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META-QUALITY DEPLOYMENT METHOD IN PREVENTIVE QUALITY ASSURANCE

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1. Introduction

Successful development of products requires strict orientation towards the requirements of customers and application of system and process approach in the preventive quality assurance. For successful development of a new product it is nowadays possible to use the preventive quality assurance method Meta-Quality Deployment (MQD), which deals with quality assurance during all phases of product's life cycle.

2. Meta-Quality Deployment

The first foundation stone of MQD method (Fig. 1) is the Quality, Safety and Organizational Function Deployment method (QSOFD), which was developed in 1999 on the basis of the analysis of the factors influencing the process of design and the methods of quality assurance QFD, FTA and FMEA [Hering 1994].. After year 2000 it was necessary to adapt this method to the requirements of ISO 9000:2000 series of standards [Blecha 2003].
MQD covers all stages of the life cycle of a product from its development and design to its safe disposal. Realization of QSOFD method for each stage begins always at the first suitable opportunity; that means that when procedure of QSOFD for disposal stage begins, all procedures are being realized concurrently. The procedures overlap each other and at the same time they are closely linked to the parallel risk analysis, which is required by law at the present. Risk analysis is carried out as soon as during the system analysis [Marek 1996], [Knoflíček 1996] of the new product and it also deals with all potential risks that can arise during the whole life cycle of the new product. Risk analysis is therefore the second foundation stone of MQD method.
Furthermore, MQD respects and applies:

- Integrated Product Development
- Concurrent Engineering
- Life Cycle Engineering
- System approach
- Process approach
- Strategic marketing
- Scientific design
- Continual improvement
- Continual innovation
- All requirements on the product
- Tools of Quality Assurance

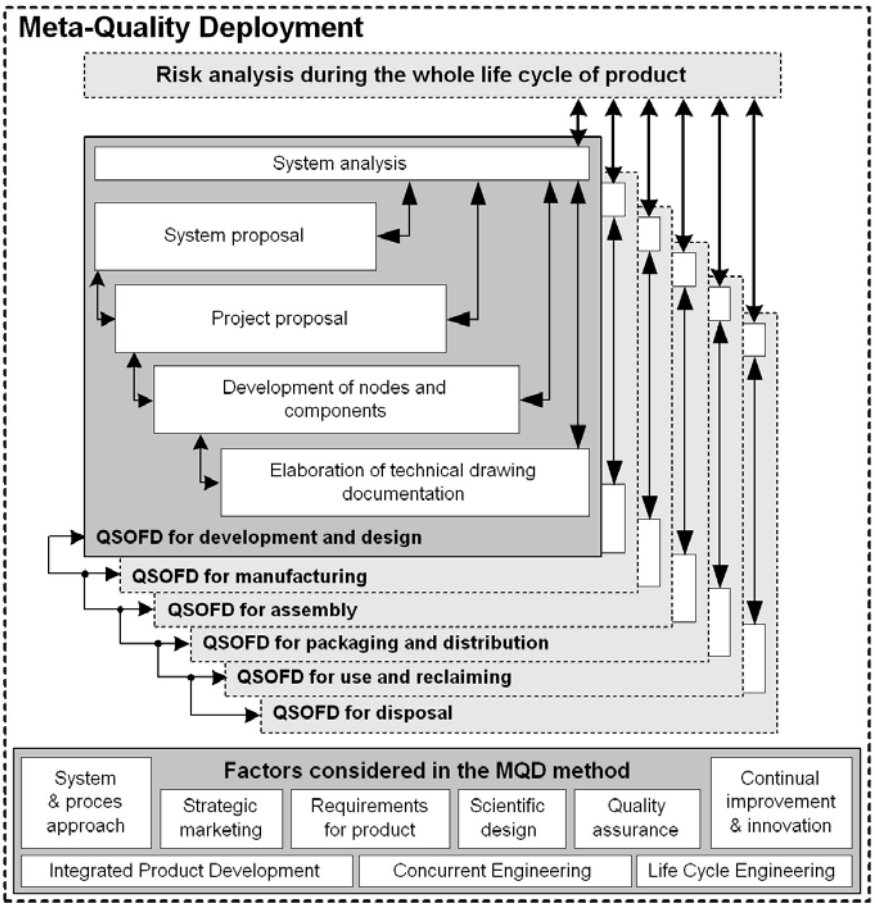

Figure 1. Meta-Quality Deployment method

2.1 Quality, Safety and Organizational Function Deployment method

Application of the QSOFD method in construction and design of a product consists of 76 steps grouped into four phases of development (S1 – S4). These steps are logically ordered in three quality houses (as seen in Fig. 2), which bring order and discipline into the development and design of a new product [3, 4].

2.1.1 The first development phase of a product with QSOFD application

The first development phase of a product (S1- as seen in Figure 3) with QSOFD application is the system proposal. First, the requirements of customers are gathered {1} and must be very accurately recorded. Then, they are supplemented with the requirements of laws and regulations {2} related to the designed product. Further, requirements of the organization itself to be incorporated into the overall requirements for the new product are selected {3}. In the next step, the recorded requirements are reviewed by the service department and classified with Service Activities Quotient (SAQ) - value from 1 (the least problematic requirements) to 10 (the most problematic ones) {4}. Subsequently, the list of the requirements is supplemented with the requirements arising from the most important activities of the service department {5}, which may be of great economical significance for the organization itself and therefore also for the customer. As not all of the requirements are equally important, in the next step it is necessary to classify them according to their significance using the Requirement Significance Quotient (RSQ) {6} with values from 1 (the least important) to 10 (the most important). In the next step, the interaction of each requirement with each of the remaining requirements is analysed and recorded into the triangular field {7} in the quality house. In order to determine the mutual discrepancies between individual requirements, we classify each requirement with a Negative Interaction

Quotient (NIQ) {8} – value from 1 (no discrepancy) to 10 (great discrepancy). As we have determined all of the requirements for the new product by now, we can begin to define its functional structure by setting the functional attributes of the product {9} and their parameters {10} represented by measurable target values. Subsequently, it is necessary to estimate how technologically advanced is this functional structure in comparison with those of competitors {11}. In the next step, evaluation of the level balance of this functional structure is performed {12}. On the basis of this evaluation it is decided if the functional attributes and their parameters have been set correctly {13} and the level of complexity of their technical realization is expressed using the Realization Complexity Quotient (RCQ) {14}. Now as we have finally determined the functional structure of the new product, we can begin to define its organ structure by assessing the organ attributes of the product {15} and their parameters {16} represented by measurable target values. The matrix of interactions of functional and organ attributes is filled-in {17} and the evaluation of technological maturity {18} and level balance {19} of this organ structure is performed. On the basis of this evaluation it is then decided if the organ attributes and their parameters have been set correctly {20} and the level of complexity of their technical realization is expressed using the Realization Complexity Quotient (RCQ) {21}. Thus, the system proposal is completed and subsequently its system analysis is performed. A block diagram of the product is created in order to determine the potential failure modes {22} and their causes {23}. The table of the occurrence of these causes is compiled {24}, correctional measures are proposed {25} and responsibility for their realization is defined {26}. Then the evaluation of the system proposal from the viewpoint of the customer is performed by setting the profile of competitors {27} using the Profile of Competitors Quotient (PCQ), which is then numerically expressed as the Profile of Competitors Parameter (PCP - Equation 1){28}. Further it is necessary to perform evaluation of the system proposal from the viewpoint of competitiveness. A matrix with Quotients of Mutual Relations (QMR) between attributes and requirements is worked out {29}; this matrix is then used, together with the RSQ, to set the technical significance {30} of the individual attributes of the product (Technical Significance Quotients – TSQ - Equation 2). Next step is the selection of the critical requirements. First it is necessary to assess the technical complexity of the individual requirements {31} with the use of Technical Complexity Quotient (TCQ – Equation 3) calculated from QMR and RCQ. Then the Complex Significance Quotients (CSQ_I) are determined {32} expressing the significance of each requirement from the viewpoint of the customer as well as of the organization itself. CSQ is calculated as a weighted mean of NIQ, RSQ, TCQ, PCQ, SAQ, where W_{xxx} is weigh of the quotient (Equation 4). On the basis of RSQ and CSQ_I, the critical requirements are selected {33}. The last step of this stage of design is the assessment of the critical functional and organ attributes of the product {34}. They are selected according to TSQ and RCQ.

$$PCP = \sum_{i=1}^{n} PCQ_i \cdot RSQ_i \tag{1}$$

$$TSQ = \sum_{i=1}^{n} RSQ_i \cdot QMR_i \tag{2}$$

$$TCQ = \sum_{i=1}^{k} RCQ_i \cdot QMR_i \tag{3}$$

$$CSQ_I = \frac{NIQ \cdot W_{NIQ} + RSQ \cdot W_{RSQ} + TCQ \cdot W_{TCQ} + PCQ \cdot W_{PCQ} + SAQ \cdot W_{SAQ}}{W_{NIQ} + W_{RSQ} + W_{TCQ} + W_{PCQ} + W_{SAQ}} \tag{4}$$

2.1.2 The second development phase of the product with QSOFD application

The second development phase of the product (S2 - as seen in figure 3) with QSOFD application is the project proposal. First, the functional and organ structure of the product is converted into project requirements {35}, which are then grouped together for individual product nodes and supplemented with the previously determined critical requirements {33}. In the next step, the service department comments on the problems connected with the project requirements and sets their Potential Fault Quotient (PFQ) {36} using the scale from 1 to 10. At this point it is also necessary to classify the significance of the individual requirements with RSQ (37) and to determine the mutual interactions of the requirements {38} and NIQ {39}. Then we define the basic construction structure of the product by setting its project attributes {40} and their parameters {41}, thus determining the „design space". Next, the level balance of the attributes within a node {42} and between the individual nodes {43} is evaluated. On the basis of this evaluation it is then decided if the project attributes and their parameters have been set correctly {44} and the level of complexity of their realization is expressed with the RCQ {45}. Thereby the work on the project proposal is finished and it is possible to proceed to the specification of the system analysis. The potential failure modes of the product are listed {46}, their causes determined {47} and Risk Priority Numbers (RPN – Equation 5) assessed according to the probability of occurrence of potential failure mode cause (P), its significance (S) and possibility of early detection (D) {48}. Remedial measures are proposed {49} and responsibility for their realization defined {50}. Subsequently, the project proposal is evaluated from the viewpoint of the customer; this means that the profile of the competitors is worked out {51} and expressed numerically {52}. Then the system proposal is examined for its competitiveness. The matrix of QMR is prepared {53}, which enables us, together with RSQ, to set TSQ {54}. Next, it is necessary to determine TCQ {55} and CSQ_{II} {56}. CSQ_{II} is calculated as a weighted mean of NIQ, RSQ, TCQ, PCQ, PFQ (Equation 6). On the basis of RSQ and CSQ_{II} it is now possible to select the critical requirements {57}. The last step of this phase is the determination of the critical functional and organ attributes {58}.

$$RPN = P \cdot S \cdot D \tag{5}$$

$$CSQ_{II} = \frac{NIQ \cdot W_{NIQ} + RSQ \cdot W_{RSQ} + TCQ \cdot W_{TCQ} + PCQ \cdot W_{PCQ} + PFQ \cdot W_{PFQ}}{W_{NIQ} + W_{RSQ} + W_{TCQ} + W_{PCQ} + W_{PFQ}} \tag{6}$$

2.1.3 The third development phase of the product with QSOFD application

The third development phase of the product (S3 - as seen in Figure 3) with QSOFD application is the design of the individual nodes and parts. First, the basic construction structure of the product is transformed into construction requirements {59}, which are then supplemented with the earlier determined critical requirements {33, 57}, and their RSQ is determined {60}. Further we define the detailed construction structure of the product by setting its construction attributes {61} and their parameters {62}. This is followed by evaluation of technological maturity {63} and level balance {64} of this structure. On the basis of this evaluation it is decided if the construction attributes and their parameters have been set correctly {65} and the level of complexity of their realization is expressed with RCQ {66}. Then the system analysis is further specified. The failure modes {67}, potential construction faults {68} and occurrence of these faults {69} are listed, suitable measures are proposed {70} and responsibility for their realization is determined {71}. Further it is necessary to gather organizational information for construction of the network diagram: designers, deadlines and links between departments {72} and to construct this diagram. Matrix of QMR is worked out {73} and TSQ are determined {74}. In the last step, RCQ, TSQ and the network diagram are used for the determination of the critical construction attributes {75}.

2.1.4 The fourth development phase of the product with QSOFD application

The fourth and final development phase of the product (S4 - as seen in Figure 5) with QSOFD application is the elaboration of technical drawing documentation of the product. This is in fact the implementation of the solution, i.e. application for the specific conditions in which this solution will be used. The result is then a complete construction structure of the new product represented by the complete construction documentation (76). Links between individual phases of development are well illustrated in Figure 2 that shows all of the described quality houses.

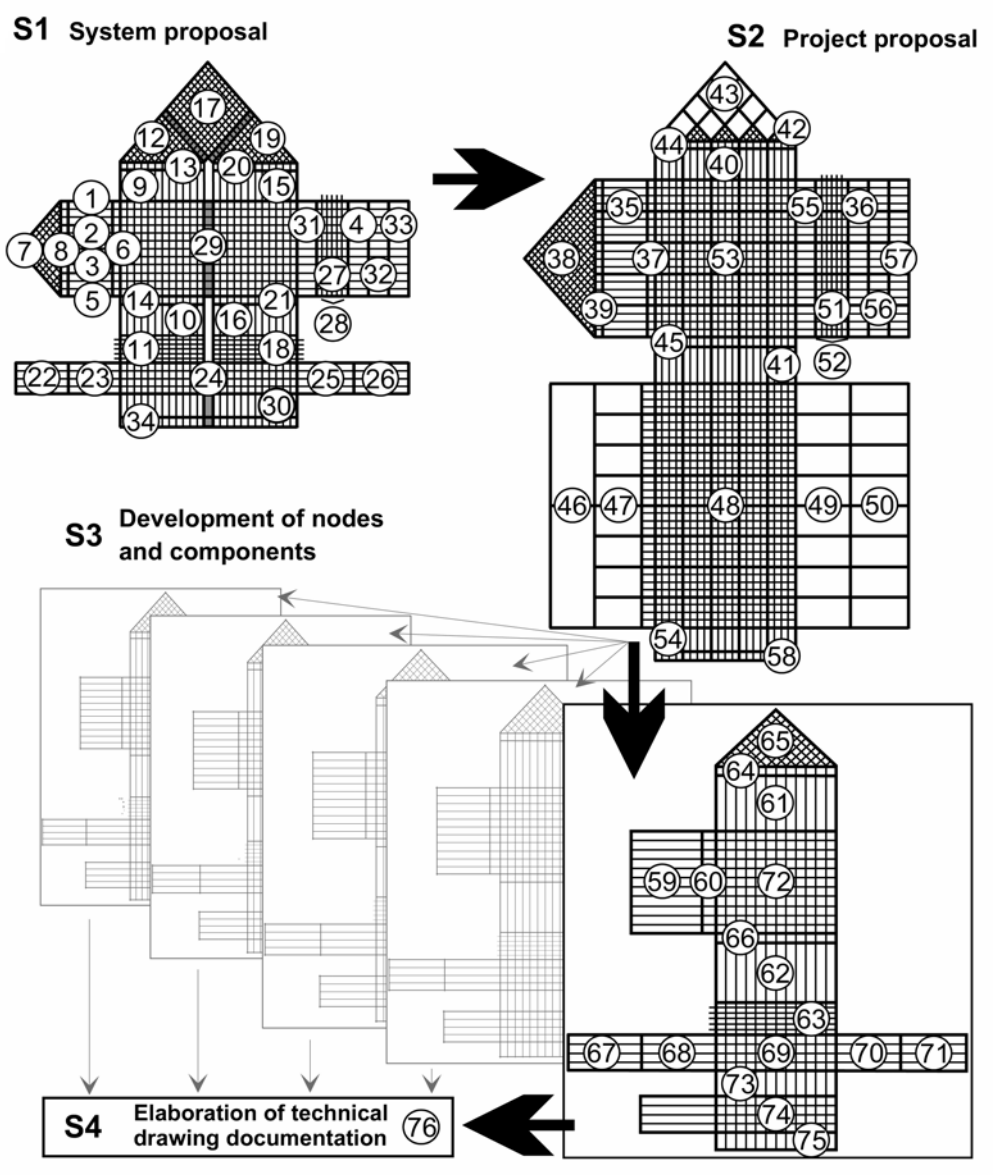

Figure 2. Quality houses of QSOFD method

QSOFD methods for preparation of manufacturing, assembly, packaging, distribution, use, reclaiming and disposal of the product are based on analogous quality houses as the QSOFD for development and design of the product.

2.2 Risk Analysis

Many European conventions dealing with safety of product binding for both the manufacturer and user of the product have been introduced recently or will come to force soon. In convection with that, the EU has issued a number of directives that are reflected in the Czech legislation in the form of government decrees. One of them is the Government Decree No. 378/2001 Coll. on requirements for the safety of product. The obligation to perform risk analysis is set by the Law. No. 22/1997 Coll., its § 8 declares that both the manufacturer and importer are obliged to launch to the market only safe products.

Risk analysis is a systematic examination of all aspects of work performed with the objective to find out what could cause an injury or damage, if the threat can be eliminated and if not, what preventive or protective measures of risk control exist or should exist. Furthermore, risk analysis is a continuous process. It is a subjective activity with two possible dangers – overestimation or underestimation of the risk. Both of these cases are undesirable, overestimation due to economic reasons and underestimation due to safety reasons, which will, in their effect, be reflected in the economy of the enterprise as well.

During risk analysis performance it is necessary to abide by the government decrees related to Law No. 22/1997 Coll. (especially government decrees no. 24/2003 Coll., 17/2003 Coll., 18/2003 Coll. and 20/2003 Coll.) and harmonized technical standards on product safety, especially by EN 292-2 and EN 1050:2001. Risk assessment must be performed in such a way that enables documentation of the procedure and results achieved during risk elimination. Risk assessment is a succession of logical steps aimed at detection of risk connected with operation of the equipment. The analysis of risks is based on considerate decisions that must be supported by experience of the design engineers and the methods of risk elimination must ensure high injury protection.

2.2.1 System analysis – foundation stone of risk analysis

The objective of system analysis is creation of a block diagram of the product (with application of the Top – Down approach) showing interactions between individual parts. This block diagram is then analysed with the use of the list of serious risks and the risks on its individual parts are identified. In a prepared form it is then marked if a certain risk defined in standard of type C (or in the report sheet) exists in the analysed product; if it does, its localization is recorded.

2.2.2 Estimation of risk

Estimation of risk can be performed according to EN 1050. This standard sets the general principles of risk estimation that incorporate all knowledge and experience from design, usage, accidents, injuries and failures in the product so that we can estimate the risk during the whole life cycle of the product.

1) Determination of limit values of the product

- Definition of limiting technical parameters of the product (set by the manufacturer).
- Expected application of the product (set by the manufacturer).
- Expected level of knowledge, experience or abilities of the potential user, i.e. operating personnel.
- Danger to other persons by fault condition of the product that can be anticipated to a certain level, for example presence of persons in the area of material or workpiece handling.

2) Risk identification

- Main dangerous zones of the product can be divided into external zones (i.e. electrical case, workspace of a robot etc.) and internal zones (i.e. engine space, zones of toothed gears etc.).
- Conditions of the product must be determined in accordance with EN 292-1 for normal operation of the product (when the product performs the expected function) and for product failure mode (i.e. due to breakdown of one or more components or functions, software fault or shortcoming, power failure etc.).

3) Risk estimation

- Seriousness (level of possible damage) can be estimated with respect to the object of protection (person, property, environment), with respect to the seriousness of injury (mild temporary after-effects, serious permanent after-effects or death), or extent of damage.
- Aspects for determination of risk factors include, for example, number of exposed persons (operating personnel), relation between exposure and impacts, human factors, reliability of safety functions, possibility of inactivation or avoiding of safety measures, possibility of safety measure maintenance and information for usage.

4) Risk elimination or reduction

- This goal can be achieved by total elimination or maximum possible minimization of each factor that presents a certain risk.

5) Information and warning of users against remaining risks

- In case it is not possible to absolutely eliminate all risks, it is necessary to inform the users and warn them against the remaining risks. These are such risks that cannot be eliminated by construction or safety measures. Instructions and warnings must set the procedures and operation regimes that should be used in order to overcome the specific risks.

6) Evaluation of risk

- At the end of each risk analysis it is necessary to perform the evaluation of risk. In this way we can find out if sufficient safety of the product has been achieved, or if it is necessary to work on further lowering of its risks. In case that further risk minimization is required, suitable safety measures must be chosen and applied and the whole procedure is repeated. If some other risks are detected during this process, they must be included into the list of all identified risks.

2.2.3 System safety

Estimation of system safety, regulated by EN 61069, must include all activities connected with a system during its life cycle from the phase of installation through operation to disposal. It must also cover all ecological aspects. During each of these phases it is necessary to consider especially the following measures and activities:

- operational procedures, maintenance and discard procedures
- warnings in the form of symbols or text
- disposal of packaging material, waste products as well as cleaning compounds

The following aspects must be taken into consideration during estimation of the system safety:

- types of risks
- subject of risk outcomes

- ways of spreading
- measures for risk reduction

Assessment of safety and risk estimation can be easily performed with the use of standards of type C. This standard contains a list of all serious risks connected with a product that was worked out in accordance with procedures described in EN 1050. In case it is not possible to use the standard of type C for the analyzed PM, in the next realization step it is necessary to create (in agreement with the corresponding standards) protocols facilitating estimation of risk in the analyzed product [10].
Further it is suitable to estimate the system safety in accordance with EN 61069. Estimation of system safety must include all activities connected with a system during its life cycle from the phase of installation through operation to disposal [8]. It must also cover all ecological aspects

3. Conclusion

MQD is one of the team methods that support Concurrent Engineering and Integrated Product Development. Thanks to application of system approach and system analysis, introduction of this method can be gradual. The MQD method not only meets the requirements of ISO norms 9000:2000 series, but it also supports the system and process approach to quality assurance in all creative activities in the planning and design of product.
MQD also integrates consistent risk analysis in planning of all stages of the life cycle of the newly developed product. Risk analysis of the whole life cycle of the product is closely connected with system analysis of the product and analysis of potential faults with the use of QSOFD method. In this way the MQD supports Life Cycle Engineering and is likely to become an effective tool of preventive quality assurance.
Application of MQD method supports the creative way of work, understanding of interactions between individual elements of the product including its structure and easier detection of the unspoken customer's requirements. The support of proposal of efficient preventive and corrective measures is also important as it greatly contributes to the assurance of future success of the product in competitive environment.

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