*
> *"...the interrelationship between the RISK MANAGEMENT PROCESS of ISO 14971:2007 and the USABILITY ENGINEERING PROCESS described in this standard is shown in Figure A.4."*

Note also that the third edition of ISO 13485[6] added further references to usability throughout the standard, strengthening the linkages even further. As such, it is appropriate to review any Quality Management System and Risk Management System procedures to ensure that product realization process linkages are established and documented, and that the Usability Engineering Process performed complies with applicable requirements.

[5] ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes

[6] ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Clause 5: Usability Engineering Process

The new standard clarifies the elements contained in a "Use Specification" as compared to a "User Interface Specification" and both terms are new ones, replacing the arguably confusing terms "Application Specification" and "Usability Specification," respectively.

Now, "Frequently used functions" need consideration only when they are safety-critical, such as when a function must be performed frequently for the device to be effective. Note that some countries may still require compliance with the preceding version of the standard, so it might be desirable to retain the reference to frequently used functions for an appropriate period of time.

User interface characteristics related to safety must now be identified, similar to the ISO 14971 requirement to identify product characteristics related to safety. Primary operating functions and user interface characteristics related to safety are then considered in the course of identifying potential use errors and scoping the summative (i.e., validation) usability test.

The preceding standard only required consideration of "Frequent Use" and "Worse Case" scenarios. However, the new standard explicitly calls for the identification and consideration of "Hazard-Related Use" scenario. This new term is broader than "Frequent Use" and "Worse Case" scenarios, resulting in the potential need for additional scenarios to be described, documented, assessed, and validated. Note that if a subset of the hazard-related use scenarios is selected for summative testing, justification for choosing the subset must be documented in the usability engineering file.

Regarding the user interface evaluation plan, the new standard explicitly calls out elements to be included in both formative (if applicable) as well as summative evaluations. Test protocols are expected to cover and indicate due consideration of elements such as the following:

- Participant selection in accordance with the identified, distinct user groups
- Training (withheld, delivered, or both)
- Learning decay period between (1) training and (2) device use in a usability test session
- Simulated environment equivalency to the actual environment
- Data collection approach and tools
- Post-test analyses to be performed on such data as use errors, close calls, difficulties, anecdotal comments, including responses to interview questions.

Regarding products that move past planning and into actual design and implementation, the standard strongly suggests that developers conduct iterative formative evaluations to refine and ultimately optimize the user interface. The new standard reinforces the need to follow ISO 14971 to address other hazards or hazardous situations that may be discovered through iterative formative evaluations and resulting user interface design changes.

The requirements for summative evaluations reference and incorporate many of the new concepts introduced throughout the standard. Importantly and as mentioned above, the standard no longer calls for the establishment of discrete acceptance criteria. Instead, it calls for practitioners to perform intense root cause analysis of all interaction problems (e.g., use errors, close calls, difficulties) that could lead to harm. IEC 62366-2 in particular encourages developers to hold users blameless for observed interaction problems and, instead, search for user interface design-related causes. This Technical Report Guidance anticipates that developers will call upon a multidisciplinary team to determine if interaction problems that persisted in the validation usability test pose an acceptable or unacceptable level of residual risk. If the finding is acceptable, then the developer will likely want to freeze the given product's design and seek regulatory approval for it. If the finding is unacceptable, the product's design is likely to require modification, which could involve changes to hardware, software, labeling, packaging, and/or training.

Throughout the usability engineering process as prescribed by IEC 62366-1, there is a steady focus on use-related risk reduction. There is a high expectation that developers will use multiple approaches to identify potential use errors, which could number in the hundreds for even simple products; that developers will develop user interface designs that are as inherently safe as possible; that developers will then implement additional protections (e.g., guards, warnings, labels, instructions for use, training) that are as effective as possible at preventing use errors that cannot be eliminated in a more fundamentally effective manner; and that developers will validate that users can complete essential and safety-related tasks without experiencing egregious interaction problems that pose an unacceptable residual risk.

CONCLUSION

IEC 62366-1 describes a usability engineering process that is comprehensive and requires the investment of considerable resources and time, but is regarded to be an excellent means to lower the risk of device-user interaction problems that could lead to harm. The new standard has much in common with the human factors engineering (HFE) guidance issued by the US FDA and, as is true with its predecessor, we expect global regulators to leverage the work and expertise of those who updated the standard. In a future article, we will explore the similarities and differences between the IEC 62366 standard and the FDA's HFE guidance documents in more detail.

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