Understanding Risk Priority Numbers

In Risk Management, risk is the combination of severity of the harm and probability that it will occur. For medical device manufacturers, the relevant standard is ISO 14971:2007 which uses this definition of risk. The traditional method develops a two dimensional table in which the cells represent risk acceptability.

Risk Management

Risk Management identifies hazards and tracks them through a sequence of events that creates a hazardous situation. This hazardous situation could result in harm to people, property, or the environment. The resulting harm has a severity and a probability of occurrence. The combination of severity and probability establishes the risk. Figure 1 illustrates the approach.

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

Key: R3 – Unacceptable risk
       R2 – Further risk reduction investigation needed
       R1 – Insignificant risk

Figure 1 A Risk Table

The table in Figure 1 maps five levels of severity and five levels of probability to three levels of risk acceptability. This is a $5 \times 5 \rightarrow 3$ map. Notice that the 5×5 table has 25 cells, but we use only 3 values of risk acceptability; some values must be in more than one cell.

The map doesn't have to be 5×5. For example, a device manufacturer could have seven severity and five probability levels mapping to two risk acceptability levels: unacceptable or acceptable. This is a $7 \times 5 \rightarrow 2$ map.

FMECA

One tool often employed in Risk Management is Failure Modes, Effects, and Criticality Analysis (FMECA). This tool is common in reliability and addresses the issues when a product fails. Typically these are single point failures, but the tool is applicable in multiple failures as well.

There is, however, an important distinction to make. FMECA deals with failures and their failure modes. Medical device risk management deals with hazards; they can be present in normal and in failure conditions.

RPN

One common approach in FMECA calculates a Risk Priority Number (RPN). Each failure (mode) has an assigned severity, probability, and detectability values. This common approach uses the following qualitative scale for ranking.

- The severity score (S) is an integer between 1 and 10, where the most severe is a 10

- The probability score (P) is an integer between 1 and 10, where the highest probability is a 10

- The detectability score (D) is an integer between 1 and 10 where most difficult to detect is a 10.

The RPN is the product of the three ranks. For example, with $S = 5$, $P = 3$, $D = 6$, the RPN is $90 = (5)(3)(6)$.

The RPN is not a measure of risk, but of <u>risk priority</u>. You would apply your limited resources to the most important problems. The RPN gives you a model to allocate these resources. Higher numbers are higher priority, so you should work on an RPN of 900, before you put resources on an RPN of 30.

One interesting issue, not well understood, is that some numbers cannot be an RPN. Many people have the mistaken belief that any number from 1 to 1,000 can be an RPN. Consider 17. It cannot be an RPN because it is a prime number larger than 10. You cannot multiply 3 numbers from 1 to 10 and get 17.

In contrast, many numbers can occur in multiple ways, the highly composite numbers. Consider 120. There are 24 different ways it can become an RPN. Two examples are $(S)(P)(D) = (2)(6)(10) = (8)(5)(3)$. In the first case the severity is near the bottom of the scale, 2, while in the second case, the severity is near the top of the scale, 8.

Also, note that there are long stretches of numbers that can't be an RPN. For example, no number from 901 to 999 is an RPN.

There are only 120 possible RPN values.

The two dimensional case maps levels of severity and probability to risk acceptability. In Figure 1 there are 25 cells, but only 3 values. Similarly, in the three dimensional RPN case there are 1,000 cells, but only 120 values. This is a $10 \times 10 \times 10 \rightarrow 120$ map.

Summary

The RPN is a valuable tool for setting priority. In the conventional approach, higher RPN values represent higher priority. While the conventional approach develops 1,000 cells, there are only 120 different RPN values. Some values can't occur (17, 22, and 925) while others can occur multiple times. There are 24 different ways to get 60, 72, and 120.