

### FMEA analysis effectiveness determinants

Just to remind you, FMEA is a method concerned with specifying what failures may occur in the process or product analyzed, what causes of such occurrence could be, and how the customer may experience them (fig. 1).

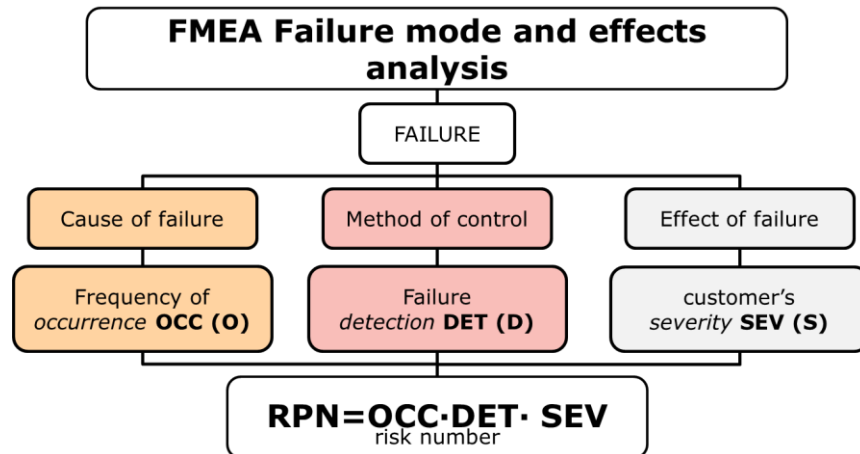


Fig. 1. FMEA method  
Source: own elaboration

FMEA analysis is time-consuming and requires a considerable knowledge of the process and product. One of the first steps under PFMEA (process FMEA) is to specify a precise course of the process. It is important that the aforesaid course includes all actions specified in the process flow diagram. In the process of conducting the analysis, it may turn out however that the enterprise adopts invalid diagrams; this being the case, FMEA analysis must be based on a real process course, while flow diagrams corrected.

Another thing you need to remember when carrying out the analysis is a proper assessment of cause occurrence. Depending on the type of process and product serving as a subject of the FMEA analysis (manufacturing processes, non-manufacturing processes, e.g. logistic, material assets or services), there are various sources which provide valuable information on occurrence of the cause (fig. 2).

The problem in enterprises is also the fact that control actions stipulated in FMEA do not correspond to the ones listed in control plans (CP).

To lower the risk priority number, it is often necessary to enter additional or more precise control actions which you then forget and fail to include in control plans, thus fail to adopt them. This leads to „fictitious” risk reduction.

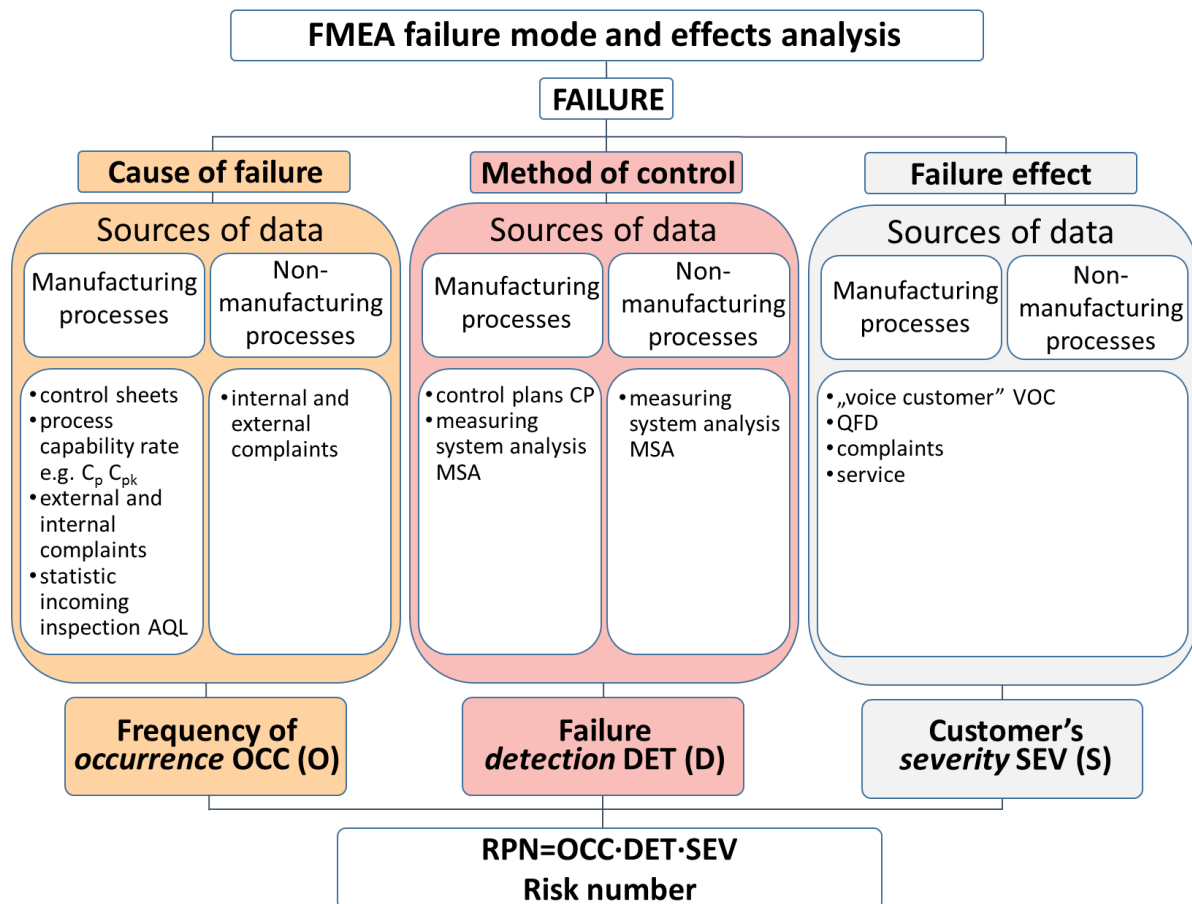


Fig. 2. Source of information used during FMEA analysis

Source: own elaboration

The results of measurements carried out during process control may serve as a basis for further analyses supported with such instruments as histogram, Pareto analysis and scatter diagram. Based on these, you can specify additional special specification of the product, weak points in the process or dependency between product features and process parameters. This information may be useful when improving the process, and if supplemented with the so-called voice of customer (VOC) established on the basis of marketing research, serves as a basis for designing (supported with QFD method) new and better products.

Most instruments supporting quality management are based on data deriving from measurements (including assessment of occurrence frequency in FMEA), thus their credibility is of paramount importance. The instrument used to check correctness of results should be MSA analysis (measuring system analysis). It is necessary to conduct it with regard to all measuring systems specified in control plans and FMEA. In addition, a properly conducted analysis of measuring systems (in particular for visual controls, attribute MSA) may serve as a basis for lowering risk priority number in FMEA analysis.

## Summary

It may be very beneficial to enterprises if their quality management is supported with various methods and techniques. Yet, it will be effective and translate into efficient operation if the aforesaid instruments form a uniform whole and supplement one another. The results of analysis conducted with the use of one of the methods should be considered an input data to another, and all methods and techniques adopted in the enterprise should be combined to form a uniform system whose priority is to improve the product, process and entire organization.

### Katarzyna Karmelita (consultant and coach)



A graduate of Wrocław University of Science and Technology in the Faculty of Computer Science and Management.

Since she started her professional career, she has been dealing with quality and environment management systems, statistical methods in quality management, process approach and studying customers' and employees' satisfaction.

She conducts training and workshops for manufacturing and service-providing companies from various lines of business (incl. automotive) as well as classes related

to process management for Wrocław University of Science and Technology students. She is also an internal auditor of quality and environment management systems. She supports enterprises in terms of preparing for external and independent audits regarding quality and environment management systems.

Her specialization is statistical instruments supporting quality management and process control. She also has a long-lasting experience in managing quality, based on many accomplished projects and publications.

The subjects of her workshops and advisory projects:

process approach, classic quality management instruments 7&7, FMEA analysis, Statistical Process Control (SPC), Measurement System Analysis (MSA), process modeling based on BPMN, TRIZ – fundamentals.

### PhD Eng Tomasz Greber (consultant and coach, Managing Partner)



He has been dealing with quality and environment management systems, statistical methods in quality management, risk management, work organization, audits and surveys, KAIZEN/Lean and Six Sigma approaches for over 20 years. He implements and improves management systems, conducts training for internal, external and independent auditors. He moderates group workshops dedicated to risk analysis in manufacturing, trade and logistics processes.

He conducts training, workshops and consultancies for companies from various lines of business. He is a lecturer at state and private universities and post-graduate colleges. A speaker during many management-related conferences.

He is a Lower Silesia Quality Award holder, a long-time editor-in-chief in "Zarządzanie Jakością" magazine, member of the Control Council of certification unit, quality management system auditor. He publishes in the following magazines: "Zarządzanie Jakością", "Normalizacja", "LAB", "Problemy Jakości", "Computerland" and in conference publishing houses. He is an author of the following books: "FMEA analysis. Compendium of practical knowledge", "Statistical process control – quality improvement with STATISTICA package" and co-author of the book entitled "Quality management in European integration".

He has a long-lasting experience in the field of managing quality, based on a number of accomplished projects and publications.