

## ALARP v AFAP

EN ISO 14971:2012, Annex ZA, points out that the requirements in the Medical Device Directive, MDD, do not align with ISO 14971:2007. Content Deviation #3 has created some confusion; this article explains the issue and makes recommendations for device manufacturers implementing EN ISO 14971:2012.

### Glossary

ALARP – As Low as Reasonably Practicable

AFAP – As Far as Possible

*Risk* is the combination of the probability of occurrence of harm and the severity of that harm.  
[Clause 2.16]

### The Risk Matrix

The best place to start is the traditional risk matrix. The underlying concept of ISO 14971:2007 is to estimate risk (the output of Risk Analysis in Clause 4), evaluate the estimate against the acceptability criteria (in Clause 5), and determine the need for risk reduction (by applying Clause 6). In addition, after risk reduction, evaluate the residual risk estimate (in Clause 6.4) against the acceptability criteria to determine the need for additional risk reduction measures.

EN ISO 14971:2012 inherits this approach, but modifies some of the details for alignment with the MDD. Annex ZA content deviations describe the modifications.

The first approach starts with the idea that both severity and probability are continuous variables and the combination represents a point on a severity  $\times$  probability plane. In the next step, the manufacturer assigns attributes to regions in the plane. For some regions the risk is acceptable while for other regions the risk is unacceptable.

ISO 14971:2007 Clause 3.4 Note 3, 2<sup>nd</sup> paragraph, 2<sup>nd</sup> indent recommends dividing the plane into acceptable and unacceptable regions and further subdividing the acceptable region in Acceptable – Negligible and Acceptable with Risk Minimization regions.

Figure 1 illustrates this approach. Note that the manufacturer determines the location of each of the three regions.

Because the initial concept assigns numerical values to both severity and probability, this is a quantitative approach. However, the state of knowledge doesn't usually allow assignment of specific numerical values. Instead, manufacturers utilize the risk matrix to express severity and probability in qualitative values. As a result, the plane becomes a table – the risk matrix. Figure 2 provides an example.

As above, the manufacturer assigns acceptability/unacceptability values to each cell. The risk matrix assigns one of the three values described above to each cell.

- R1 Acceptable – Negligible
- R2 Acceptable with Risk Minimization
- R3 Unacceptable

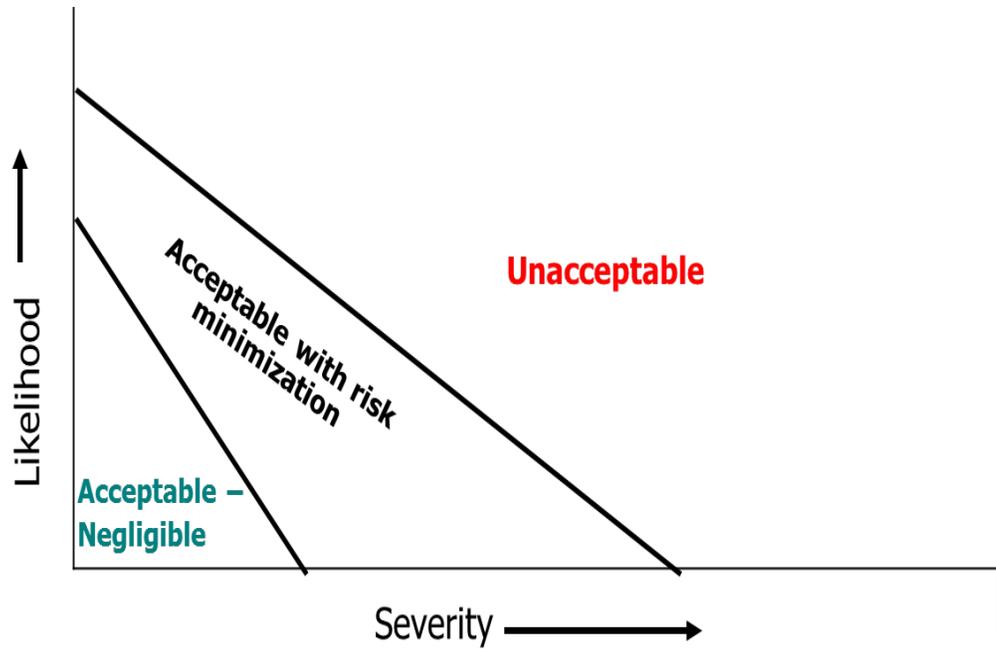


Figure 1 Risk Region

		Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability Levels	Frequent	R2	R2	R3	R3	R3
	Probable	R2	R2	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Improbable	R1	R1	R2	R2	R3

Figure 2 Example Risk Matrix

### **Content Deviation #1**

While not relevant to the topic, this content deviation informs that ISO 14971:2007 allows the manufacturer to “discard negligible risks” and cites Clause D.8.2 that includes the statement, “Below a certain level the residual risk will be regarded as so insignificant that it is comparable with the everyday risks we all experience and tolerate. Such risks can be called negligible.”

However, MDD Annex I Sections 1 and 2 requires reduction of all risks “as far as possible”, regardless of acceptability assessment. The practicable result is that the MDD requires risk reduction for Acceptable – Negligible risks.

### **ALARP (ISO 14971:2007)**

As stated above, ALARP is a method to reduce risk. In particular, ISO 14971:2007, Clause D.8 describes the ALARP approach.

Clause D.8.1 informs that the approach identifies the results of applying a risk control option:

- a) The residual risk exceeds the manufacturer’s criterion for risk acceptability
- b) The residual risk is acceptable because it is so small as to be negligible
- c) The residual risk is between the two states specified in a) and b)

Clause D.8.4 has a discussion of practicability considerations

Reduce all risks to the lowest level practicable, bearing in mind the state of the art, the benefits of accepting the risk, and the practicability of further reduction. Practicability refers to the ability of a manufacturer to reduce the risk utilizing two components:

- Technical practicability;
- Economic practicability.

Technical practicability refers to the ability to reduce the risk regardless of cost.

Economic practicability refers to the ability to reduce the risk without making the medical device an unsound economic proposition.

Figure 3 shows the concept of ALARP from ISO 14971:2007.

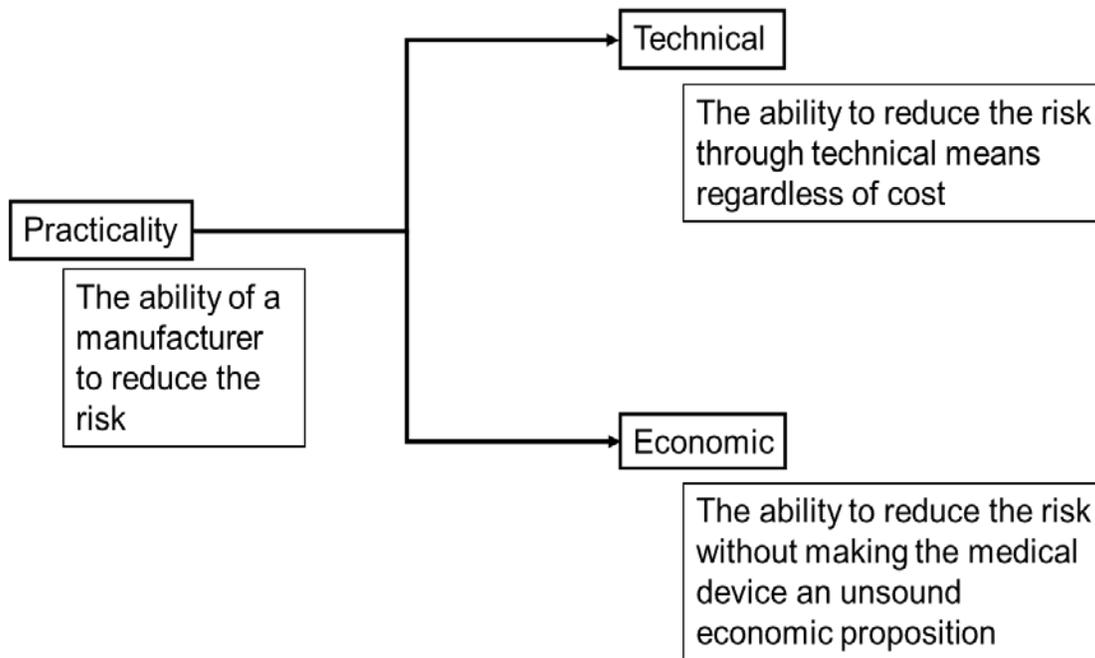


Figure 3 Concept of ALARP

### Content Deviation #3

The content deviation has three parts.

The a) part says that Annex D.8 to ISO 14971:2007 contains the concept of reducing risks "as low as reasonably practicable" (ALARP concept). The ALARP concept contains an element of economic consideration.

The b) part says that the MDD, Annex I, Section 2, 1<sup>st</sup> indent requires that risks be reduced "as far as possible" without room for economic considerations.

MDD, Annex I, Section 2, 1<sup>st</sup> indent, "In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: eliminate or reduce risks as far as possible (inherently safe design and construction)".

The conclusion, in the c) part says, "Accordingly, manufacturers and Notified Bodies may not apply the ALARP concept with regard to economic considerations".

### The Analysis

The criteria, based on the content deviations, has not changed. Risks should fall into either the "acceptable with risk minimization" region or the "acceptable – negligible" region. (If a risk is unacceptable and the manufacturer cannot reduce the risk, a risk/benefit analysis may determine that the residual risk is acceptable.)

The issue is the tools available to reduce the risk.

### **Risk Minimization**

Using the risk matrix in Figure 3, the manufacturer needs to implement risk minimization. This means moving the residual risk into a cell that is lower or to the left, or both. Risk minimization means reducing risk, using the available methods, to get the residual risk estimate to the lowest and left-most cell possible. The residual risk may not be at the lower left corner, but the manufacturer cannot move it to a better cell.

In ISO 14971:2007, one could stop using technical means when economic considerations apply. For example, there may be technical means that could bring the residual risk to a “better” cell, but would make the design too costly. As a result, the device is too expensive and society does not have its benefit. The device, in the words of Clause D.8.4, is “an unsound economic proposition”.

Content Deviation #3 removes economic considerations from the tool kit, and leaves only technical considerations.

### **Implementation**

Using the risk matrix, consider if ALARP (both technical and economic considerations) or AFAP (technical considerations only) would result in the residual risk falling into a different cell.

In nearly all cases, the residual risk would fall into the same cell. It is rare for a design project to know how to reduce risk, but fail to implement it for cost reasons. The manufacturer would assert, “We have a way to reduce the risk, but concluded that it would make the selling price unacceptably high”.

Review the risk management file to determine if any risk reduction measures included cost considerations. Search for key words such as “cost” “expense”, “dollars”, *etc.*

If you find any, reevaluate the decision for that residual risk.