CHARACTERISTIC OF QUALITY IMPROVEMENT THE PROPOSAL OF MEASUREMENT THE PROCESS IMPROVEMENT MANAGED BY FMEA

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S u m m a r y

The paper presents a concept of index for measuring the quality of improvement managed by FMEA (Failure Mode and Effects Analysis). Quality assessed only by RPNs (Risk Priority Numbers) does not properly describe achieved improvement in terms of risk reduction, which can be obtained by preventive and / or detective controls. With increasing criticism of RPN based FMEA philosophy, a need for more relevant measures of quality improvement arises. The paper introduces a set of indices which can help FMEA teams / leaders, project managers, quality managers, SQA (Supplier Quality Assurance) engineers, etc. to identify at each stage of product/process development what improvement strategy has been applied – focusing on detection of problems or rather preventing their causes.

Keywords: FMEA, failure detection, failure prevention, improvement, risk analysis, RPN

„Jakość doskonalenia jakości" – propozycja wskaźników oceny poprawy jakości procesu wspomaganej metodą FMEA

S t r e s z c z e n i e

W pracy przedstawiono nową koncepcję wskaźników opisujących skuteczność doskonalenia jakości uzyskiwanej przez zastosowanie metody FMEA (Failure Mode and Effects Analysis – Analiza Rodzajów i Skutków Wad). Podstawą przyjętej koncepcji jest postulat kwestionujący jednoznaczność oceny efektów doskonalących uzyskiwanych przy użyciu wskaźnika RPN (Risk Priority Number) podstawowego dla metody FMEA. Nie uwzględnia bowiem strategii uzyskiwania zmniejszenia ryzyka, która może być nastawiona na działania prewencyjne lub kontrolne (w konstrukcji wyrobu lub projekcie procesu). Nasilająca się krytyka wskaźnika RPN jako miary ryzyka stwarza konieczność stosowania innej miary doskonalenia jakości. Przedstawiono zestaw wskaźników istotnie wspomagających analizę ryzyka wyrobu / procesu (liderzy zespołów, kierownicy projektów, kierownicy jakości, osoby odpowiedzialne za jakość dostawców) w ocenie realizowanej strategii zmniejszenia ryzyka. Zaproponowane wskaźniki pozwalają na ilościową ocenę udziału i skuteczności działań kontrolnych – wykrywających wady lub przyczyny oraz działań zapobiegawczych, eliminujących przyczyny powstawania wad, z uwzględnieniem ich następstw dla wyrobu, procesu i klienta.

Słowa kluczowe: FMEA, wykrywanie wad, zapobieganie powstawaniu wad, poprawa jakości, analiza ryzyka, RPN

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Introduction

A need for continuous improvement is obvious nowadays for most organizations, both commercial and non-profit ones. Looking at manufacturing or service companies operating in competitive environment one can notices significant differences in their approach to improvement strategy and procedures (if such are in place). To distinguish between various attitudes towards improvement actions performed in organizations the following criteria could be used:

- Objectives (quality improvement / cost reduction);
- Motivation (internal – management / external – customer, 3rd party – auditor);
- Rate (continuosly in many areas, step by step – like Kaizen / by revolutionary projects – like Six Sigma);
- Resources constraints (what can be done vs what should be done; in other words: money to spend vs money expected to return);
- Method of coming to decision (no method and no team-work / simple review, competition of suggestions, brain-storming / Pareto of concerns / risk analysis / statistical analysis / financial analysis);
- Method of coming to solution (no method and no team-work / review of records, documents, patents / brain-storming / external experts / innovation tools e.g. TRIZ);
- Time effectiveness (short term / long term / permanent);
- Time of initiation (preventive approach: at product or process design stage – before a concern and its cause occurs / corrective approach: after product or process sign off – after a concern and/or its cause can be noticed);
- Last but not least: time of impact (preventing a cause of concern, detecting a cause of concern, detecting a concern).

Author of the article observes that in some companies, continuous improvement is perceived by responsible personnel as an external and unjustified requirement, creating extra effort and costs. Moreover, in many organizations featuring positive attitude towards continuous improvement, the direction of improvement is far from optimal, wasting opportunities and resources. Thus, “improvement of the improvement process”, or even “an improvement strategy” seems to be an important issue, not comprehensively covered from FMEA point of view. Contemporary recommendations convince quality practitioners to employ preventive improvement strategy (reduce Failure occurrence) in contrast to detection improvement strategy (enhance Failure detection). The most known industry standards addressing FMEA [1-5] and FMEA recognized authors like Stamatis (2003) set industry good practices in defining improvement strategies, however, from FMEA management point of

view it seems reasonable to strengthen recommended strategies by dedicated indices measuring quality and effectiveness of selected improvement strategy.

The above mentioned criteria could be used for assessment of improvement strategy of a company. Adding evaluation points for each criterion could assist management in self-assessment of company improvement procedures before not satisfied improvement effects are reported. Also, second and third party auditors could easily pinpoint weaknesses of improvement efforts to make a company better aware of potential opportunities to "improve the improvement".

The last two criteria seems decisive for improvement effectiveness. So, the management should assure relevant resources to initiate preventive actions at product and process design stage. This however does not directly affect a quality of improvement solutions, referred to above as a last criterion "time of impact". Applying a relevant risk analysis tool like FMEA may considerably contribute to making wise improvement decisions aiming to eliminate causes (sometimes called "errors") rather than detect them or even worse – detect their effects – failures (called also "concerns", "problems", etc.). This is a prerequisite for achieving a permanent, robust improvement as opposed to temporary improvement.

Types of improvement decisions in FMEA

FMEA describes each risk of failure with three indices: Severity of Effects, Occurrence of Cause and Detection of Cause/Failure. All three multiplied give the most popular FMEA result: a Risk Priority Number (RPN), an overall measure of a specified risk. In cases when FMEA team is given a task of reducing product/process risk below a set RPN threshold, it is common that teams plan improvement actions aiming to reduce RPN as a value rather than actually mitigate anticipated risk. Thus the best improvement actions become ones which reduce RPN in the possibly cheapest way – in short term perspective. Review of long term effects of improvement actions focused mainly on RPN reduction show that incurred costs of non-conformances are much higher than savings obtained thanks to "cheap" improvement action. Looking for inexpensive and quick improvement usually means efforts to enhance detection of problems – which stays in contradiction to TQM philosophy (of course it is better to detect a cause than its effect – a failure). On the other hand – a better model of improvement, i.e. reducing a chance of a problem, requires an introduction of prevention (or enhancement of current one), which in short term might be costly, but in long term it pays back by preventing causes of problems from occurring. Depending on effectiveness of applied prevention, a cause of a problem may partly or even totally disappear, giving no justification for costly detection measures.

The above two models of improvement can be observed in each organization. The criterion distinguishing between these models was referred to in the introduction as a “time of impact”. Contemporary FMEA forms show clearly these two ways of assuring quality by two columns: Prevention (of a Cause) and Detection (of a Cause or a Failure). The better the prevention, the lower the Occurrence index. The better the detection, the lower the Detection index. Severity index does not depend on prevention and detection since it takes into account potential effects (for organization and its customers) of a potential failure. When a reduction of risk measured by RPN is achieved an important question arises: was risk reduction obtained by improving prevention (lower Occurrence index) or by improving detection (lower Detection index)? Compare:

Before improvement: Sev = 7, Occ = 8, Det = 8; RPN = 7 * 8 * 9 = 448

After improvement: RPN = 112

Improvement scenario #1: Sev = 7, Occ = 8, Det = 2

Improvement scenario #2: Sev = 7, Occ = 4, Det = 4

Improvement scenario #3: Sev = 7, Occ = 2, Det = 8

No doubt the best scenario from quality management point of view is #3, but improvement actions resulting in Occ = 2 might have been costly. Presumably the cheapest (in short-term perspective) and fastest in introduction is #1. In case of Design FMEA scenario #1 relies on testing prototypes rather than on design expertise, methods and tools. In case of Process FMEA scenario #1 relies on product quality inspection rather than on process capability. To identify which kind of approach FMEA team usually selects, one should perform a thorough, time consuming review of planned and performed actions. Review of FMEA results through RPN alone does not give any possibility of assessment which scenario is predominant in a given company/project/team (#1,#2 or #3).

A measure of a “quality of quality improvement”

Author of this paper, basing on practical experience in facilitating FMEA teams, developed a measure of improvement process preventive effectiveness, called “FMEA Risk Overload Index” – FMEA ROI and “FMEA Detection Overload Index” – FMEA DOI.

Concept of the index was based on the following observations:

- The higher is the potential Severity of failure, the more justified is preventive improvement (resulting in reduction of Occurrence index), as opposed to detection effectiveness enhancement (resulting only in reduction of Detection index);
- The higher is the potential Severity of failure, the bigger reduction of Occurrence is necessary, treating a reduction of Detection as a secondary (supporting) resort;

- Total (maximum and theoretical) improvement through prevention (i.e. resulting in no risk of failure) would reduce all Occurrence indices to 1;
- "Total" improvement through prevention would reduce also Detection index to 1 (according to FMEA 4th Edition, AIAG 2008: Detection = 1 means that no inspection is necessary due to eliminated risk of failure, in other words: there is no risk of missing a failure due to elimination of its occurrence);
- Sum of Severity times Occurrence values Σ(*Sev*Occ*) in a given FMEA describes "a distance" from ideal ("total") prevention situation, in which sum of Severity times Occurrence values equals a sum of Severity values (since all Occurrence indices would equal 1);
- Sum of Severity times Detection values Σ(*Sev*Det*) describes "a distance" from ideal detection situation, in which sum of Severity times Detection values equals a sum of Severity values (since all Detection indices would equal 1);
- Improvement through prevention reduces Σ(*Sev*Occ*); the higher is the Severity, the bigger is the reduction of Σ(*Sev*Occ*), which complies with observation 1 and 2;
- Improvement through detection reduces Σ(*Sev*Det*); the higher is the Severity, the bigger is the reduction of Σ(*Sev*Det*), which complies with observation 1 and 2;
- Comparing current Σ(*Sev*Occ*) with theoretical target, i.e. minimum Σ(*Sev*Occ*) calculated for situation of total prevention (when Σ(*Sev*Occ*) = = Σ *Sev* due to all *Occ* = 1) measures relative "preventive bias" of applied improvement strategy (advantageous feature of improvement strategy);
- Comparing current Σ(*Sev*Det*) with minimum Σ(*Sev*Det*) calculated for total inspection (Σ(*Sev*Det*) = Σ *Sev*) measures relative "detective aspect" of applied improvement strategy (secondary – supporting means of improvement).

Basing on observations 9 and 10, the following formulae for calculating above mentioned indices are proposed.

For describing relative "preventive bias" of applied improvement strategy FMEA Risk Overload Index (ROI):

$$FMEA\_ROI = \frac{\sum_{i=1}^{n} Sev_i \cdot Occ_i}{\sum_{i=1}^{n} Sev_i} \tag{1}$$

The index is of "the lower the better" type.

Its current value describes the relative amount of "total occurrence of risk" remained within the FMEA scope (product/process). Its abbreviation should by the way suggest the preferable direction of improvement investments (however – the lower the better type of FMEA ROI is contrary to financial ROI index).

The reciprocal of FMEA ROI index would reflect the obtained, current % of perfection (understood as "total prevention") of a given product/process in terms of risk estimated by FMEA:

$$FMEA\%\mathrm{Prev} = \frac{\sum_{i=1}^{n} Sev_i}{\sum_{i=1}^{n} Sev_i \cdot Occ_i} \cdot 100\% \tag{2}$$

The index is of "the higher the better" type (maximum value of 100% sets an unobtainable quality goal: perfection through prevention – no failures made).

For describing relative "detective aspect" of applied improvement strategy: FMEA Detection Overlook Index (DOI)

$$FMEA\_DOI = \frac{\sum_{i=1}^{n} Sev_i \cdot Det_i}{\sum_{i=1}^{n} Sev_i} \tag{3}$$

Its current value describes the relative amount of "total detection of risk" remained within the FMEA scope (product/process).

The reciprocal of FMEA DOI index would reflect the obtained, current % of perfection (understood as a "total detection") of detective controls for a given product/process in terms of risk estimated by FMEA:

$$FMEA\%Det = \frac{\sum_{i=1}^{n} Sev_i}{\sum_{i=1}^{n} Sev_i \cdot Det_i} \cdot 100\% \tag{4}$$

Maximum value of 100% defines a costly total detection situation – no failures overlooked, irregardless of their effects, measured by Severity (however, according to AIAG FMEA 4th Edition [2], max. FMEA %Det for process would equal 50% in case of on station, automated detection of all causes).

Both indices describe current state of the risk comparing it to an ideal (no risk) state. Their meaning for improvement assessment is however totally different. One could distinguish between the following cases (strategies):

A. If improvement was based mainly on preventive controls than FMEA ROI would be decreasing (FMEA %Prev would be increasing).

B. If improvement was based mainly on detective controls than FMEA DOI would be decreasing (FMEA %Det would be increasing). This could mean either:

• Detection of severe failures has been improved, as support for preventive controls (justified, reasonable decisions), or;

• Detection is a primary concern of FMEA team, who, instead of applying preventive controls in the first place, eliminates risk mainly through inspection, causing (often permanent) increase of project/process costs with non-value adding activities (justified temporarily, e.g. at project start-up).

Monitoring of both FMEA ROI and DOI indices as project progresses (concept, design, process, production, service, etc.) would give a quick assessment of improvement strategy in place. FMEA ROI and DOI magnitude and rate of change (usually descent) would indicate whether FMEA teams effort is biased towards strategy A, B1 or B2.

Example 1

To visualize behavior of FMEA ROI and DOI indices an example follows.

Assume preliminary PFMEA worksheet containing 120 rows (causes) with risk distribution presented in Fig. 1.

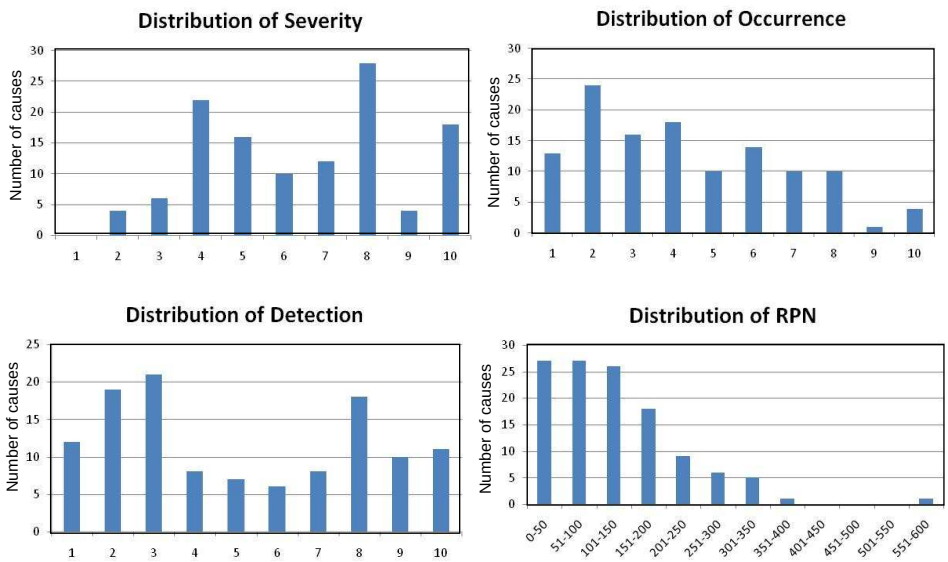

Fig. 1. Preliminary distribution of FMEA indices for considered process (before improvement actions). *X* axis: value of index, *Y* axis: number of instances (total 120)

For the described process state (no improvement actions yet) the FMEA ROI and DOI indices, according to equations (1) and (2), are:

FMEA ROI = 4,07 (or equivalent: FMEA %Prev = 24,6%)

FMEA DOI = 4,69 (or equivalent: FMEA %Det = 21,3%)

During each improvement stage of the process, a specified number of actions has been planned, performed and verified/corrected. Actions were focused on preventive or detective controls (or both). After each improvement stage a thorough FMEA review was conducted, including calculating of both FMEA ROI and DOI indices, reflecting improvement strategy applied – see Tab. 1, Tab. 2 and Fig. 2 for comparison. A following abbreviations were used: PC – number of effective improvement actions – preventive controls, DC – number of effective improvement actions – detective controls.

Table 1. Preventive controls dominant improvement

FMEA review #	**PC**	**DC**	**FMEA ROI FMEA%Prev**	**FMEA DOI FMEA%Det**
1	20	2	4,07 → 3,34 24,6% → 29,9%	4,69 → 4,53 21,3% → 22,1%
2	20	2	3,34 → 2,81 29,9% → 35,6%	4,53 → 4,44 22,1% → 22,5%
3	20	2	2,81 → 2,55 35,6% → 39,2%	4,44 → 4,36 22,5% → 22,9%
4*	29	10 **	2,55 → 2,17 39,2% → 46,1%	4,36 → 3,55 22,9% → 28,2%

Table 2. Detective controls dominant improvement

FMEA review #	**PC**	**DC**	**FMEA ROI FMEA%Prev**	**FMEA DOI FMEA%Det**
1	2	20	4,07 → 3,97 24,6% → 25,2%	4,69 → 4,21 21,3% → 23,8%
2	2	20	3,97 → 3,88 25,2% → 25,8%	4,21 → 3,65 23,8% → 27,4%
3	2	20	3,88 → 3,80 25,8% → 26,3%	3,65 → 3,29 27,4% → 30,4%
4*	9	33	3,80 → 3,48 26,3% → 28,7%	3,29 → 2,81 30,4% → 35,6%

* Final review was forced by a requirement RPN ≤ 100. To fulfill the above requirement, one had to implement both preventive and detective controls in a few instances (as long as technically possible, actions were designed according to selected predominant strategy). A few times a “total prevention” had to be applied, which, in accordance to [2], made also a detection index achieve value of 1 (meaning no detection necessary due to effective prevention, e.g. error-proofed design).

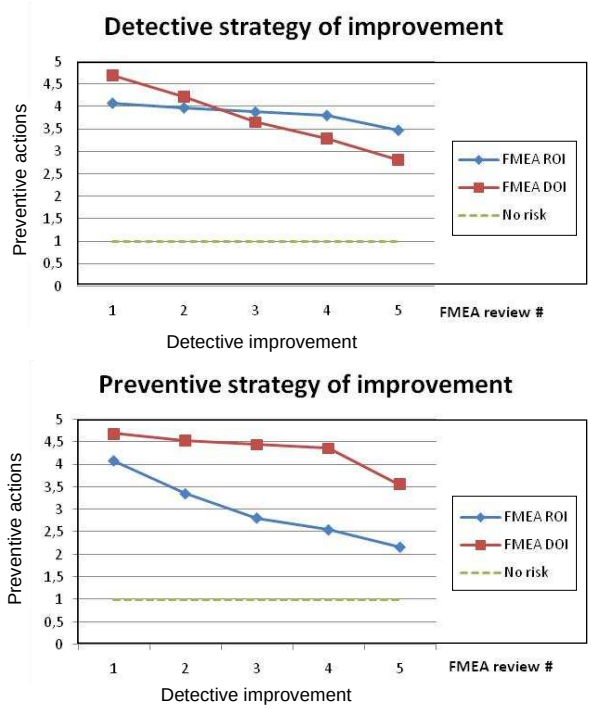

Fig. 2. Effects of improvement actions – preventive vs detective improvement strategy

Both strategies involved the same number of performed actions, but the final outcome was significantly different. Figure 3 compares the obtained risk distributions.

Example 2

Assume initial risk distribution presented in Fig.1 (120 rows in FMEA). FMEA team has introduced a few improvement actions investing only in preventive controls, without making any changes in detection controls. Although this approach goes in line with quality improvement recommendations, still it might be reasonable to asses quality of such improvement by taking into consideration subjects of the improvements. One has to realize that the team might have looked for improvement opportunities (by preventive controls!) in two ways:

- Trying mainly to lower the highest RPNs (e.g. customer expectation);
- Trying to reduce risk of the most critical, then probable, failures (causes).

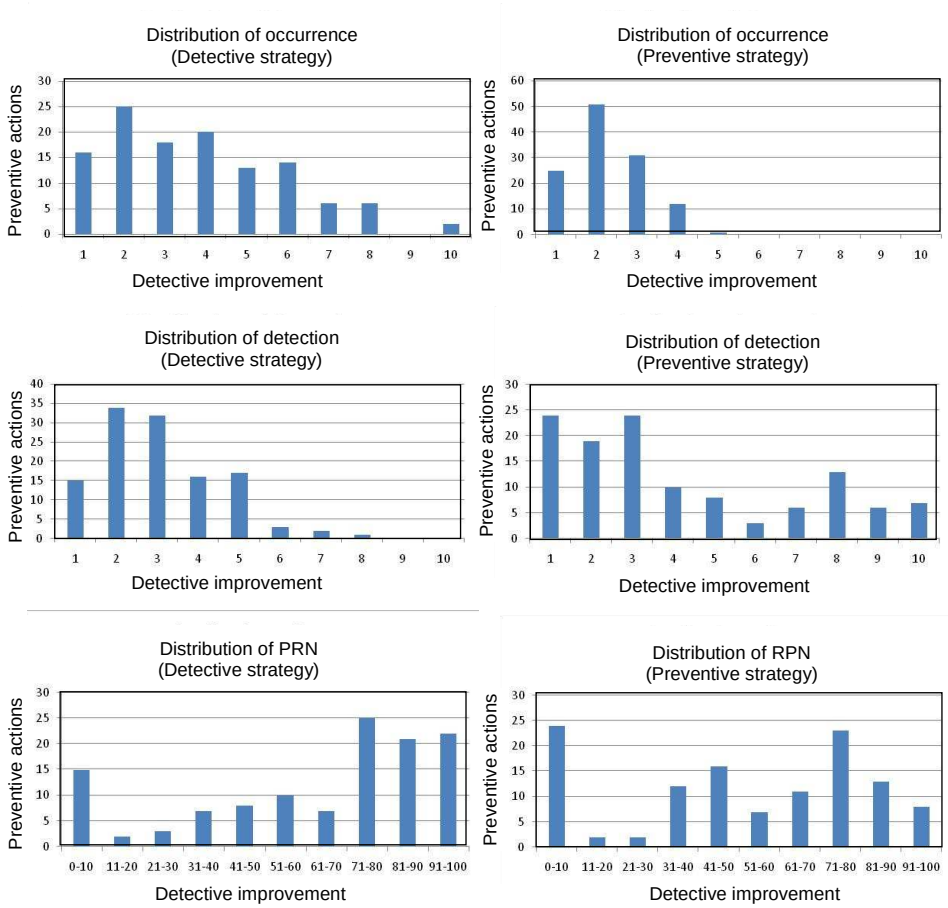

Fig. 3. Risk distributions resulting from improvement actions: preventive vs detective improvement strategy

The FMEA ROI index would distinguish between both improvement strategies, as opposed to distribution plot, which would suggest both strategies give the same results in terms of failure occurrences.

Strategy 1 is based on RPNs, strategy 2 is based on Severity (considered first while making improvement decisions), and then Occurrence (considered as second criterion). Fig. 4 reflects a difference between the two approaches. Both gave similar distribution of Occurrence, but Strategy 1 resulted in significantly smaller reduction of FMEA ROI than strategy 2 (FMEA DOI remained unchanged due to no improvement in detection controls). This gives additional insight in quality of improvement process conducted by preventive controls. It complies with observations 1 and 2 mentioned earlier as a basis for concept of FMEA ROI and DOI indices.

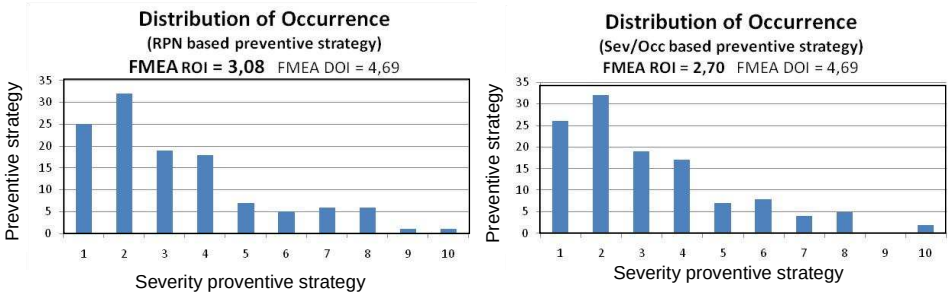

Fig. 4. Risk distributions resulting from improvement actions: RPN preventive strategy vs Severity & Occurrence preventive strategy

Conclusion

Judging by RPN alone (traditional approach still observed in many companies), one is not able to:

- Correctly asses potential risk;
- Correctly plan the improvement process with emphasis on prevention rather on detection controls;
- Correctly and in an objective way assess the quality of improvement process that took place (and consumed a lot of resources).

On the other hand, judging by Occurrence alone, one is not able to assess applied preventive strategy and identify whether preventive controls were applied to reduce overall risk (RPN strategy) or to reduce most severe risks most likely to happen (Severity & Occurrence strategy). To make such assessments it would be necessary to make and understand 3D graphical FMEA reports (e.g. distribution of Occurrence vs Severity), which might require advanced software and qualified specialists able to prepare and interpret such reports.

Review of graphical distributions of FMEA indices supported by proposed FMEA ROI (or FMEA %Prev) and FMEA DOI (or FMEA %Det) measures would allow quick and easy assessment of improvement strategy. It could allow managements to control FMEA process and better deploy resources. This would contribute to improving FMEA quality, and thus, team's capability to actually reduce risks instead of relying on detecting it in time – before accepting design, accepting process or, eventually, before dispatching a non-conforming product to a customer.

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