# Risk Based Decisions

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# Topics

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- Other Risk Based Exercises
- Possible Process for Addressing
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# Formal Risk Managment per ISO 14971

# Formal Risk Managment per ISO 14971

- ISO 14971 specifies ***a process*** for a manufacturer to ***identify the hazards*** associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, ***to estimate and evaluate the associated risks***, to ***control these risks***, and to ***monitor the effectiveness of the controls***.

- It is a risk management system, focused only on controlling the potential for physical injury or damage to the health of people, or damage to property or the environment.

- It also is directly primarily at “absolute”, rather than “relative” or “comparative” risks.

- It does not address regulatory risks, supply risks, manufacturing risks, business risks or any other type of risk.

# Other Risk Based Exercises

# Other Risk Based Requirements

- In many communications, the term “risk assessment” is being used as a general term. This can, and is being confused with risk assessments performed according to the ISO standard.
- Although some of the terms and concepts are similar to those in the ISO 14971 standard, the processes, mechanisms and outcomes are different.

- However, in many cases what is requested is a “risk BASED assessment” or “risk based approach”.
- This usually applies to any exercise where the potential consequence or risk of more than one option is the primary consideration.
  - These are not new, but are proliferating

# Other Risk Based Requirements

## Example of Risk Based Assessments

From the Preamble to 21 CFR Part 820 published in 1996.

"In fact the new regulation is less prescriptive and gives the manufacturer the flexibility to ***determine the controls that are necessary commensurate with risk***. The burden is on the manufacturer, however, to describe the types and degree of controls and how those controls were decided upon. Such determinations are made in accordance with standard operating procedures (SOP's) established by the manufacturer.

However, because the regulation requirements are basic, they will apply in total to most manufacturers subject to the regulation. The extent of the documentation necessary to meet the regulation requirements may vary with the complexity of the design and manufacturing operations, the size of the firm, the importance of a process, and the risk associated with the failure of the device, among other factors.

The extent of testing conducted should be governed by the risk(s) the device will present if it fails."

# Other Risk Based Requirements

- This defined an expectation that the company would use some “method” defined in an SOP, to justify the following:
- Types and degree of controls
  - Which sections/parts of the regulation applied to the company/procut
- Extent of the documentation
  - The level of documentation needed
- Extent of testing conducted
  - The amount of testing, if any, that was required

# Other Risk Based Requirements

**Example of Risk Based Assessments**

The newest version of ISO 13485, published last year, has the same type of requirement

- 13485:2016 section 4.1.2 b "apply a risk based approach ***to the control*** of the appropriate processes needed...."
  - Justify (and document) which processes, and the depth of each process you implement in your quality management system (QMS), based on the product risk.

## Example of Risk Based Assessments

In the latest FDA guidance on Changes to a 510(k)

**Initial risk-based assessment –** To determine whether a change or modification could significantly affect the safety or effectiveness of a device, the manufacturer should first conduct a ***risk-based assessment, using the guidance below, of whether the change could significantly affect the device's safety or effectiveness, either positively or negatively.*** This risk-based assessment should identify and analyze all new risks and changes in existing risks resulting from the device change, and lead to an initial decision whether or not submission of a new 510(k) is required.

For the purposes of this guidance, we have chosen the term "risk-based assessment" to describe the analysis that should be completed to assist in the determination of whether or not a change could significantly affect safety or effectiveness of the device. Although common risk analysis methods define risk in terms of device harms and their effects on safety, it is important to note that whether submission of a new 510(k) is required depends on whether the change could significantly affect the safety *or effectiveness* of the device. Therefore, manufacturers should also consider the possible effects a device change may have on device effectiveness. As such, we have chosen to use the distinct terminology of "risk-based assessment."

# Other Risk Based Requirements

**Initial risk-based assessment –**

For instance, in your supplier controls do you assign tiers or levels to suppliers based on risk/criticality to your product? Are there different requirements for each tier? That is a risk based approach. Does your CAPA System have a risk assessment in it that impacts the rest of the process (timing, containment etc) - that is a risk based approach. Does your design control procedure allow for an "accelerated" process for small projects? That too can be a risk based approach, if the definition of "smaller" includes a risk assessment.

# Other Risk Based Requirements

## Example of Risk Based Assessments

Set/Justify Specifications, Justify Requirements

ISO 11608-1

The manufacturer shall conduct risk assessments in accordance with ISO 14971. These risk assessments shall:

- Identify which NIS functions represent essential performance of the system (including the medicinal product) in relation to the intended use of the NIS;
- Justify excursions/deviations from specifications (tighter or less restrictive), conditions or methods contained in or referenced in this document;

NOTE This might include foreseeable “worst case” or “extreme” device use-cases (e.g. vibration as in-use test), conditions, requirements, or configurations (e.g. wear position, device orientation with respect to gravity) which could impact the essential performance of the system (including the medicinal product).;

- Justify substitutions or omissions of methods or specifications/limits when those provided in this document are not directly applicable to the NIS;
- If not provided or referenced in this document, identify and establish additional system specifications and limits unique to each specific NIS (including the medicinal product).

# Other Risk Based Requirements

**Example of Risk Based Assessments**

Human Factors request to Provide a “Use related risk analysis”.

This is NOT a use FMEA per ISO 14971

It is a request to Determine ***Criticality of Use Tasks***

Uses the concept of a ***Hazard assessment*** to ***prioritize*** which task must be validated. It is not a risk assement, but a ***relative classification of criticality***.

- Possible Process for Addressing

# Possible Process for Addressing

There are many instances of a requirement of guidance to make a decision, or justify a position with a ***risk based analysis***. When asked for your risk assessment, before sending you FMEA, Hazard Analysis or Risk Management Report:

**Best to step back and determine several things:**

- What is the decision I need to make? Some examples may be:
  - set specification
  - Justify level of control – Supplier controls
  - Justify testing (or no testing), clinical study or no clinical study
  - quality level or sample size
  - Relative importance of characteristic or task
- Am I only considering Hazards (consequences) not complete risk (potential for hazard to occur and cause harm)
- Who or What will suffer the consequences of outcomes
  - Patients
  - Regulatory
  - Business
- Am I comparing to an existing product, data set, etc
  - Comparative vs. Absolute Risk
- OR is it some other free-form justification of a decision or position that has some relation to the impact on opatients

# Possible Process for Addressing

**Then document your "risk based assessment".**

- Clearly state and maintain focus on the objective of the assessment
- Confirm the type of risk (patient, user, regulatory, compliance or other)
- Logically out the decision(s)
- Justify and support these decision with appropriate references, data of other scientific or objective evidence

**Address the issues/answer the question being asked, not the terms used to ask them!**

# Summary

# Summary

- Risk assessments and risk based assessments are not the same
  - Be sure you understand what has been asked/requested/required
- Do not send in your FMEA or other risk management documents just because you have them!
- Focus your documentation on the objective of your evaluation
  - Clearly address whose risk may be being considered as part of the assessment
- Justify your assessment and decision with objective arguments, and when appropriate, supported by data
- You clear understanding and addressing the request will be appreciated.