**14971 Status**

One common question is when the various versions of 14971 take effect. This is a complicated question with three aspects: regulatory regions, standards bodies, and regulators.

**International**

Standards Bodies

The standards body is ISO. The international standard is ISO 14971:2019 which replaces the withdrawn ISO 14971:2007. As far as I know, ISO does not have a formal transition period.

Regulator

This is not a regulatory region; there are no regulators.

**US**

Standards Bodies

The standards body is ANSI, which is a collection of standards bodies. The US standard is ANSI/AAMI ISO 14971:2019 which supersedes ANSI/AAMI ISO 14971:2007. As far as I know, neither ANSI nor AAMI has a formal transition period.

Regulator

The regulator is FDA and it is easier to divide their activities into two parts: pre-market submissions and inspections.

*Premarket Submissions*

Premarket submissions allow the use of a declaration of conformity. FDA will accept declarations of conformity, in support of premarket submissions, to ISO 14971:2007 or ANSI/AAMI 14971:2007 until December 25, 2022.

Some devices are eligible for third-party submissions. The FDA approach should apply.

*Inspections*

QSR inspections by FDA Investigators check the risk management requirements in design control. QSR does not require either version of the standard. However, a declaration of conformity for the pre-market submission would obligate the manufacturer to implement the standard.

FDA accepts reports from MDSAP AOs. Individual AOs may have their own policy on transition. See the section on Canada for a discussion the MDSAP Companion Document.

**EU**

Standards Bodies

The standards body is CEN (European Committee for Standardization). The EU standard is EN ISO 14971:2019.

CEN is composed of national standards organizations that publish the standard adding a prefix. For example, NSAI (National Standards Authority of Ireland) publishes I.S. EN ISO 14971:2019.

The Date of Withdrawal, the last date by which national standards conflicting with EN ISO 14971:2019 is June 30, 2020.

Harmonized Standards

The EU has a system of harmonized standards that provide a legal presumption of conformity with the Annex I requirements of the directive or regulations. The Official Journal publishes the list of harmonized standards for each directive or regulation. It also includes the “Date of cessation of presumption of conformity of superseded standard” For the MDD, for example, Note 1 says, “Generally the date of cessation of presumption of conformity will be the date of withdrawal, set by the European standardization organization, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise”.

EN ISO 14971:2019 is not harmonized to any directive or regulation. Following Note 1, the presumption of conformity to EN ISO 14971:2012 ends on June 30, 2020, the Date of Withdrawal. However, the lack of harmonization raises a question.

Regulator

In the EU the *de facto* regulator is the Notified Body. The NB performs the roles of evaluating the pre-market submission, performing the initial audit, and conducting follow-up audits. The NBs seem to have different policies. Some require harmonized standards only while others require the current EN standard only. The situation of the MDR without harmonized standards is not clear.

**Canada**

Standards Body

The standards body is CSA (Canadian Standards Association). As of Jan. 23, 2019, CSA has not published a Canadian version of ISO 14971:2019.

Regulator

In Canada the regulator is Health Canada. They publish the List of Recognized Standards for Medical Devices. The current version does not include the new version of 14971.

Inspections

MDSAP AOs conduct inspections. The current *Companion Document* lists ISO 14971 without a revision. This means that the AO should accept any version of ISO 14971 implemented by the manufacturer.