Expert commentary

PD CEN ISO/TR 24971:2020 — *Medical devices – Guidance on the application of ISO 14971*

Jos van Vroonhoven, Philips, The Netherlands, convener of the ISO/IEC Joint Working Group on the application of risk management to medical devices

bsi.

...making excellence a habit.™

1 Overview

1.1 Reasons for change

The first edition PD ISO/TR 24971:2013 provided some guidance on selected clauses of BS EN ISO 14971:2007, *Medical devices – Application of risk management to medical devices*. Since the standard needed a revision, it was decided to revise the guidance report in parallel. This work has resulted in the publication of BS EN ISO 14971:2019 and PD CEN ISO/TR 24971:2020. Publishing the requirements and the guidance in separate documents enables updating the guidance with the latest experiences while keeping the requirements in the standard unchanged.

1.2 Summary

The second edition PD CEN ISO/TR 24971:2020, *Medical devices – Guidance on the application of ISO 14971*, provides extensive guidance on all clauses of BS EN ISO 14971:2019. The report follows the same structure and clause numbering as the standard. The requirements in the standard and the guidance in the report are intended to be applied together. Several annexes of BS EN ISO 14971:2007 have been moved to the report, merged with the guidance of the first edition PD ISO/TR 24971:2013, restructured, updated and supplemented with additional guidance. The informative annexes in the report cover special topics and specific aspects of risk management, namely:

A. Identification of hazards and characteristics related to safety
B. Techniques that support risk analysis
C. Relation between the policy, criteria for risk acceptability, risk control and risk evaluation
D. Information for safety and information on residual risk
E. Role of international standards in risk management
F. Guidance on risks related to security
G. Components and devices designed without using ISO 14971
H. Guidance for in vitro diagnostic medical devices

This commentary focuses on the guidance in the report, while the expert commentary on BS EN ISO 14971:2019 provides an explanation of the changes in the requirements of the standard. Background information on the risk management concepts underlying ISO 14971 is provided in the BSI white paper, *Risk management for medical devices and the new ISO 14971* (Van Vroonhoven, 2019).

The next sections explain more about the guidance given in PD CEN ISO/TR 24971:2020, especially on:

- risk management policy defined by top management;
- identification of hazards and hazardous situations and estimation of associated risks;
- risk control and benefit-risk analysis;
- evaluation of overall residual risk;
- production and post-production activities;
- the informative annexes.

2 Main commentary

2.1 Risk management policy defined by top management

Subclauses 4.1 and 4.2 explain the responsibilities of top management, in particular in defining an appropriate policy and a suitable and effective process for risk management. The policy is important for establishing adequate criteria for risk acceptability based on applicable regulations, international standards, the generally acknowledged state of the art, and stakeholder considerations. These criteria and the risk management process ultimately determine the safety of the medical device.

The relation between the policy, the criteria for risk acceptability, the risk control measures and the risk evaluation are explained in detail in Annex C (see also Section 2.6 below). This annex gives examples of elements that can be included in the policy, and how those elements can relate to the criteria for risk acceptability and to performing risk control and risk evaluation. It needs to be emphasized that the policy and the criteria are much broader than only a risk matrix based on the severity and probability of occurrence of harm. The requirements in BS EN ISO 14971 regarding the policy and the criteria for risk acceptability have not changed with the new edition of the standard. However, since experience has shown that some manufacturers overlooked the need to define and document a suitable policy for risk management, this guidance is included in PD CEN ISO/TR 24971:2020.