Content Deviation #7
Information for Safety as a Risk Control Measure

ISO 14971:2007 Clause 6.2 includes risk control options in a priority order. The third option is "information for safety".

EN ISO 14971:2012 Annex ZA Content Deviation 7 concludes, "manufacturers shall not attribute any additional risk reduction to the information given to the users".

Notify Bodies often take this conclusion to mean that, in the context of the Medical Device Directive, information for safety is not a valid risk control option, and its use does not reduce risk. This position is a misunderstanding of Content Deviation #7 as explained below.

Information for Safety *v.* Residual Risk

The cause of the confusion is failure to distinguish between two important terms "information for safety" and "residual risk". Providing information for safety is a risk control option, while disclosing residual risk is not. The content deviation concerns disclosing residual risk.

The standard doesn't define information for safety, but defines residual risk as the "risk remaining after risk control measures have been taken". In other words, after implementing the risk controls options, including information for safety, some risk may remain. This is the residual risk.

Annex J.1 of the standard provides a comparative analysis of the terms.

> "Information for safety gives instructions on action to take or not to take to avoid a risk.
>
> "Disclosure of individual and overall residual risk gives background and relevant information necessary to explain the residual risk so users can proactively take appropriate actions to minimize exposure to the residual risk(s)."

There is a similar discussion in ISO/TR 24971:2013 *Medical devices – Guidance on the application of ISO 14971*.

> Information for safety is instructive and can be provided in the form of warnings or cautions. Often these are required acts or prohibited acts accompanied by the appropriate symbol.
>
> Disclosure of residual risk is descriptive and can provide background on the residual risks involved in using the medical device. It enables the patient or user to make an informed decision that weighs the residual risks against the benefits of using the medical device.

Content Deviation #5 – Information for Safety is Required

This content deviation says the MDD requires cumulative application of the three risk control measures. It concludes that the manufacturer must apply all the "control options" and may not stop the activities if the first or the second control option has reduced the risk to an "acceptable level".

In other words, this content deviation requires the third risk control option, information for safety. This is not consistent with an interpretation that information for safety does not reduce risk. The problem, as stated above, is that content deviation #7 is about disclosing residual risk and does not apply to information for safety.

The MDD Hierarchy

The risk reduction hierarchy in the MDD Annex I Paragraph 2 is not the same as the hierarchy in ISO 14971:2007. The MDD requires, "In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order". Table 1 is a side-by-side comparison.

Table 1 Comparative Analysis of Risk Reduction Hierarchy

ISO 14971:2007	MDD Essential Requirements
inherent safety by design	eliminate or reduce risks as far as possible (inherently safe design and construction)
protective measures in the medical device itself or in the manufacturing process	where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated
information for safety	inform users of the residual risks due to any shortcomings of the protection measures adopted

Notice that Content Deviation #6 addresses the differences in the first risk reduction option. Content Deviation #7 address the differences in the third.

One of the differences in the second risk reduction option is the use of "protection measures" in the MDD, which includes information for safety. ISO 14971:2007 divides this concept into "protective measures" (and identifies two kinds) and "information for safety".

The fact that Content Deviation #7 concerns residual risk is clear in the title, "Information of the users influencing the residual risk".

The a) part of the content deviation says, in part, "6.2 of ISO 14971 regards "information for safety" to be a control option". This is true and, following Content Deviation #5, is a mandatory control option. It goes on to say, in the b) part, "However, the last indent of Section 2 of Annex I to Directive 93/42/EEC says that users shall be informed about the residual risks." The last indent is the requirement to inform users of residual risk in Table 1.

The content deviation concludes, in the c) part, "Accordingly, manufacturers shall not attribute any additional risk reduction to the information given to the users." What information is this? It is the information in the last indent, *i.e.*, the information to "inform users of the residual risks due to any shortcomings of the protection measures adopted".

The important point is that informing patients and user of any residual risk does not reduce risk. The content deviation does not apply to information for safety. Disclosing residual risk doesn't reduce the risk, because residual risk is the risk after implantation of the risk control measures.

Comparison of the Methods

In ISO 14971:2007, the manufacturer follows a process:

- Define acceptable risk (Clause 3.4.d)
- Estimate risk for each combination of hazard, hazardous situation, and harm (Clause 4.4)
- Evaluate the estimate against the acceptability criteria to determine the need for risk reduction (Clause 5)
- Apply risk reduction options in a hierarchal manner to achieve an acceptable risk Clause 6.2)
- If the risk reduction does not achieve an acceptable risk, the perform a risk/benefit analysis (Clause 6.5)
- Determine which residual risks to disclose (Clause 6.4)

EN ISO 14971:2012 modifies this process:

- Define acceptable risk (Clause 3.4.d)
- Estimate risk for each combination of hazard, hazardous situation, and harm (Clause 4.4)
- ~~Evaluate the estimate against the acceptability criteria to determine the need for risk reduction (Clause 5)~~
    - Conduct risk reduction regardless of the acceptability criteria (Content Deviation #1)
- ~~Apply risk reduction options in a hierarchal manner to achieve an acceptable risk Clause 6.2)~~
    - Continue to apply the risk reduction options cumulatively even if the risk is acceptable (Content Deviation #5)
    - The first risk reduction option is revised (Content Deviation #6)
- ~~If the risk reduction does not achieve an acceptable risk, the perform a risk/benefit analysis (Clause 6.5)~~
    - Perform a risk/benefit analysis for each combination of hazard, hazardous situation, harm, and risk reduction (Content Deviation #4)
- ~~Determine which residual risks to disclose (Clause 6.4)~~
    - Disclose all residual risks (Content Deviation #7)

Conclusion

The cause of the confusion is failure to understand the difference between providing information for safety and disclosing residual risk.

Content Deviation #7 says that disclosing residual risk does not reduce risk. This content deviation does not apply to information for safety.

Content Deviation #5 requires information for safety as a risk control option.