BSI Medical Devices: Webinar Q&A

ISO 14971:2019 Risk Management for Medical Devices

13 November 2019

Q&A

Q. Should EN ISO 14971:2012 be used to demonstrate continued compliance to the ERs or GSPRs or use the 2019 revision of the standard?

A. A manufacturer must demonstrate compliance to the applicable legislation. Harmonization of a standard allows for a presumption of conformity to the applicable legislation where the standard is applied and the manufacturer considers the Qualifying remarks/Notes in Annex Z.

Additional clarification has been made available from the European Commission, whereby it is now considered that the recent editions of standards published by standardizers reflect the state of the art, regardless of its referencing in the OJEU and therefore the ISO 14971:2019 version represents the state of the art for the Medical Device Directives and Regulation. This update is welcomed as it provides clarity for industry and ensures manufacturers need only to comply with a single version of a standard.

It is anticipated the 2019 revision will be harmonized to the Regulations.

Q. From the Date of Application of the MDR and IVDR will the technical documentation for existing Directive certificates be required to be updated to the 2019 revision of the standard, considering the transitional provisions of MDR Article 120 and IVDR Article 110?

A. A manufacturer must demonstrate compliance to the applicable legislation. Harmonization of a standard allows for a presumption of conformity to the applicable legislation where the standard is applied and the manufacturer considers the Qualifying remarks/Notes in Annex Z.

Additional clarification has been made available from the European Commission, whereby it is now considered that the recent editions of standards published by standardizers reflect the state of the art, regardless of its referencing in the OJEU and therefore the ISO 14971:2019 version represents the state of the art for the Medical Device Directives and Regulation. This update is welcomed as it provides clarity for industry and ensures manufacturers need only to comply with a single version of a standard.

Q. Is there a transition period for manufacturers to adopt the revision of the standard?

A. There is no transition timeline. Manufacturers need to determine the impact of the revision on their risk management files and establish a plan to address any gaps resulting from the revision.

BSI expectation is that manufacturers will have a plan to implement the 2019 revision when BSI next audits or reviews. From a pragmatic perspective we acknowledge application of a revised standard takes time. If you have the standard and a plan to update your files, this may be acceptable, but the assessor will consider the impact and status at the time and make the final decision, as this is a case by case assessment based on the number of devices a manufacturer has, their risk classification etc.

Q. When is the 2019 revision expected to be harmonized?

A. The European Commission has indicated harmonization by May 2020. BSI continues to monitor for updates to the harmonization process and will issue a communication once harmonization is complete.

Q. Is there a current version published of ISO/TR24971 or is this a new document?

If the ISO/TR 24971:2019 is not ready, is it possible to adopt the revised ISO 14971?

A. A current version of ISO/TR 24971:2013 is currently available. The Technical Report is a guide to the application of the corresponding standard but is not itself a normative text. Application of the 2019 revision does not require the revised TR to be available.

Q. Any guidance/updates to ALAP vs ALARP (2012)? Is there is a mismatch between the step in ISO 14971 that says 'if risk reduction required' vs the MDD/MDR which requires all risks to be reduced ALAP?

A. The Directives and Regulations all require risks to be reduced as far (low) as possible. ALARP (As Low As Reasonably Practicable), is a Risk Management Policy and not a method of conducting Risk Analysis. In order to achieve as low as possible, risk control options should be applied cumulatively until either no further risk reduction is achieved or further application of control options negatively impacts the benefit-risk ratio.

ISO 14971 requires a manufacturer to determine if risk reduction is required based on the criteria established in the risk management plan. The criteria is based on the policy established by top management which takes into account applicable national or regional regulations and relevant International Standards and available information such as the generally acknowledged state of the art and known stakeholder concerns. The EU regulations provide an input to this policy as an applicable regional regulation.

The requirement of the standard is to determine if risk reduction is required to achieve the criteria in the plan. If a risk is considered to be as low as possible when assessed against the criteria then risk control options may not be required, in particular where a control option may negatively affect the benefit-risk ratio.

Q. What is a good way to get notified when the new ISO 14971 version is released?

A. There are several online standards platforms with auto-notification systems. BSI continues to monitor for updates to the harmonization process and will issue a communication once harmonization is complete.

Q. What are the big differences between 14971:2019 and the MDR?

A. The Regulations are aligned to the principles laid down in ISO 14971. The Regulations do not provide the same level of detail as the standard and the descriptive order of the process is not identical, the principles of risk management for medical devices remain aligned. The 2019 revision has removed the 2007/2012 Annex D which provided much of the difference between the Directive and the 2007 version, resulting in the Content Deviations of the 2012 version.

Q. When would it be appropriate to perform a gap analysis?

A. A gap analysis may be appropriate due any change that may impact the benefit:risk analysis. For

example, changes in the ISO 14971 standard, changes in a manufacturer's risk management procedure, changes to the device or manufacturing process or changes to the predicted rates of adverse events or types of events observed once the device is on the market.

Risk management is an iterative process that should be continued throughout the device life cycle. Regular reviews should be conducted at defined intervals to update and verify assumptions made during the pre-market phase with post-market data and a process to allow ad hoc reviews in response to changes in state of the art, rates of observed adverse events, new and emerging risks etc. should be in place.

Q. Will BSI Technical reviewers under MDR require all residual risks to be disclosed (such as in the IFU)?

How does the requirement in EU MDR about disclosing all residual risks relate to requirements in ISO 14971:2019?

A. Article 32 paragraph 2 (h), GSPR 4 and 23.4 (g) require manufacturers to inform users of any residual risks and any undesirable effects, warnings and precautions in the SSCP and/or information supplied with the device.

MDCG document 2019-9 on SSCPs also reiterates the need for disclosing any residual risks in the SSCP.

However, GSPR 23.1(g) states that residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer. This seems to suggest that there may be residual risks that are not required to be communicated to the user/and or other persons. This is also consistent with clause 8 of ISO 14971:2019 whereby manufacturers decide which residual risks to disclose and what information is necessary to include in the accompanying documentation in order to disclose those residual risks.

Until further guidance is available that clarifies the above requirements, BSI will accept both approaches – disclosing all residual risks or disclosing only those that are required to be communicated to the user and/or other persons. In the latter case, the Manufacturer must have clear documented rationales within their risk documentation for why a specific residual risk has been communicated in the IFU or not.

Q. Will BSI Technical Reviewers expect to see a formal product risk management plan (separate from an SOP)?

A. A formal risk management plan is a requirement of ISO 14971:2007 (clause 3.4) and ISO 14971:2019 (clause 4.4). The plan should include the scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable. The 2019 revision has clarified that the criteria for risk acceptability (clause 4.4d) needs to establish risk acceptability criteria that are appropriate for the particular medical device.

The standard does not define the specific documents a manufacturer must develop to meet this requirement. If a single document meets the requirements of clause 4.1 Risk management process and clause 4.4 Risk management plan this may be acceptable.

Q. Are subcontractors certified to ISO 13485:2016 required to perform risk analysis according to the 2019 version of the standard?

A. ISO 13485:2016 requires manufacturers apply a risk-based approach to the control of the appropriate processes needed for the quality management system and to document one or more processes for risk management in product realization. ISO 14971 represents the state of the art for such a system. Organizations certified to ISO 13485:2016 therefore need to comply to ISO 14971 or provide due justification for not doing so.

When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to ISO 13485:2016 and to customer and applicable regulatory requirements for outsourced processes.

A Legal Manufacturer holding CE mark must comply to state of the art for risk management and quality system processes including demonstration of control over outsourced processes. For the Medical Device Directives, EN ISO 14971:2012 remains the state of the art harmonized standard. In the absence of a harmonized standard for the Medical Devices Regulations, ISO 14971:2019 will represent the state of the art once published. It is anticipated the 2019 revision will be harmonised to the Regulations.
A subcontractor operating an outsourced process for a customer may be required by their customer to demonstrate compliance to the 2019 revision of the standard as this may be used by the customer for demonstration of conformity to the state of the art and the applicable regulation.

Compliance to the applicable regulation remains the full responsibility of the Legal Manufacturer.

Q. Is it still expected that a manufacturer complies with the annexes that are now removed from the 2019 version and added to ISO/TR:ISO 24971?

A. The Annexes (and ISO/TR 24971) provide informative guidance and compliance is not required. Compliance is only necessary to the normative text covered by the clauses of the standard.

Q. Should the 2019 revision be used in conjunction with the usability standard IEC 62366-1:2015 or IEC 60601-1?

A. ISO 14971:2019 cross references to IEC 62366-1:2015 for accompanying documentation, use error, identification of intended use and reasonably foreseeable misuse and the verification of the effectiveness of risk control measures. Further, Annex A states that the process defined in ISO 14971 does not preclude use of other applicable standards such as IEC 62366-1:2015 and IEC 60601-1. Annex A of IEC 62366-1:2015 provides a graphical relationship between ISO 14971 and IEC 62366-1:2015.

ISO 14971:2019 does not itself describe a process for the determination of usability, rather it requires identification and assessment of risks associated with use, use error and reasonably foreseeable misuse. IEC 62366-1:2015 specifies a process which may be used to analyse, specify, develop and evaluate the usability of a device, enabling identification and mitigation of risks associated with correct use and use errors. IEC 62366-1:2015 may therefore be used alongside ISO 14971:2019. IEC 62366-1:2015 can also be used to identify but not mitigate risks associated with misuse.

Definitions in the 2019 revision are aligned with IEC 62366-1:2015, IEC 60601-1, ISO/IEC Guides 51 and 63 and IMDRF terminology.

Q. When Software is used a Medical Device and if we don't have any Safety Related Risk then can we go ahead with mentioning no Product Safety related Risk and Project has only Operational Risk aligned to ISO9001:2015

A. Where software is categorized as a medical device in its own right, ISO 14971 represents the state of the art risk management standard. Software is itself a product, so operational risk as understood by the ISO IEC Directives, HLS (Annex L) and ISO 31000:2018 & ISO 9000:2015 does not apply.

User (operator) error is an attribute of product use risk and is an element of ISO 14971.

Q. For software that is classified as a medical device, does accompanying documentation include tooltips, online help, etc?

A. The Notes to entry of clause 3.1 state that the accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc. and is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types. This may encompass tooltips, online help etc.

Q. Does reasonably foreseeable misuse include mis-storage, e.g. the product is stored outside its prescribed temperature conditions prior to use?

A. Yes, this could be either un-intended or intended reasonably foreseeable misuse as per clause 3.15 and 5.1 of ISO 14971:2019.

Q. Please can you explain the required process for identifying safety characteristics now the questions have been removed from the annex?

A. ISO14971:2019 clause 5.3 defines the requirement to identify characteristics related to safety. Clause 5.3 references ISO/TR 24971 (Annex A) for a list of questions that can serve as a guide in identifying medical device characteristics that could have an impact on safety.

ISO 14971:2007 Annex C listed questions that can be used to identify medical device characteristics that could impact on safety. Annex C.1 states the list is not exhaustive, or representative of all medical devices, and the reader is advised to add questions that can have applicability to the particular medical device and to skip questions that are not relevant to the particular medical device. The reader is also advised to consider each question not only on its own but also in relation to others.

The list is not intended to be used as a checklist; using it as such may lead a manufacturer to miss key characteristics and therefore risks associated with their device because the characteristic is not listed in Annex C. Manufacturers should consider for themselves the characteristics related to the design, manufacture, use, usability, decommissioning and disposal etc. specific to their particular device.

Q. What do you see as the biggest change? It feels like 10.3 Action is a fairly big change in the text for "old school" manufacturers that still have static risk reports.

A. ISO14971:2019 clause 10 replaces and clarifies ISO 14971:2007/EN ISO 14971:2012 clause 9. The requirement to collect information via a post-market system and to evaluate previously implemented risk management activities and review the risk management file for unrecognized hazards or unacceptable

risk estimates has not changed. Clause 10 is now aligned to IMDRF and IOS 13485:2016 on corrective and preventive actions. There is much greater emphasis on post-production information and monitoring in ISO14971:2019; this is consistent with the increased emphasis in the Regulations.

The ISO 14971:2019 revision in clause 9 introduces the formal requirement to determine when subsequent reviews of the execution of the risk management plan need to be performed and when the risk management report needs to be updated.

ISO 14971:2019 clause 9 also introduces a new requirement to define in the risk management plan the responsibility for the review of the execution of the risk management plan to be assigned in the risk management plan to persons having the appropriate authority.

Q. Can misuse be an input in order to increase the indications if supported by acceptable risk and clinical data?

A. A manufacturer must not promote misuse or off-label claims. If post market data indicates misuse, manufacturers should consider the robustness of their existing risk controls on preventing misuse and take any relevant corrective/preventive actions. While there is no harm in considering instances of misuse as an input to future expansion of indications, any extension to the clinical indications requires sufficient clinical data to support the new claims made by the manufacturer.

Q. Under the MDR how does a manufacturer determine the benefits of a device with no medical intention?

A. Article 61.9 states that in the case of products without an intended medical purpose listed in Annex XVI, the requirement to demonstrate a clinical benefit shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.

Further, pursuant to Article 9 paragraph 2, devices that are in conformity with the common specifications shall be presumed to be in conformity with the requirements of the MDR covered by those common specifications or the relevant parts of those common specifications.

Q. You mentioned" top management review" – can you comment a bit more on whether this is new or how it may be modified?

A. The involvement of 'Top Management' is not a new requirement. ISO 14971:2007/EN ISO 14971:2012 clause 3.2 Management responsibilities has been clarified under ISO 14971:2019 clause 4.2 but remains broadly unchanged.

Q. Is it possible under any circumstances to have technical documentation without risk analysis or assessment under MDR or IVDR?

A. Both the MDR and IVDR require the manufacturer to establish, document and maintain a system for risk management, aligned to and inter-dependant with the clinical evaluation. The risk management system must be regularly updated. Article 10 requires the quality management system to address risk

management. Notified Bodies are required, under the Regulations, to ensure that the clinical or performance evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements and to verify the adequacy of the benefit-risk determination and risk management. The GSPRs defined in Annex I and in particular GSPR 3, are aligned to the principles of ISO 14971.

A manufacturer that does not have risk management within its technical documentation would not be compliant with the regulations.

Q. Is the consideration for devices already on the market specific to my product or is there a requirement to monitor for other manufacturers products and events relating to these products?

A. ISO 14971:2019 clause 10.3 requires the manufacturer to consider the need for actions regarding medical devices on the market where the collected post market information is determined to be relevant to safety.

The post market information collection system should collect and review information on the manufacturers device and the generally acknowledged state of the art which includes new or revised standards, published validated data specific to the application of the medical device under consideration, the availability of alternative devices and/or therapies, and other information.

While information impacting safety may be sourced from other devices available on the market, a manufacturers actions are limited to their own devices.

Q. Can you clarify what is meant by state of the art?

A. ISO 14971:2019 introduces the definition of state of the art: developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. The Note to entry further describes this as the state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the "generally acknowledged state of the art".

In considering the state of the art, manufacturers should consider all available data on devices and alternative therapies (including non-intervention) for the claimed indications with respect to safety and performance.

If a particular medical device presents more hazards to a user, or a greater probability of occurrence or increased severity compared to available alternatives without a commensurate increase in benefit, the device may not be consistent with the state of the art. A manufacturer has to make this assessment on a case by case basis.

Both ISO 14971 and ISO/TR 24971 require manufacturers to update their risk acceptability criteria if the state of the art changes; therefore the state of the art must be continuously assessed throughout the lifecycle of a particular medical device and is not a fixed time during the design or launch phases for example.

The economic cost of a device may influence the available data on state of the art. The Note to entry clarifies that the state of the art is not necessarily the most technologically advanced option. However, economic practicability should not be used as a rationale for the acceptance of unnecessary risk.

Q. How can unreasonable psychological stress be documented?

A. A manufacturer must consider all possible harms to a user or patient. The 2019 revision amends the definition of harm to remove the word 'physical'. Psychological harms may now need to be considered. These harms should be documented in the same way as other harms. The standard does not prescribe how a manufacturer documents hazards, harms etc or how a manufacturer identifies hazards and harms.

Q. What is the best way to carry out and document the overall risk benefit analysis for a product?

A. There is no best way. This depends on the manufacturer's risk management procedure and specifics of the device. The overall risk:benefit analysis should consider all the residual risks and justify them in context of the clinical benefit.

Q. Would FMEAs still be one of the best ways to do risk evaluation?

A. An FMEA is a risk management tool and is not itself risk management. FMEA is a technique by which the consequences of an individual fault mode are systematically identified and evaluated. As components of the device, manufacture, design and use are assessed one at a time, this is done in a 'bottom-up' mode. In order to identify these components, outputs of design control activities are usually required. ISO 13485:2016 clause 7.3.3 on product realization describes risk management outputs to be inputs to the design process. Conducting effective FMEA may therefore not always be possible at early development stages as outputs of risk management precede finalization of design outputs.

FMEA also operates from a single fault mode, so may not identify hazards arising from multi-component faults and does not consider normal use as required by ISO 14971:2019 clause 5.4.

FMEA may not present a complete analysis of possible faults and may need to be complemented with a 'top down' method such as Fault Tree Analysis (FTA) which starts from a postulated undesired consequence.

Q. BSI has consistently stated information provided to the user cannot be seen to reduce risk. Please can you clarify.

A. The probability of occurrence of a risk may, depending on the risk, be reduced by information for safe and effective use of the device. It is important to distinguish between information for safe and effective use and warnings on residual risk disclosed by the manufacturer.

Residual risk is by definition the risk remaining after all risk mitigation or control options have been applied and further mitigation or control options will not reduce the risk further (without adversely affecting the benefit:risk ratio). Residual risk cannot be reduced by warnings on labels.

Information on how to use a device properly and safely may reduce the probability of a risk that relates to use error, for example, but this should be used with caution and justified. A manufacturer should also consider the manufacturer to the risk control options in the priority order listed in the Directives and Regulations i.e., (a) inherent safety by design; (b) protective measures in the medical device itself or in the manufacturing process; (c) information for safety. Information provided to the user as the only control option may not be sufficient and should be used in conjunction with (a) and (b) where appropriate and duly justified if not.

Q. Which is better? Quantitative Risk Management or Qualitative Risk Management?

A. Quantitative Risk Analysis uses available relevant and verifiable data to produce a numerical value which is then used to predict the probability of a risk event outcome.

Qualitative Risk Analysis applies a subjective assessment of risk occurrence probability against the potential severity of the risk event outcome based on the expert judgement of the team.

ISO 14971:2019 requires post market data to be collected and reviewed. This data should allow quantitative risk management to be performed as the estimates generated in the pre-market phase can be verified against real-life data collected in the post market phase.

Risk management conducted using actual data will be more accurate for that particular device and may provide clearer evidence of the effectiveness of risk control. The standard allows for both qualitative and quantitative methods to be used.

Q. Is there any impact from Brexit?

A. The development of international standards is not impacted by Brexit.