



Planning R&D Management System Based on ISO 9001

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Abstract

To cope with stringent global competition, enterprises are forced to invigorate product design function, thus, much attention has been paid to the performance of the R&D activities. The ISO 9000 quality control system is viewed as a norm to enhance QC systems and to promote product quality. Among the series, the design control section in 9001 is regarded as an effective means to strengthen the function of the R&D department. Based on the requirements of ISO 9001, this paper presents useful methods to plan and evaluate the R&D systems to strengthen the design capability of various

industries.

Keywords : R&D, ISO 9001, QFD, FMEA, FTA



I. Introduction

Since the International Standards Organization (ISO) published the quality control system of ISO 9000 series in 1987, the ISO standard has become internationally accepted and regarded as a norm for making quality products. As reported [3], more than 45,000 official ISO 9000 certificates were issued up to 1994. ISO 9000 standards include five individual sets of international standards on quality management and quality assurance, ISO 9000 and 9004 are served as guidelines, whereas ISO 9001, 9002 and 9003 are used as certification schemes. Among the series, ISO 9001 is the most comprehensive model covering quality assurance in all phases including design, development, production, installation, inspection, test and servicing. Notably, the ISO standards are generic in nature and are not designed specifically to any particular industry, product, or service. ISO standards are implemented through a third party process, usually a local standards organization. The registration affirms that the company adheres to acceptable quality standards and will be perceived as a viable supplier to their customers. Nevertheless, even after registration, the auditors come back periodically to ensure that the standards remain to be fulfilled.

Few investigations have addressed the related issues of ISO 9000. Mclachlan [1] described the relationship between formal quality standards and total quality, and concluded that a formal quality system is required for most businesses. Scotto [2] pointed out that although the ISO certification process could make registration expensive, companies can earn significant additional revenue shortly after beginning the process. Vloeberghs and Bellens [3] surveyed the relationship between human resources management and quality management, and found that ISO 9000 implementation is a popular activity in many different economic sectors with high satisfaction. Johannsen [4] presented an implementation model of ISO 9000 for professional services based on the experiences from the information sector. Critical success factors concerning ISO application are discussed in [5, 6, 7, 8].



II. ISO 9001 Design Control

In the ISO 9001 guidelines, only item "4.4 design control" regulates research and development management. Nine subitems are further categorized to respectively control different phases of the entire R&D process. The emphasis of each subitem is described as below:

1. General:

Establish and maintain documented procedures to control and verify the design

of the product in order to ensure that the specified requirements are met.

2. Design and Development Planning :

(1). Prepare strategies for each design and development activities, and define responsibility for their implementation.

(2). The design and development activities shall be assigned to qualified personnel equipped with adequate resources.

(3). The plans shall be updated as the design evolves.

3. Organizational and Technical Interfaces :

(1). Organizational and technical interfaces between different groups which input into the design process shall be defined.

(2). The necessary information shall be documented, transmitted and regularly reviewed.

4. Design Input :

(1). Design input requirements relating to the product including applicable statutory and regulatory requirements shall be identified and documented.

(2). Selection of input requirements shall be reviewed for adequacy.

(3). Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for imposing such requirements. Design input shall consider the results of any contract review activities.

5. Design Review :

(1). At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted.

(2). Participants at each design review shall include representatives of all functions concerned with the design stage being reviewed as well as other specialist personnel, as required.

(3). Records of such reviews shall be maintained.

6. Design Output :

(1). Design output shall be documented and expressed in terms that can be verified and validated against design input requirements.

(2). Design output shall contain or make reference to acceptance criteria.

(3). Design output shall adhere to design input requirements.

(4). Design output shall identify those characteristics of the design that are crucial to the safe and proper functioning of the product.

7. Design Verification :

(1). At appropriate stages of design, design verification shall be performed to ensure that the design stage output fulfills design stage input requirements.

(2). The design verification measures shall be identified and include activities such as

- performing alternative calculations.
- comparing the new design with a similar proven design, if available.
- undertaking tests and demonstrations.
- reviewing the design stage documents before release.

(3). The design verification measures shall be recorded.

8. Design Validation :

(1). Design validation shall be performed to ensure that the product conforms to defined user needs and/or requirements.

(2). Validation is normally performed on the final product under defined operating conditions.

(3). Multiple validations may be performed if there are different intended uses.

9. Design Changes :

- (1). All design changes and modifications shall be identified and documented.
- (2). Design changes shall be reviewed and approved by authorized personnel before their implementation.

From the nine subitems described above, the design control section in the ISO 9001 deals not only with detailed product design, but also the entire process from idea generation, design activities, functional review to the stage that the product meets the designers' or users' expected requirements. In other words, all activities related to the whole product design cycle are within the scope of R&D control system; thus, it is important to take various aspects into account when planning and establishing a R&D management system.



III. ISO 9001 Applications

The scope of ISO 9001 is defined as "quality systems: model for quality assurance in design, development, production, installation and servicing". Two cases that are appropriate for applying the ISO 9001 articles are identified as:

- (1). Involve contractual design requirements.
- (2). Design products to satisfy requirements and acquire customers' satisfaction.

On the other hand, the companies that are suitable for applying ISO 9001 standards can be divided into the following two categories:

- (1). Enterprises capable of receiving design contracts:
Given customers' defined requirements, the firm can independently perform design activities or apply accumulated technologies to redesign a product, excluding the partial reform of the existing product.
- (2). Enterprises capable of finding customers' needs:
The company can make a survey of the market to obtain the product trend, and systematically perform product design/development to the extent that the product design cycle can be clearly defined.

Before introducing ISO 9001, the enterprises must be aware of its own characteristics. Since the R&D activities of many companies aim solely at planning a better manufacturing process for a specific product to pursue high production efficiency at a low manufacturing cost. Enterprises of this kind design process instead of product, they are inappropriate for employing ISO 9001. Otherwise, to fulfill practical requirements and ISO requirements at the same time, a deformed and inefficient system could be developed.



IV. Planning Design Control Activities

When planning the R&D management system, the enterprises should carefully allocate the related resources and assign the responsible manpower to adhere to the ISO requirements more aptly. Several issues relating to the design control are addressed as follows:

1. Establish organization and define responsibility

Whether the R&D activities are carried out by a functional department or a project organization, all professionals must be administrated to efficiently control design resources. Additionally, the R&D function is composed of all activities before production, and participants usually come from different departments. Therefore, the responsibility of the R&D team, the project manager, and all relevant personnel must be clearly defined and documented so that limited resources will not be wasted.

2. Collect and comply with technical laws and standards

As long as the final products are to be marketed, the R&D activities must comply with certain technical laws and standards. Management's unfamiliarity with those laws and standards implies that an unlawful, unsafe, and irrational product will be produced, and unpredictable risk can occur since the likelihood of achieving the expected market share is small. Thus, designing products must focus not only on creating new function, but also be responsive to the related laws and standards in order to launch successful products.

3. Evaluate software and hardware

Good tools are a prerequisite for successfully executing a job. During the entire R&D process, various equipment such as a computer, plotter, prototyper, and tester must be carefully planned and evaluated. In particular, the lease-or-buy decision must be estimated precisely. Moreover, any measure capable of accelerating the R&D process or promoting the R&D atmosphere should also be carefully examined. Common approaches may include the acquisition of external technologies to fill the gap, the selection of the joint venture, the expansion of the software, and the purchase of the patent.

Once investment of software and hardware are proved to be profitable, action shall be taken immediately to prevent company from being impressed that the management is incompetent and the outlook is limited. Otherwise, tardy decision may be excused for not completing the project on schedule.

4. Train R&D engineers

Recruiting and training design engineers are critical issues in a R&D management system. The academic environment gives the basic understanding to the scientific theories, to obtain professional knowledge for a specific industry needs extensive practical training and operation. Most companies frequently use attractive offers to lure away employees from other organizations. This may seem to be a short cut to obtain general experts; however, R&D engineers work with confidential information all the time. Anyone who can be lured into this firm can be lured away. Therefore, the best approach in the long run is to build up experts internally and avoid technology concentration.

Many tools can be used to facilitate research and development, such as Quality Function Deployment (QFD), Failure Mode and Effect Analysis (FMEA), Failure Tree Analysis (FTA), Reliability Engineering (RE), Experimental Design (ED), and Taguchi Method (TM). These techniques can optimize the design quality; thus, engineers should be trained to apply them to the real problems.

5. **Plan R&D document**

During the design processes, an enormous amount of data and information can be produced. These are the accumulated experiences and technologies that can be applied to the succeeding R&D activities and, therefore, should be documented. The documentation type can be defined in the planning stage and varies according to the product designed. Two conventional ways of preserving the results are

(1). Working notes

It is frequently used in the cases where clearly describing the product is difficult or generating the design is highly creative. Software design and electronic circuit design are two typical examples. Firms of this kind usually view the working notes as the estate of the company. Thus, before leaving the office, engineers must return notes to a secure centralized cabinet.

(2). Designed table

This is adopted by most enterprises. Tabular records are made regularly as the project evolves, and are kept by the project manager. When certain predefined stage is reached, all records must be transmitted to an information center for permanent preservation. Nevertheless, the project members are allowed to keep a reference copy. The management procedures of the research results should be announced formally, and implemented stringently. All confidential records are not only the know-how of the company, but can also be used as the proven documentation to convince the appraiser when applying for the ISO 9001 certificate or to convince the judge when having the patent lawsuit.



V. **Planning R&D Management System**

The phases of the research and development vary, depending on the type of product. Briefly, five stages can be classified: 1. idea generation stage, 2. planning stage, 3. design stage, 4. pilot production stage, and 5. initial production stage. Figure 1 illustrates each process and the corresponding responsible departments. The emphasis of each stage is described as below:

1. **Idea generation stage**

This stage is the origin of the research/development process. Ideas of the product may originate from customers' responses collected by the sales department, the market trend surveyed by the planning department, or the strategic command of the top management. All of these factors are merely the conceptual description of a new product. This stage focuses on describing the product idea as clearly as possible. Formal written descriptions and the business specifications must be

prepared to evaluate the feasibility of the following three aspects:

- (1). Technological feasibility: such as engineering human resources, production equipment, inspection capability, and the like.
- (2). Marketing feasibility: such as strategies of the competitors, market potentiality, and product positioning.
- (3). Synthetic feasibility: such as cost estimation and return on investment analysis.

2. **Planning stage**

Once a decision is made, a project team should be organized to perform the design tasks. A project leader must be allocated. to ensure that the product is completed with high quality, on schedule, and at low cost. In this stage, the business specifications are converted into manufacturable engineering specifications and the quality function deployment (QFD) can be used to assist the transformation. A master schedule should be established for each project. Schedule of the contractual design project should include the customer's requirements and due date. The engineering specifications and design schedule should be carefully reviewed to ensure that the design objective can be achieved. Information that can be collated should include to enforce the design function and to reduce the research/development risk. Previous design project and customers' complaint records are two of the useful references.

3. **Product design stage**

The converted engineering specifications are the quality level that should be accomplished in the design stage. The major tasks of this stage consist of:

- (1). Preservation of complete design records, including numerical computations, selection of components, simulation of interference between parts, and so on.
- (2). Construction and verification of prototypes.
- (3). Production of design output, such as bill of materials, component and assembly drawings, circuit charts, and software.
- (4). Estimation of production cost.
- (5). Application of patents.

The design output and records should be reviewed, and the results of FMEA or FTA must be checked. The design review emphasizes the following points:

- (1). Correspondence of design output and standards, and engineering specifications.
- (2). Appropriateness of design processes.
- (3). Manufacturability of design output.
- (4). Testability of design output.
- (5). Acceptability of cost variation.
- (6). Purchasability of materials.
- (7). Acceptable allowances of the design output.

All reviewed records must be preserved. If the project leader observes a significant deviation between planned schedule and actual schedule, the remaining phases should be rescheduled accordingly. If any engineering

specification must be adjusted, the exact revision should be determined in the review meeting.

4. **Pilot production**

When the design output is proven acceptable after modification, the next step is to construct the prototype and perform the pilot production. This stage aims to transfer the designed results from the R&D department to the production department. Several tasks should be completed before pilot production; therefore, a separate stage is implemented by some enterprises. The preparatory tasks include the following:

- (1). Preparation of quality control plan, such as QC engineering table, inspection standard, and sampling.
- (2). Preparation of test equipment.
- (3). Design of production flow, such as layout, power, and construction works.
- (4). Preparation of jigs and fixtures.
- (5). Preparation of operation sheets.
- (6). FMEA of processes.
- (7). Procurement, installation, and examination of production and testing equipments.
- (8). Determination of quantity of prototype and pilot production.
- (9). Training of relevant personnel.

When the preparatory activities are completed, the project team should call a meeting to smoothly transfer the designed results. If a separate stage is performed, a review meeting can be used to determine the right time of pilot production. The available time span of the production line and workpower must be arranged in advance; the working order can then be released. The responsibilities of related departments at this stage are

(1). Quality assurance

- Inspection of product quality and analysis of process capability.
- Review of inspection plan.
- Review of QC engineering table.
- Review of test equipments.

(2). Manufacturing department

- Review of production flow
- Review of jigs & fixtures.
- Review of operation sheets.
- Review of manufacturability of materials.
- Review of assembly plan.
- Review of production efficiency
- Estimation of production capability.

(3). R&D department

- Problem solving and data collection.
- Design changes.

After pilot production, each department should prepare a report concerning the production tryout. A review meeting is then summoned to determine whether another pilot production is necessary or the mass production is ready. If another pilot production is necessary, the causes of failure and responsibility of reform must be determined. Planing of the pilot production may also need to be adequately revised.

5. **Initial mass production**

Once the pilot production confirms that the project is feasible, the utilization of the samples and preparation of the mass production can be subsequently arranged. The samples can be used in two-fold: (1) buildup of the standard sample, and (2) trial marketing. The former is established on the basis of the firm's or customer's sampling procedures. The latter is implemented based on the initial evaluation of the targeting customers and regions, and results of the experimental sale must be reported.

The key tasks of mass production are to modify the documents related to the production and inspection, revise the jigs, fixtures and molds, adjust the operational conditions, confirm the procurement and subcontract procedures, and rectify the bill of materials and engineering drawings. Those tasks attempt to eliminate all unsatisfactory states occurred in the pilot production.

The first mass production or initial product management focus on reverifying the process capability and precisely estimating the manufacturing cost to ensure that the design is successfully transferred to the production. By incorporating the results of the test sale, the design project is terminated until the product corresponds to the initial expectation and meets the overall objective of the enterprise. Figure 2 briefly lists all design activities and the applicable tools.



VI. Cconclusions

As widely known, educated people usually demand an independent working environment. Research/development staff are characterized by disregarding trifles, and superficialness, whereas, at the same time, they are cautious and sharp. They dislike to be bound in an uniform management style, such as check in and out, standard operation time, and the like. The main reason is that design processes involve creation and imagination, excessive control will constrain the imagination and, consequently, retard the creation. Therefore, when planning the design management system, it is necessary to convince staff that reporting the progress is to seek problems for management support, rather than to dig every design detail. Otherwise, they may feel intruded. To accomplish this, the checking points of the design stages should be carefully applied so that the required information can be extracted without invading the design engineers. Furthermore, design engineers tend to strive for technological leader, and appropriate award system can be designed according to their perception. To avoid trial and error, the external management consultant can be utilized to accelerate the system's maturity.



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