ISO 14971:2012

Ensuring Compliance to Annex Z Requirements

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Agenda

- Risk Management Best Practices Overview
- ISO 14971:2012 overview
- Annex Z changes
- How to address content deviations
• ISO 14971:2012 is very controversial: please note that solutions presented herein attempt to balance business needs with patient safety / product effectiveness
• Case studies may not be representative or guaranteed to work 100% of the time
• Most Annex Z presentations tell you what not to do – we take a stab at giving you solutions and what to do to navigate these new obstacles
David Amor, MSBE, CQA is partner at MEDgineering, a medical device compliance consulting firm specializing in remote consulting solutions, remediation projects and quality systems. A graduate of the Senior Innovation Fellows program at the University of Minnesota’s Medical Device Center, David was named a Top 40 Under 40 Medical Device Innovator in 2012. David has helped set up med-tech start-ups with quality systems, risk management infrastructures and product development programs that were cited as ‘best practices’ by the FDA and European notified bodies likes DEKRA and TUV. Most recently, David co-founded and helped launch Remind Technologies, a Texas based mobile health company developing the world’s first smartphone based pill dispenser.

More importantly: I have worked directly in managing teams performing risk management remediation (483s, warning letters, NB audits, etc.) for several of the top medical device companies.
Maintaining an appropriate risk management file per ISO 14971 ensures that you comply with most of FDA and EU Essential Requirements for risk management.
Risk Management

Best Practices in Risk Assessment

- **Risk**: combination of the probability of occurrence of harm and the severity of that harm
- **Risk Assessment**: overall process comprising a risk analysis and a risk evaluation
- **Risk Analysis**: systematic use of available information to identify hazards and to estimate the risk
- **Risk Control**: process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
- **Risk Evaluation**: process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

**REMEMBER**: ISO 14971 defines risk in terms of HARM only
Risk Management

Best Practices in Risk Assessment

- **Predicate device information**
  - On-market product performance
  - Known device failures
  - CAPAs, design changes
  - Complaint data / MDRs

- **Functional analysis**

- **Product characterization studies**
  - Bench-top testing, animal or clinical studies

- **Product labeling**

- **Intended Use**
  - Known off-label use
  - Normal state hazards

- **Clinical and scientific literature**

- **Task Analysis**
  - Forseeable mis-use
  - Interaction with accessories or other products
  - Clinical use environment

- **Regulatory Standards**
  - Product specific standards
  - Safety standards

### Table E.1 — Examples of hazards

<table>
<thead>
<tr>
<th>Examples of energy hazards</th>
<th>Examples of biological and chemical hazards</th>
<th>Examples of operational hazards</th>
<th>Examples of information hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic energy</td>
<td>Biological</td>
<td>Function</td>
<td>Labelling</td>
</tr>
<tr>
<td>Line voltage</td>
<td>Bacteria</td>
<td>Incorrect or inappropriate output of functionality</td>
<td>Incomplete instructions for use</td>
</tr>
<tr>
<td>Leakage current</td>
<td>Viruses</td>
<td>Incorrect measurement</td>
<td>Inadequate desorption of performance characteristics</td>
</tr>
<tr>
<td>— enclosure leakage current</td>
<td>Other agents (e.g. prions)</td>
<td>Erroneous data transfer</td>
<td>Inadequate specification of intended use</td>
</tr>
<tr>
<td>— earth leakage current</td>
<td>Re- or cross-infection</td>
<td>Loss or deterioration of function</td>
<td>Inadequate disclosure of limitations</td>
</tr>
<tr>
<td>— patient leakage current</td>
<td>Chemical</td>
<td>Use error</td>
<td>Operating instructions</td>
</tr>
<tr>
<td>Electric fields</td>
<td>Exposure of airway, tissues, environment or property, e.g. to foreign materials:</td>
<td>Attentional failure</td>
<td>Inadequate specification of accessories to be used with the medical device</td>
</tr>
<tr>
<td>Magnetic fields</td>
<td>— acids or alkalis</td>
<td>Memory failure</td>
<td>Inadequate specification of pre-use shovels</td>
</tr>
<tr>
<td>Radiation energy</td>
<td>— residues</td>
<td>Rule-based failure</td>
<td>Over-complicated operating instructions</td>
</tr>
<tr>
<td>Ionizing radiation</td>
<td>— contaminates</td>
<td>Knowledge-based failure</td>
<td>Warnings</td>
</tr>
<tr>
<td>Non-ionizing radiation</td>
<td>— additives or processing aids</td>
<td>Routine violation</td>
<td>Of side effects</td>
</tr>
<tr>
<td>Thermal energy</td>
<td>— cleaning, disinfecting or testing agents</td>
<td></td>
<td>Other hazards likely with re-use of single-use medical devices</td>
</tr>
<tr>
<td>High temperature</td>
<td>— degradation products</td>
<td></td>
<td>Specification of service and maintenance</td>
</tr>
<tr>
<td>Low temperature</td>
<td>— medical gasses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical energy</td>
<td>— anaesthetic products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gravity</td>
<td>Bio-compatibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— falling</td>
<td>Toxicity of chemical constituents, e.g.:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— suspended masses</td>
<td>— allergenicity/immunity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td>— pyrogenicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stored energy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moving parts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Torsion, shear and tensile force</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moving and positioning of patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acoustic energy</td>
<td>High pressure fluid injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— ultrasonic energy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>— infrasound energy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>— sound</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Risk Management

Best Practices in Risk Assessment

Hazard Analysis

- Top down analysis
- Hazard → Hazardous Situation → Harm
- Sequence of events analysis
- Normal state hazards
- Interface hazards
- Correlates to post-market surveillance
- Does not provide root cause failure information

FMEA / FMECA

- Bottom up analysis
- Single fault failures
- Allows for discrete failure perspectives (use, design, process)
- Allows for multiple levels of analysis
- Single failure / single level focus is limiting
• Manufacturer should utilize a consistent approach to determining probability of occurrence and severity of harm
  – Qualitative or quantitative
  – Clearly define how probability and severity values are determined
  – Master library of harms and associated severities to ensure consistency
  – FTA to provide supportive evidence of probability values (sequence of events)
• Risk level is defined by the manufacturer
  – Matrix format
• Risk level drives risk reduction activities based on manufacturer definitions
• Refer to 14971 Annex D.3 Risk Estimation for additional guidance

KEY TAKE AWAY: Proceduralize how to determine all values utilized in risk analysis, and implement the approach in all product files!
Probability of occurrence of harm should take into account the probability of the hazard (i.e. product failure, use error) and the occurrence of the hazardous situation (i.e. failure detected prior to use vs during clinical use).

The resulting risk should also account for the likelihood of this harm occurring at a specified level of severity (i.e. patient exposure to product with compromised sterility has a higher likelihood of resulting in a treatable infection than sepsis).

KEY TAKE AWAY: Don’t overestimate your occurrence values! An accurate risk profile is important for post-market risk monitoring.
• **Inherent safety by design**
  – Needless design
  – Proprietary connectors
  – Use of appropriate materials
  – Back check valves

• **Protective measures in the medical device itself or in the manufacturing process**
  – Fuse
  – Back up internal battery
  – Design for assembly
  – Alarms

• **Information for safety**
  – Safety symbols
  – Warnings
  – Preventative maintenance

• Refer to 14971 Annex D.5.1 for additional guidance

Remember: all risk controls must be evaluated to determine whether or not they introduce additional risk
• **Final assembly inspections / 100% in process inspection**
  – Quality inspections may reduce out of box failures, but will not reduce failures due to inadequate reliability
  – 100% in process inspection will not catch all non-conformances

• **Compliance to standards as risk controls**
  – Standard requirements for product performance may not be rigorous enough for the defined use environment
  – Risk controls should be based on product design requirements; compliance to relevant standards can be referenced as evidence of risk control effectiveness
  – Exception for standards that provide direct verification (i.e. EMC, biocompatibility, sterilization)

• **Labeling**
  – Manufacturers shall not attribute any additional risk reduction to the information for safety given to the users
  – Can be referenced in conjunction with other risk control options
  – Do not reduce risk to an acceptable level based on information for safety alone
• **Manufacturer defines criteria for risk acceptability**  
  – documented in RMP

• **Manufacturer should define (on a procedural level) risk reduction activity required as a result of risk evaluation**  
  – Clearly identify when risk reduction is not required  
  – Required risk reduction dependent on identified risk level

• **Residual risk evaluation**  
  – Shall be performed on an individual risk basis as well as overall, considering all residual risks combined  
  – If residual risk is unacceptable, further risk reduction must be applied  
  – Residual risk disclosed to user

**KEY TAKE AWAY:** Clearly defined risk acceptability criteria is critical for a compliant Risk Management process!
Risk Management

Best Practices in Risk Assessment

• Evaluate risk controls early and often
• Be aware of all applicable product specific standards
• Utilize clinical input
  – Thorough understanding of the use environment is critical
  – Identifying actual likelihood of exposure of hazard to the patient / user
• Do not artificially over-inflate occurrence levels
  – Risk levels should be baselined such that expected values are evaluated for acceptability
    in order to serve as a post-market threshold
  – Ensure that you are taking into account the hazardous situation when determining
    occurrence values (i.e. occurrence of out of box failure that is not exposed to the user
    vs. failure during clinical use)
• Utilize tools to determine SOE where necessary
  – High severity harms
  – Fault tree analysis to show more actual likelihood of occurrence of HARM
  – Consider detectability
**Risk Management**

- Residual risk acceptability should take into account state of the art
  - does not necessarily mean the most technologically advanced solution
  - Implement all feasible risk controls consistent with the accepted state of the art to achieve as low as possible risk

- Risk Benefit Analysis
  - Utilized when individual residual risk is unacceptable
  - Further risk reduction should be implemented prior to considering benefit

- Can consider restricting intended use or use environment
  - i.e. indicate not for pediatric populations, or provide information on allowable operating conditions (temperature and humidity ranges)
Many of the content deviations described in Annex Z overlap and are similar.
“RISK MANAGEMENT begins with the development of design input requirements. As the design evolves, new risks may become evident. To systematically identify and, when necessary, reduce these risks, the risk management process is integrated into the design process. In this way, UNACCEPTABLE RISKS can be identified and managed earlier in the design process when changes are easier to make and less costly.”
ISO 14971 – Medical Devices – Application of Risk Management to Medical devices

- As ISO 13485 is more specific to QMS than ISO 9001, ISO 14971 ~ ISO 31000
- Normative text update in 2007
- European harmonized standard released in 2009 and recently updated in 2012
## Risk Management

### EU Essential Reqs

<table>
<thead>
<tr>
<th>“Risk”</th>
<th><strong>MDD 93/42/EEC</strong></th>
<th><strong>AIMDD 90/385/EEC</strong></th>
<th><strong>IVDD 98/79/EC</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>“Risk”</td>
<td>ERs: 1, 2, 6, 7.2, 7.4, 7.5, 7.6, 8.1, 8.6, 9.2, 9.3, 11.2, 11.4, 12.1, 12.5, 12.6, 12.7, 13.5, 13.6</td>
<td>ERs: 1, 5, 8, 9, 10, 11, 15</td>
<td>ERs: A – 1, 2, B – 1.2, 2.1, 2.2, 2.5, 2.7, 3.2, 3.3, 3.4, 5.3, 6.2, 6.3, 6.4, 7.1, 8.6, 8.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>41</strong></td>
<td><strong>18</strong></td>
<td><strong>24</strong></td>
</tr>
</tbody>
</table>

*Source: BSI Group*
• **Good news:** none of the **normative text** changed from ISO 14971:2007

• **Bad news:** harmonized standard to comply with EU directives includes Informative Annex Z which clarifies gaps between global standard and Essential Requirements

**Bottom Line:** Annex Z has many “minor” clarifications that have significant impact on how risk is analyzed, assessed, mitigated and evaluated and which together = new “requirements”
1. All risks need to be mitigated.
2. Risk / benefit analysis must be performed for all risks.
3. All risks must be reduced as low as possible.
4. All risk mitigations should be taken regardless of the risk level.
5. Risks must be reduced by inherent design.
6. Labeling and use information does not constitute risk reduction.

NOTE! Many of the above are interrelated.
## ISO 14971:2012

### Summary of Deviations

<table>
<thead>
<tr>
<th>Deviation</th>
<th>MDD</th>
<th>AIMDD</th>
<th>IVDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Treatment of negligible risks</td>
<td>1, 2, 6, 7.1</td>
<td>1, 5, 9</td>
<td>A.1, A.2, B.1.1</td>
</tr>
<tr>
<td>2 – Discretionary power of mfr as to acceptability of risks</td>
<td>1, 2, 6, 7.1</td>
<td>1, 5, 9</td>
<td>A.1, A.2, B.1.1</td>
</tr>
<tr>
<td>3 – Risk reduction “as far as possible” vs “as low as reasonably practicable”</td>
<td>1, 2, 6, 7.1</td>
<td>1, 5, 6, 9</td>
<td>A.1, A.2, B.1.1</td>
</tr>
<tr>
<td>4 – Discretion as to whether a risk-benefit analysis needs to take place</td>
<td>1, 6, 7.1</td>
<td>5 &amp; 9</td>
<td>A.1 &amp; B.1.1</td>
</tr>
<tr>
<td>5 – Discretion as to the risk control options / measures</td>
<td>2 &amp; 7.1</td>
<td>-</td>
<td>A.2 &amp; B.1.1</td>
</tr>
<tr>
<td>6 – Deviation as to the first risk control option</td>
<td>2 &amp; 7.1</td>
<td>-</td>
<td>A.2 &amp; B.1.1</td>
</tr>
<tr>
<td>7 – Information of the users influencing the residual risk</td>
<td>2 &amp; 7.1</td>
<td>-</td>
<td>A.2 &amp; B.1.1</td>
</tr>
</tbody>
</table>

*Source: BSI Group*
Deep dive review

Whereas previously you were able to determine risk acceptability and only mitigate risks above a certain threshold, all risks must now have mitigations in place.

1. “All risks need to be mitigated”
Directives (MDD/AIMD/IVD)

Where’s the deviation?

ISO 14971:2009

“Ensure that all risks, regardless of their dimension, need to be reduced as much as possible (and need to be balanced, together with all other risks, against the benefit of the device).”

“...the manufacturer may discard negligible risks.”
1. “All risks need to be mitigated”

## The Current Dilemma

<table>
<thead>
<tr>
<th>Potential Failure Mode</th>
<th>Potential Root Cause(s) of Failure Mode</th>
<th>Prod Spec Ref</th>
<th>Preventive Measures / Current Controls</th>
<th>S</th>
<th>O</th>
<th>RI</th>
<th>Recommended Actions (Further Risk Mitigation Needed?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core fracture</td>
<td>Diameter too small</td>
<td>6.0 8.1</td>
<td>OD/ ID specification per drawing 9011392</td>
<td>3</td>
<td>1</td>
<td>(Acc)</td>
<td>None - Risk is 'Acceptable' (RI = 2)</td>
</tr>
<tr>
<td></td>
<td>Material fault/fatigue/defect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kinking of core</td>
<td>Diameter too small</td>
<td>6.0</td>
<td>OD/ ID specification per drawing 9011392</td>
<td>2</td>
<td>1</td>
<td>(Neg)</td>
<td>None - Risk is 'Acceptable' (RI = 1)</td>
</tr>
<tr>
<td></td>
<td>Material fault/fatigue</td>
<td>8.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Improper use</td>
<td>14.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Damaged during removal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inner Core Penetration</td>
<td>Diameter Too Small</td>
<td>6.0</td>
<td>OD/ ID specification per drawing 9011392</td>
<td>2</td>
<td>1</td>
<td>(Neg)</td>
<td>None - Risk is 'Acceptable' (RI = 0)</td>
</tr>
<tr>
<td></td>
<td>Material Fault/Fatigue</td>
<td>8.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Improper Use</td>
<td>11.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Negligible or Acceptable risks require mitigation!!
Deep dive review

1. “All risks need to be mitigated”

**Possible Solutions**

- Blanket Mitigation: in the FMEA conclusions or risk management report, include list of clinical or design mitigations that cover multiple risks (if possible- all).
- 1:1:1 Rule: is there a mitigation in place for use, process and design that can act as a mitigation for a certain set of risks?
- If all else fails, do a line item analysis of **why the risk is mitigated as low as possible, without referring to financial / cost considerations**
Deep dive review

Risk benefit analysis was traditionally only required if an unacceptable risk was determined. A risk benefit analysis would be performed to demonstrate that the medical benefit outweighed the risk to allow for continued development/manufacturing.

2. Risk / benefit analysis must be performed for all risks.
Where’s the deviation?

Directives (MDD/AIMD/IVD)

‘...an overall risk-benefit analysis must take place in any case, regardless of the criteria established in the risk management plan and requires undesirable side effects to "constitute an acceptable risk when weighed against the performance intended".’

ISO 14971:2009

‘...an overall risk-benefit analysis does not need to take place if the overall residual risk is judged acceptable when using the criteria established in the risk management plan.’
**The Current Dilemma**

<table>
<thead>
<tr>
<th>Verification / Validation References</th>
<th>S</th>
<th>O</th>
<th>RI</th>
<th>Clinical Risk Benefit Analysis (CRBA)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>no</td>
</tr>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>no</td>
</tr>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>yes</td>
</tr>
</tbody>
</table>

*RBA must be available for all risks, not just above a threshold!"
Deep dive review

2. *Risk / benefit analysis must be performed for all risks.*

**Possible Solutions**

- Line item risk benefit analysis
- Overall risk benefit analysis (in risk analysis documents)
  - Clinical Evidence Report (CER) / Clinical Risk Benefit Analysis (CRBA) / Clinical Experience Summary (CES)
  1. **CER:** leverage predicate or similar devices and demonstrate low risk profile. Involves literature searching, product comparisons, etc. Reference GHTF SG5/N2R8: 2007
  2. **CRBA:** analysis all risks and assigns medical opinion, literature and validation work as basis.
  3. **CES:** demonstrates safety through small trial data or predicate data (if for example submitting a special 510(k)). Best for “me-too” products.
Example solution

<table>
<thead>
<tr>
<th>Verification / Validation References</th>
<th>S</th>
<th>O</th>
<th>RI</th>
<th>Risk Benefit Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>The benefits described in Clinical Evidence Report 12345 outweigh the risk associated with [hazard, harm].</td>
</tr>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>[HARM] likelihood is low per X, Y, Z.</td>
</tr>
<tr>
<td>90331637; 90340453 per section 8.2 EN ISO 11070; 90033662</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>Per input from Medical (approver of this document), clinical benefit of this product outweighs the risks herein.</td>
</tr>
</tbody>
</table>

An overall risk benefit analysis that is referenced in a line item fashion.

Instead of by line item, RBA by Harm category with a reference to literature, market data, etc.

KOL or Medical Input as RBA is valid.

2. Risk / benefit analysis must be performed for all risks.
Deep dive review

ALARP – “as low as reasonably practicable” is replaced by ALAP – “as low as possible”. Risks must now be reduced as low as possible independent of any business / cost considerations.

3. All risks must be reduced as low as possible.
Where's the deviation?

Directives (MDD/ AIMD/ IVD)

‘...risks to be reduced "as far as possible" without there being room for economic considerations.’

ISO 14971:2009

‘...contains the concept of reducing risks "as low as reasonably practicable.”

The ALARP concept contains an element of economic consideration.’
3. All risks must be reduced as low as possible.

*Source: ASU group*
Deep dive review

The Current Dilemma

3. All risks must be reduced as low as possible.

ALARP must be eliminated as a risk level.

*Source: MasterControl*
Deep dive review

Possible Solutions

- Remove ALARP from documentation
- Reducing risk without regard to cost is impractical and several organizations are fighting this resolution
  1. Current effective strategy has included implementation of overall risk benefit analysis
  2. If a design input can be tied to risk, it may be used as evidence of mitigation consideration
- Overall, the risk management documentation and process should indicate that risks are reduced as low as possible.

3. All risks must be reduced as low as possible.
Traditionally, if a risk was acceptable, you would stop there. New interpretation is that all possible mitigations (design, information, mfg) should be in place. This is very similar to all risks should be mitigated and ALAP.”

4. All risk mitigations should be taken regardless of the risk level / 5. “... by design”
Directives (MDD/AIMD/IVD)

ISO 14971:2009

Where’s the deviation?

‘...by applying cumulatively what has been called "control options" or "control mechanisms" in the standard.’

‘...indicates that further risk control measures do not need to be taken if, after applying one of the options, the risk is judged acceptable according to the criteria of the risk mgmt plan.’
Deep dive review

Labeling (IFU/ Warning Labels/ etc.) was used as a risk mitigation to reduce risk indices. Now, labeling may be used as a risk control but not as a control that reduces risk levels.

6. Labeling and use information does not constitute risk reduction.
Where’s the deviation?

Directives (MDD/AIMD/IVD)

ISO 14971:2009

‘...users shall be informed about the residual risks. This indicates that...the information given to the users does not reduce the (residual) risk any further.’

‘...regards "information for safety" to be a control option.’
### The Current Dilemma

<table>
<thead>
<tr>
<th>S</th>
<th>O</th>
<th>RI</th>
<th>Recommended Actions (Further Risk Mitigation Needed?)</th>
<th>Responsibility</th>
<th>Actions Implemented and Supporting Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>3</td>
<td>ALARP</td>
<td>Yes</td>
<td>Quality</td>
<td>IFU - Warn against bending / flexing</td>
</tr>
</tbody>
</table>

*Source: MasterControl*
Deep dive review

**Possible Solutions**

- Reference labeling (including IFU) but do not use it as a residual risk reduction.
- As with other deviations, consider design mitigations.
- “Assume the doctors toss the IFU when they open the package.”

6. Labeling and use information does not constitute risk reduction.
Thanks!

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