Developing an objective FMEA

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The problem of Risk Priority Numbers

The comments in this document would have the ambition to be an extension to the article written by Donald J. Wheeler with title "Statistical Process Control". This article finally point out a problem of many FMEA developments where the classical data referred as Severity (S), Occurrence (O) and Detectability (D) have all assigned numerical values but the related numerical fields are effectively simply considered as ordinal scale data. In other words, it is only possible to establish an order relationship between each value af a numerical field, (that is $2 > 1$), but without ratio scale references to provide to this numbers an objective meaning. Nevertheless, the numbers representing S, O and D are multiplied together to obtain a function called Risk Priority Number RPN in this way:

$$RPN = S \, * \, O \, * \, D \tag{1}$$

This is a problem, because as pointed out by the above mentioned article, if the variable S, O and D have no ratio scale and without an absolute zero, the operations of addition, subtraction, multiplication and division are all meaningless operations. Then, the next section deals with the possibility of defining all the components representing the risk function in such a way to allow a risk calculation with a mathematical meaning.

The Risk function

In the standard ISO14971 "Application of risk management to medical devices", the risk is defined in this way: combination of the probability of occurrence of harm and the severity of that harm. The above standards accepts various methods to estimate risks, where each component: severity (S) and probability (P) could belong to a qualitative or, if possible to a quantitative scale. When a full qualitative approach is adopted, both S and P are represented by a finite number of levels, each of them defined by a description, then finally defining a category potentially collecting multiple cases. This is the situation where S and P belongs to ordinal scale data fields, for this reason the risks are analyzed by a so called risk chart, where all combinations of severities and probabilities are represented on a matrix and each combination of risks is analyzed case by case. This approach is reasonable if the number of levels is low as in the following example.

The qualitative approach

Table 1: Severity of the final effect

Severity (S)	Description
Significant	Death or loss of function structure
Moderate	Reversible or minor injury
Negligible	Will not cause injury or will injurie slightly

Table 2: Probability of occurrence

Probability (P)	Description
high	Likely to happen, often, frequently
medium	Can happen, but not frequently
low	Unlikely to happen, rare, remote

Table 3: Risk Control Chart

	Severity (S)		
Probability (P)	Negligible	Moderate	Significant
high	R1	R2	
medium		R4	R5,R6
low		R3	

In the above example, a possible risk evaluation criterion could imply that only the Risk R1 and R3 are judged acceptable while the remaining should require further mitigation. However, there are situations with much higher complexity, where an higher resolution for severity and probability is required. In particular, if the probability is split in two components O & D and also the severity S, are defined by 10 levels as in the referred article, we should think to take a decision comparing 1000 different categories. Furthermore, as correctly pointed out by D.J. Wheeler, the resulting RPN = S * O * D cannot be considered a priority index, than even if S, O and D are represented by ordinal scale data fields, RPN is not an ordinal scale, so if we want to perform a risk evaluation, we have to compare case by case all 1000 combinations!. For some situations,this could not be the best approach, furthermore the comparison between close risks could be affected by subjective interpretations.

A possible quantitative approach

Therefore, in order to achieve objectivity, a theoretical solution could be to adopt a full quantitative approach. Concerning the probability of occurrence and referring it with P', we could obtain it with a ratiometric method. For instance, in medical contexts, the maximum likelihood estimation of P' could be calculated with the ratio n/N, where n = number of recorded failures/errors over N = number of treatments performed. Moreover, always keeping the ratiometric properties, we could split P' in two components as:

P' = O' * D', where:

O' is the frequency of occurrence of a failure mode and D' is not defined just as a generic difficulty of detection of the failure mode, but rather

D' is the probability to fail the final effect prevention, given the failure occurrence.

In this way the computation of P' is consistent, provided that the probabilities O' and D' are independent and this is what generally happen.

Now, in order to achieve a full quantitative calculation of risk we should get a quantitative representation of the severity, and this is what generally does not happen. A typical situation could be shown adding a column to the previous Table 1, including an ordinal scale data column as in following Table 4:

Table 4: Severity of the final effect

Severity	Description	S (ranking)
Significant	Death or loss of function structure	3
Moderate	Reversible or minor injury	2
Negligible	Will not cause injury or will injurie slightly	1

S is an ordinal number assumption without any ratiometric meaning. So, if we perform now R = S * P' or R = S * O'*D', we cannot in general achieve a ratio scale data for R, because there is no reason to assume that the severity Moderate (S = 2) is two times the severity Negligible (S = 1).

Therefore, instead to assume an arbitrary ordinal scale for S, it can be calculated in this way:

- Given the lowest severity level S_1 and assuming $S_1 = 1$
- We indicate with S_i all the remaining severity levels with i = 2,...,m
- We determine P'_i as the highest probability value that is still considered acceptable for all specific severity level S_i. Higher values are considered not acceptable, while lower or equal values are acceptable. This probability value is the consequence of a decision that is in general context dependent. In reliability contexts could be related to repair cost, while in safety context, like in medical devices risk analysis, P'_i could be in relation to the lowest probability technically achievable by the generally acknowledged state of the art, provided that there is a therapeutic benefit to outweigh the risk. The determination of the m values of P'_i should be the crucial part for any development of risk analysis, on the basis of these assumptions all risks are calculable and related to each other (see next point).
- We determine any S_i with the following equation:

$$S_i = \frac{P'_1}{P'_i} \tag{2}$$

  In this way for any severity level S_i, the corresponding risk at the probability P'_i it will be always aligned to:

$$R(P'_i)_i = S_i * P'_i = P'_1 \tag{3}$$

  Therefore for all severity levels, the maximum acceptable risk is always the same value P'_1, while for all the other probability levels, the risks are calculated in ratiometric way by R = S * P', where S = S_i are defined by equation (2) and the acceptability criterion.

Replacing P' with O' * D' and applying the above quantitative criterion, we can finally rewrite equation (1) in this way:

$$RPN = S * O' * D' \tag{4}$$

Now, RPN has finally this double meaning:

- is a quantitative risk estimation
- is a priority index

Unfortunately the full quantitative approach described so far could imply difficulties in accurate probabilities estimations, especially in complex systems where failure and errors come from very different situations. In some cases is not possible a numerical probability estimation, but rather only assumptions, like associating to a potential fault probability only an order of magnitude. So a more suitable approach, also proposed by ISO 24971 guidance, is to use a semi quantitative scale for probabilities.

A possible semi quantitative approach

In this case, the Probability of occurrence could be defined by ranking numbers, where each value represent an actual probability interval as reported in the following table:

Table 5: Semi-quantitative Probability of occurrence

Common terms	Probability range	P (ranking)
Frequent	$10^{-3} < P' \leq 10^{-2}$	5
Probable	$10^{-4} < P' \leq 10^{-3}$	4
Occasional	$10^{-5} < P' \leq 10^{-4}$	3
Remote	$10^{-6} < P' \leq 10^{-5}$	2
Improbable	$10^{-7} < P' \leq 10^{-6}$	1

We define the semi quantitative table with the constraint that any probability category represent a different order of magnitude, therefore indicating with P'_{MAX} the maximum value of the generic interval category in Table 5, we can write $P = \log_{10}(P'_{MAX})+7$. Then, P is now a logarithmic representation of the maximum value of the associated probability interval, no more only an ordinal ranking number. Each increment of P represent a probability increase of an order of magnitude with base 10. This change is what, in many situation is important to differentiate in terms of risk evaluation. For these data fields, sum and subtraction are meaningful, representing changes in probability of as many orders of magnitude as there are increases or decreases in P.

Given P, a conservative estimation of P' is $P' = 10^{P-7}$, while a possible average estimation could be $P'=0.5*10^{P-8}$

Thus, returning to the initial example based on 10 levels for O and D we could define the following tables:

Table 6: Semi-quantitative Occurrence and Detectability

Common terms	Probability range	O	D
Almost sure	$10^{-1} < O' or D' \leq 1$	10	10
very High	$10^{-2} < O' or D' \leq 10^{-1}$	9	9
high	$10^{-3} < O' or D' \leq 10^{-2}$	8	8
often	$10^{-4} < O' or D' \leq 10^{-3}$	7	7
probable	$10^{-5} < O' or D' \leq 10^{-4}$	6	6
occasional	$10^{-6} < O' or D' \leq 10^{-5}$	5	5
Remote	$10^{-7} < O' or D' \leq 10^{-6}$	4	4
Improbable	$10^{-8} < O' or D' \leq 10^{-7}$	3	3
Very Improbable	$10^{-9} < O' or D' \leq 10^{-8}$	2	2
Incredible	$10^{-10} < O' or D' \leq 10^{-9}$	1	1

Therefore given O & D, the conservative estimations for O' and D' are: $O' = 10^{O-10}$ and $D' = 10^{D-10}$, then:

$$P' = 10^{O-10} * 10^{D-10} = 10^{O+D-20} \tag{5}$$

Therefore we can convey a semi quantitative representation for P with $P \in [1,2,\ldots,20]$, where:

$$P = O + D, \; and \; 10^{O+D-21} < P' \leq 10^{O+D-20} \tag{6}$$

Then, given a 10 levels severity scale, and in similar way to the previous quantitative approach we can determine for each severity level the maximum acceptable levels for P. In the next example, referring with Pacc this vector, we suppose the maximum acceptable probability for the lower severity = 0.01 (P = 18) and the following acceptable values obtained with unitary ranking decrements for the first 7 steps, and 2 units decrements for the following 2 with the highest severities, that is:

Pacc = [18,17,16,15,14,13,12,11,9,7], so the severities can be calculated as: $S_i = 18/Pacc_i$, with $i = 1,2,\ldots,10$.

The severity table become:

	Common terms	S
1	Catastrophic	2.57
2	Critical	2.00
3	Severe	1.64
4	Very High	1.50
5	High	1.38
6	Medium	1.29
7	Moderate	1.20
8	low	1.12
9	very low	1.06
10	negligible	1.00

Finally, we can calculate a real risk priority number in this way:

$$RPN = S * (O + D) \tag{7}$$

Also this RPN, even if based on ranking numbers, has respected by construction the multiplication and sum meanings. For this reason, can be assumed as quantitative risk estimation and consequently a priority index.

Comparison with example reported in D.J. Wheeler article

In this section, comparing the example reported in D.J Wheeler article [D.J.W.], with the example of the previous section for the semi-quantitative approach, some additional considerations are pointed out.

The two approaches have the same level of complexity concerning all RPN terms S, O & D that have 10 levels each. The basic difference is due to the terms of the former method that are only qualitative ordinal data.

The next figure recall the distribution of RPN for [D.J.W.] example with RPN = S * O * D, plotting it with 100 bars rather than 1000 as in the original article.

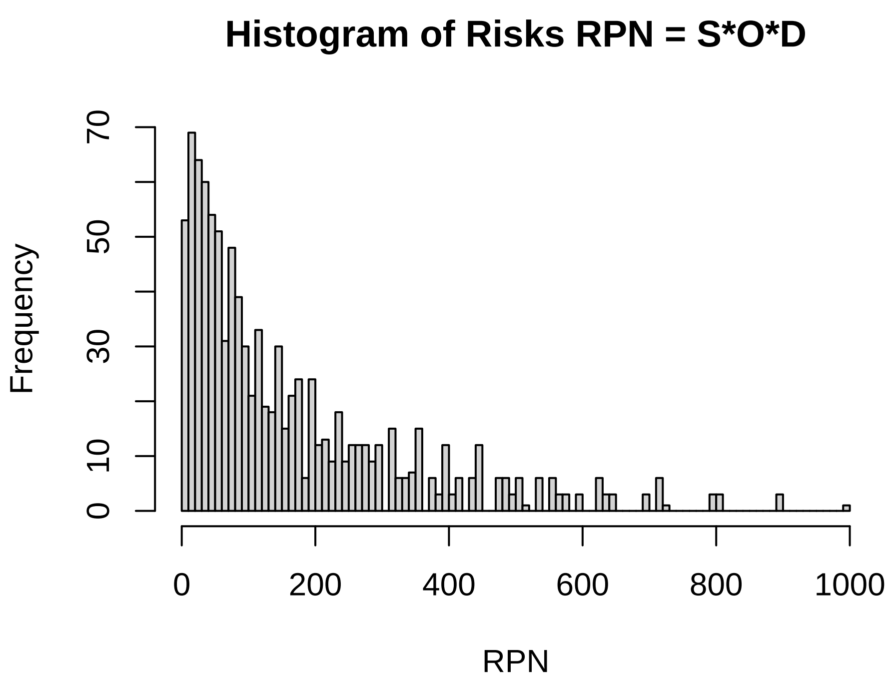

Figure 1: RPN distributions for ordinal data method

Where:

```
[1] "Number of distinct classes =  120"
```

```
[1] "Max RPN values per class =  24"
```

In the following plot is shown instead the classes distribution of the proposed method.

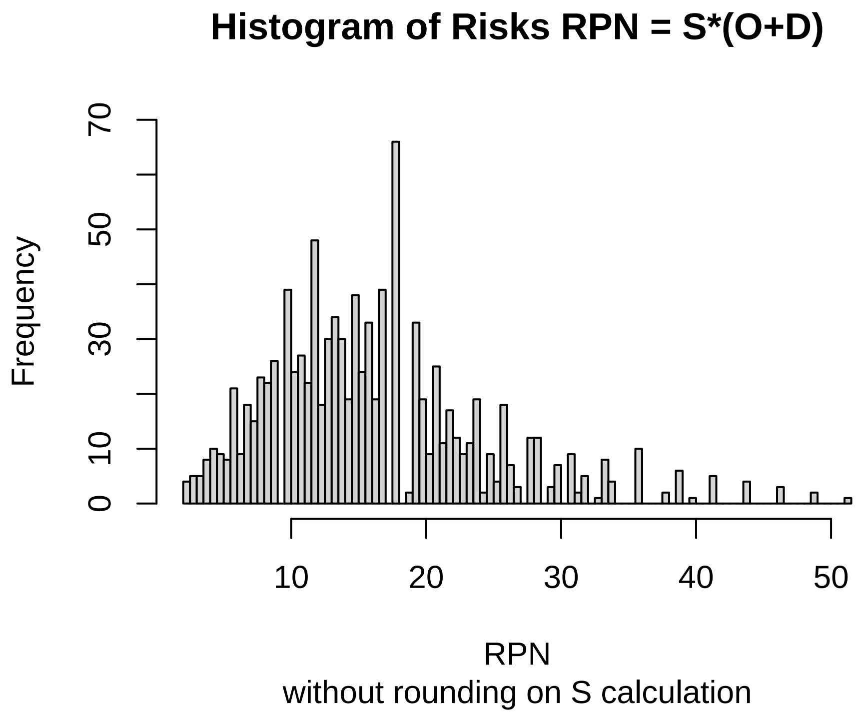

Figure 2: RPN distributions for semi-quantitative data method

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[1] "Number of distinct classes =  149"
```

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[1] "Max RPN values per class =  66"
```

The highest bar in the histogram is located at RPN = 18 that is the acceptability threshold as defined in the semi-quantitative example. The RPN density is higher for RPN close to the acceptability threshold and especially for the lower risks, that are those useful to evaluate risks and take decision on possible actions. It is worth noting that all RPN classes above the acceptability threshold do not have a particular interest.

Concerning previous Figure 1, we can only say that the distribution is more concentrated on the lower risks, but we cannot have any idea about the relevant RPN region where could be important taking decisions. However, in general the information included in Figure 1 is not really meaningful since it is not possible to identify any RPN reference because the RPN classes are not numerically comparable.

Comparing instead the number of classes, the proposed method has more classes, that are 149 against the 120 for the ordinal data method. Moreover, the class correspondent to the acceptability threshold, collects 66 different risk combinations against 24 for the most populated class in the ordinal data method.

It is worth noting that the risks distribution could be affected by the rounding effect during S calculation. In the following Figure 3 is shown the histogram adopting the rounding to the second decimal digits as in the S table shown above.

```
[1] "Number of distinct classes =  168"
```

```
[1] "Max RPN values per class =  30"
```

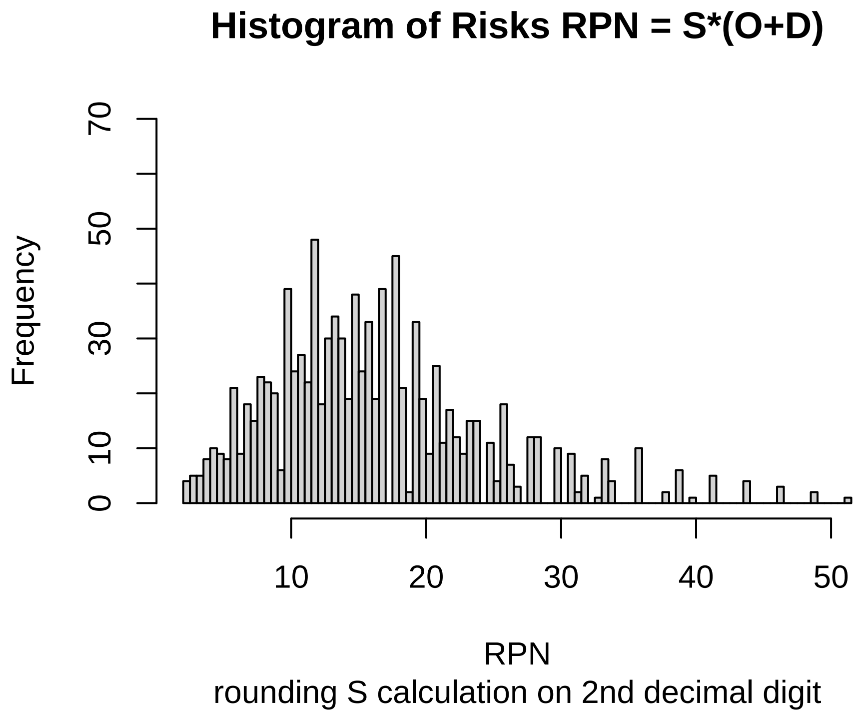

Figure 3: Effect of rounding in S calculation

In any case, for roundings with 3 or more decimal digits there is no practical difference with case without rounding.

Conclusion

Scientific thinking should pursue knowledge and the consequent potential decisions, on objective measures. I found in my experience, the proposed semi-quantitative approach a way to take effective design and operating decisions based as much as possible on an objective process. I said "as much as possible", since the determination of the maximum acceptable probability limits can be still affected by subjectivity, nevertheless, they can become more and more objective as new data and new experience are gained. The standard subjective approach, being the consequent risk evaluation affected by subjective interpretation, could imply consistent delays when is important to take a decision in a timely manner. In addition, there is a higher probability to take the wrong decision.

Finally, I think that the power of the proposed method stands on its capability to force the practitioner to define, before starting the risk analysis, some project-dependent acceptability limits, which are the core concept of any possible further decision.