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INTERNATIONAL ELECTROTECHNICAL COMMISSION

TECHNICAL COMMITTEE Nº 62: ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

SUBCOMMITTEE 62A; COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

Questionnaire

National Committee feedback needed regarding risk management process in the revision of IEC 62304, *Health software – Software life cycle processes* – Due by 14 December 2018

Background

The scope of the first edition of IEC 62304 was medical device software (i.e. both Software that is incorporated into a medical device (SiMD, software in a Medical Device) or that is intended for use as a medical device (SaMD, software as a Medical Device).

IEC/SC 62A – ISO/TC 215/JWG7 has been tasked with extending the scope of IEC 62304 2nd Edition to include all health software, such as HIT software and wellness apps that are not medical devices.

The new stakeholders of this document, caused by the scope expansion, bring different experiences and opinions on risk management.

Many traditional medium and high risk medical device manufacturers desire ISO 14971 be used for risk management in the development of the health software. Some may view not requiring ISO 14971 as 'watering down' the standard. Low risk (or no risk) HIT software manufacturers may have no interest in using what they consider to be the burdensome process of ISO 14971, and would like to pursue more flexible methods of risk management.

The following are definitions of terms used herein:

1. Harm - injury or damage to the health of people, or damage to property or the environment [SOURCE: IEC Guide 51:2014, 3.1]

2. Hazard - potential source of harm [SOURCE: ISO/IEC Guide 51:2014, 3.2]

3. Hazardous situation - circumstance in which people, property or the environment is/are exposed to one or more hazards [SOURCE: IEC Guide 51:2014, 3.4]

4. Intended use/intended purpose - use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

   Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.

   [SOURCE: IEC Guide 63:2018, 2.4]

5. Risk - combination of the probability of occurrence of harm and the severity of that harm

   Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation and the possibility to avoid or limit the harm.

   [SOURCE: ISO/IEC Guide 51:2014, 3.9, modified — Note 1 to entry updated to remove the reference to hazardous event.]

6. Risk control - process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk [SOURCE: IEC Guide 63:2018, 2.14]

7. Severity - measure of the possible consequences of a hazard [SOURCE: IEC Guide 63:2018, 2.17]

To accomplish this scope expansion, JWG7 is requesting additional information from the National Committees on how to properly specify the risk management process to be used for health software.

The following are three proposed alternatives specifying risk management within IEC 62304, 2nd Edition, clause 4.2. Please pick one that your NC would prefer and then, pick whether any other options are also acceptable. Based on the informed responses from the NCs of IEC/SC 62A and MBs of ISO/TC 215, the third CD for IEC 62304 will be circulated at the end of 2018/early 2019.

Option A:

Current draft of IEC 62304:

The manufacturer of health software shall establish and maintain the following:

1. A process for managing risks, primarily to the patient, but also to the operator, other persons, property, and the environment. This process shall provide a methodology for identifying hazards, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the risk controls, taking the intended use of the health software into account.

Where a software failure can contribute to a hazardous situation, the manufacturer shall apply a risk management process complying with ISO 14971.

Option B:

The manufacturer of health software shall establish and maintain the following:

1. A process for managing risks, primarily to the patient, but also to the operator, other persons, property, and the environment. This process shall provide a methodology for identifying hazards, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the risk controls, taking the intended use of the health software into account.

NOTE 1: Demonstration of this can be through conformance to a relevant risk management standard such as ISO 14971

NOTE 2: Other possible standards include IEC 61508, ISO 31000…, while considering the intended use of the health software

In Option B, there is no normative reference and no further risk management requirements will be added to the standard beyond what is already in Clause 7.

Option C:

The manufacturer of health software shall establish and maintain the following:

A process for managing risks, primarily to the patient, but also to the operator, other persons, property, and the environment. This process shall provide a methodology for identifying hazards, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the risk controls, taking the intended use of the health software into account.

Where there is potential of injury or death resulting from the use of health software, the manufacturer shall use a process conforming to ISO 14971.

The question

National Committees are respectfully requested to consider the options provided above for including risk management process in the IEC 62304. Please pick the one option that is preferable to you and then, any other option(s) that are acceptable to you.

What is your preferred option for including risk management process in IEC 62304? (pick only one)

☐ (A) Option A

☐ (B) Option B

☐ (C) Option C

What are other options, besides what was indicated for the question above, that may be acceptable? (may pick more than one)

☐ (D) Option A

☐ (E) Option B

☐ (F) Option C

National Committees are invited to submit their response to the above question through the IEC electronic voting system using the custom template provided by:

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