



第三部分 质量管理体系过程方法指南

Guidance on the Process Approach to Quality Management Systems

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1 前言

新的 ISO 9000:2000 标准提倡组织在建立、贯彻和改进其质量管理体系 (QMS) 时采用过程方法。Standards promote the adoption of a process approach when developing, implementing and improving a quality management system (QMS).

ISO 9000:2000 标准, 2.4 条款: 过程方法明确描述过程方法如下:

“任何一个或一组活动, 使用一定的资源, 将输入转化为输出都可视为过程。Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

要使组织有效运作, 管理者必须明确和管理许多相互独立、相互联系又相互作用的过程。通常, 一个过程的输出将是下一个或多个过程的输入。ISO 9001:2000 版标准所指的“过程方法”是系统地明确和管理这些过程, 尤其是相互作用的过程。For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the “process approach”.

新标准整体结构采用了这一过程方法, 替代 94 版标准的“20 个要素”结构。This process approach is reflected in the new structure of ISO 9004:2000 (“Quality Management Systems – Guidelines for performance improvement”), and also in ISO 9001:2000 (“Quality management systems – Requirements”), replacing the “20 element” structure of ISO 9001:1994.

质量管理八项原则中以下两项原则为新标准提供了“过程方法”的基础。Two of the eight quality management principles on which the new standards are based relate to the “Process approach” and the “System approach to management” as follows:

过程方法 – 将有关的资源和活动当作一个过程来管理, 更加有效地帮助组织达到预期的结果。Process Approach: a desired result is achieved more efficiently when activities and related resources are managed as a process.

管理的系统方法 – 在一个既定的目标下, 明确、理解和管理一个包含相互作用过程的体系, 使组织不断改进其效率和效益。System approach to management: identifying, understanding and managing of interrelated processes as a system of for a given objective contributes to the effectiveness and efficiency of the organization.



这一指南文件旨在帮助组织理解新标准的理念和“过程方法”的内涵。This guidance document is intended to help users of the new ISO 9000:2000 standards to understand the concepts and intent of this “process approach” to management.

2 过程方法 The Process Approach

过程方法旨在达到一个动态和持续改进的循环，使组织在每一次循环中获得明显收益，尤其是在其产品 and 业绩、有效性、效率和成本方面获得收益。The process approach aims at achieving a dynamic cycle of continual improvements and allows significant gains to the organization, typically in terms of product and business performance, effectiveness, efficiency and costs.

组织应以顾客为中心，通过明确主要过程，及其变化趋势和改进，提高顾客满意度，从而建立市场竞争优势。ISO 9004:2000 附录 A 中推荐了组织自我评估的方法，帮助组织确定过程的成熟度。The process approach also facilitates customer focus and increased customer satisfaction through the identification of the key processes within an organization, their subsequent development and continual improvement. Self-assessment methodologies such as the one proposed in annex A of ISO 9004:2000 may be used to evaluate process maturity levels.

过程方法鼓励组织对其所有过程建立清楚的认识。不仅局限于质量管理体系所必要的过程。一个过程包含一个或多个活动，将输入转化为输出。输入和输出通常是有形的和/或无形的，如设备、材料、元件、能源、信息和财务结果等其它。要使过程有效进行，组织必须配备适当的资源。组织可采用某中测量体系来收集与过程有关的信息和数据，分析过程的表现和/或输入和输出的特性。The process approach encourages the organization to develop a clear understanding of all its processes, not only those that are needed for its quality management system. A process consists of one or more activities that transform inputs into outputs. Inputs and outputs are generally products that may be tangible and/or intangible. Examples of inputs and outputs may include equipment, materials, components, energy, information and financial resources, among others. To perform activities within the process appropriate resources have to be allocated. A measurement system can be used to gather information and data to analyse process performance and/or input and output characteristics.

ISO 9001:2000 标准中，过程方法要求组织明确、贯彻、管理和持续改进构成质量管理体系过程的有效性，管理过程的相互作用，从而达到组织的质量目标。这包含了最高管理者、产品实现和相关支持过程，以及监控和测量过程。Within the context of ISO 9001:2000, the process approach requires an organization to identify, implement, manage and continually improve the effectiveness of the processes that are necessary for the quality management system, and to manage the interactions of these processes in order to achieve the organization's objectives. This includes top management, product realization and relevant support processes, as well as monitoring and measurement processes.

过程方法在质量管理体系中的应用如图一所示如下：

A schematic representation of a process approach implementation for a QMS is described in Figure 1.

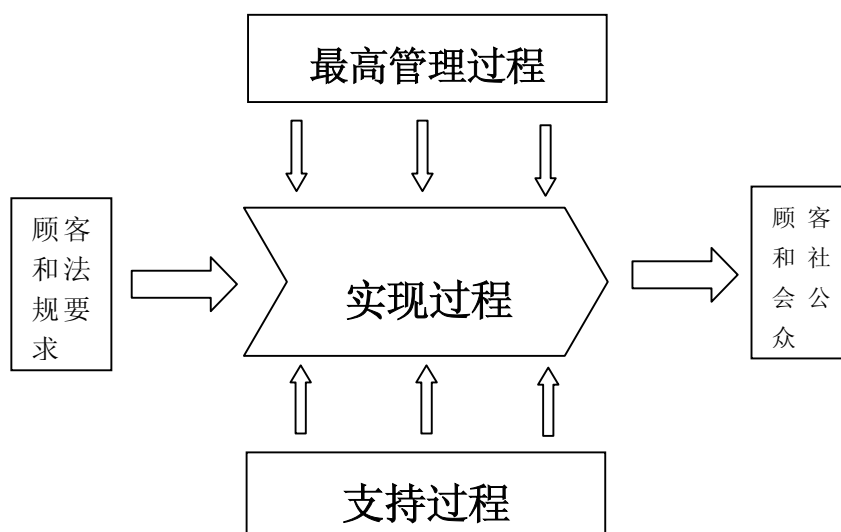


图 1 – 过程方法 Process Approach

- ✧ 最高管理过程包括策划、资源分配和管理评审等。Top management process includes for example, planning, allocation of resources and management review, etc.
- ✧ 实现过程包括与顾客有关的过程、设计和开发、产品/服务实现、采购等过程。Realization process covers for example, customer related process, design & development, produce realization process, purchasing process etc.
- ✧ 支持过程包括培训、保养和维护、环境等 Support process includes training, maintenance, environment, etc.

过程的有效性和效率可通过内部或外部评审，根据适当的成熟度指标来判定。成熟度指标可根据组织的类型、行业、周边水准、产品或服务特性建立相对的指标，如 1-5 分制，1 代表管理体系还未建立；5 代表最佳结果（质量/成本）。这一方法的优点在于将过程有效性量化，便于随时监控，从而达到持续改进的目标。过程成熟度的测量有许多方法，以使用于不同的组织和场合，ISO 9004:2000 中介绍了一种方法。Process effectiveness and efficiency can be assessed through internal or external review processes and evaluated on a maturity scale. These scales typically range in degrees of maturity from "no formal system" to "best-in-class performance". An advantage to this approach is that results can be documented and monitored over time to reach improvement goals. Numerous maturity tables have been developed for different applications. One such model is contained in ISO 9004:2000 annex A, Guideline for Self-Assessment.

3 P-D-C-A 循环和过程方法 P-D-C-A Cycle and the process approach

PDCA 是一个动态循环，可用于组织的过程，包括产品实现及其它质量管理体系过程的策划、贯彻、控制和持续改进。PDCA ("Plan-Do-Check-Act") is a dynamic cycle that can be deployed within the



organization's processes. It is intimately associated with the planning, implementation, control and continual improvement of both product realization and other quality management system processes.

在组织各个层次，均可采用 PDCA 理念保持和持续改进过程能力。不仅对高层次管理过程适用，如质量管理体系策划和管理评审，对基层运作活动也同样适用。Maintaining and continually improving the process capability can be achieved by applying the PDCA concept at all levels within the organization. This applies equally to high-level strategic processes, such as quality management system planning, or management review, and to simple operational activities carried out as a part of product realization processes.

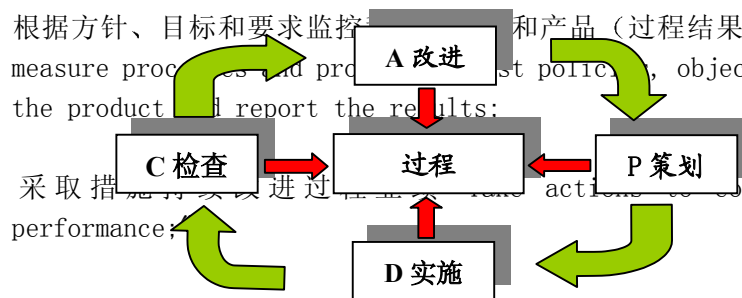
ISO 9001:2000 标准对 PDCA 循环在过程中的应用做了如下解释：The Note in Clause 0.2 of ISO 9001:2000 explains that the PDCA cycle applies to processes as follows:

“策划 Plan” 根据组织顾客要求和方针，建立目标和达到目标必须的过程。 Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies;

“实施 Do” 贯彻过程 Implement the processes;

“检查 Check” 根据方针、目标和要求监控过程和产品（过程结果），并报告结果 Monitor and measure processes and products against policy, objectives and requirements for the product and report the results;

“改进 Act” 采取措施持续改进过程性能 continually improve process performance;



4 相互作用过程的管理 The management of interacting processes

组织各种活动的相互关系有时非常复杂，从而构成各种过程及分过程的网络。这些过程的输入和输出与内部和外部顾客有关。图三举例说明过程网络的相互关系。管理的“系统方法”使得各个策划的过程相互协调和兼容，并明确各个过程之间的接口关系。The interdependencies of an organization's activities can sometimes be complex, resulting in a network of various processes and sub-processes. Inputs and outputs of these processes relate to both external and internal customers. An example of a network with interacting processes is shown in Figure 3. The "System Approach" to management allows for the coordination and compatibility of an organization's planned processes and a clear definition of their interfaces.

ISO 9001:2000 标准规定了一系列过程控制的要求。这些要求适用于各类型和不同规模的组织。组织应明确,并将质量管理体系必需的过程连接起来,使之成为一个有机的整体。ISO 9001:2000 specifies a number of requirements for the control of an organization's processes. These requirements are applicable to any type and size of organization and are typically met by defining and linking those processes that are needed for quality management and integrating them into a system.

在图三中加入 PDCA 循环,使管理体系在一个整体框架下运行,表示管理和控制不仅适用于个体过程,同样也适用于整个网络。The PDCA cycle has been added to figure 3 to illustrate in a schematic way that management and control are equally applicable to individual processes and to the network as a whole.

过程网络模式表明，顾客在确定过程输入要求的环节中起到了重要作用。顾客对过程输出的满意或不满意的反馈将成为组织质量管理体系持续改进的输入。The model of the network of processes illustrates that customers play a significant role in defining requirements as inputs. Customer's feedback on satisfaction or dissatisfaction of process output is an essential input to the continual improvement process of the QMS.

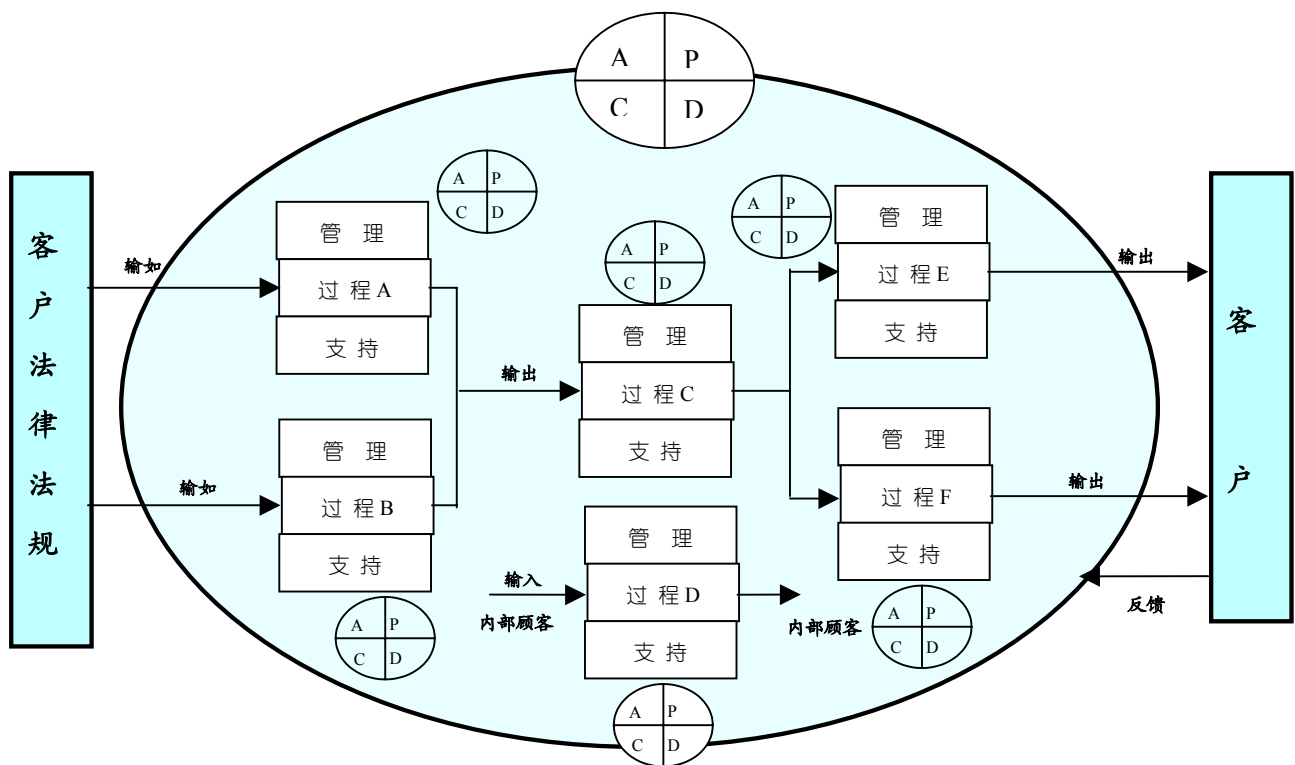


图 3 - 过程网络 Figure 3 –Network of Processes

5 结合 ISO 9001:2000 标准要求, 贯彻过程方法 Implementation of the Process Approach in relation to ISO 9001:2000 Requirements

ISO 9001:2000 标准, 前言 0.2 条款中要求: Clause 0.2 in the introduction of ISO 9001:2000 states:

“在质量管理体系中，过程方法强调下列方面的重要性：When used within a quality management system



process approach emphasizes the importance of:

- a) 理解和满足要求 the understanding and fulfillment of requirements,
- b) 需要考虑过程是否创造价值 the need to consider processes in terms of added value,
- c) 获得过程业绩和有效性的结果, 及 obtaining results of process performance and effectiveness, and
- d) 根据对目标的测量, 持续改进过程 continual improvement of processes based on objective measurement."

在新标准中, 过程方法包括产品实现所必须的过程, 以及为保证质量管理体系有效贯彻所必须的过程。对这些过程的要求, 新标准在下列章节中描述: Within the context of ISO 9001:2000, the process approach includes the processes needed for product realization, and the other processes needed for the effective implementation of the Quality Management System (QMS). Requirements for these processes are stated in the following clauses of the international standard:

- 4 质量管理体系 Quality management system
- 5 管理职责 Management responsibility
- 6 资源管理 Resource management
- 7 产品实现 Product realization
- 8 测量、分析和改进 Measurement, analysis and improvement

质量管理体系的总体要求在 ISO 9001:2000 标准, 4.1 条款中描述。下面举例说明组织在贯彻新标准时应注意的问题。The general requirements for a QMS are defined in clause 4.1 of. Some guidance is given below on what an organization may choose to ask itself in order to address these requirements, though it is stressed that these are only examples, and should not be interpreted as the only way to meet the requirements:

- a) **明确质量管理体系所必须的过程, 及其在整个组织中的应用** Identify the processes needed for the quality management system, and their application throughout the organization.

我们的质量管理体系需要哪些过程 What are the processes needed for our QMS?

是否有那些过程向外分包 Are any of these processes outsourced?

每一个过程的输入和输出是什么 What are the inputs and outputs for each process?

每一个过程的供应方和顾客是否明确 Who are the customers of the processes?

过程顾客的要求是否明确 What are the requirements of these customers?

过程的职责是否明确 Who is the "owner" of the process?

- b) **确定这些过程的顺序的相互作用** Determine the sequence and interaction of these processes.

我们所有过程的总体流程是什么 What is the overall flow of our processes?

我们怎样描述这一流程 (过程图或流程图) How can we describe this? (Process maps or flow-charts?)

过程之间的接口关系是什么 What are the interfaces between the processes?

我们需要哪些文件 What documentation do we need?

- c) **制定判定准则和方法, 确保过程的运作和控制有效** Determine criteria and methods required



ensuring that both the operation and control of these processes are effective

过程预期的和非预期的结果特性是什么 What are the characteristics of intended and unintended results of the process?

监控、测量的分析判定准则是什么 What are the criteria for monitoring, measurement and analysis? 怎样结合这些判定准则，策划质量管理体系和产品实现过程 How can we incorporate this into the planning of our QMS and product realization processes?

怎样判定过程的经济性（成本、时间、浪费等）What are the economical issues (cost, time, waste, etc.)?

采用何种适当的方法收集过程信息和数据 What methods are appropriate for data gathering?

d) 确保提供必要的资源的信息，支持过程的运作和监控 Ensure the availability of resources and information necessary to support the operation and monitoring of these processes

每一个过程需要什么资源 What are the resources needed for each process?

怎样建立信息交流渠道 What are the communication channels?

我们怎样提供有关过程的内部/外部信息 How can we provide external and internal information about the process?

我们怎样获得反馈 How do we obtain feedback?

我们收集什么过程数据 What data do we need to collect?

我们保存哪些过程记录 What records do we need to keep?

e) 测量、监控和分析过程 Measure, monitor and analyze these processes.

我们怎样监控过程的业绩（过程能力、顾客满意度）How can we monitor process performance (Process capability, customer satisfaction)?

必须的测量方法有哪些 What measurements are necessary?

我们怎样有效地分析所收集到的信息，采用哪些统计技术 How can we best analyze gathered information (Statistical techniques)?

分析的结果给我们什么启示 What does the result of this analysis tell us?

f) 贯彻措施，达到预期的结果，并持续改进过程， Implement action necessary to achieve planned results and continual improvement of these processes

我们怎样改进过程 How can we improve the process?

有哪些纠正和/或预防措施 What corrective and/or preventive actions are necessary?

这些纠正/预防措施是否得到贯彻 Have these corrective/preventive actions been implemented?

措施是否有效 Are they effective?

6 过程的文件化 Documentation of processes

每一个组织都有其管理和运作过程。管理活动起初仅限于明确所有过程，并用最合适的方法进行管理。ISO 9001:2000 版标准要求所有质量管理体系必须的过程都应根据 4.1 条款，质量体系总则要求进行管理，但并没有明确要求哪些过程应文件化。组织应根据其顾客、适用的法规要求；业务的特性及总体管理策略决定应建立的管理文件。Processes exist within the organization and the initial approach



should be limited to identifying and managing them in the most appropriate way. ISO 9001:2000 requires that all processes "needed for the quality management system" be managed according to clause 4.1 General requirements. There is no "catalogue", or list of processes that must be documented. Each organization should determine which processes are to be documented on the basis of its customer and applicable regulatory or statutory requirements, the nature of its activities, and its overall corporate strategy.

当确定是否需要建立过程文件时，组织应考虑以下因素：In determining which processes should be documented the organization may wish to consider factors such as:

- a. 该过程对最终产品或服务质量的影响 effect on quality;
- b. 该过程对顾客满意度的风险 risk of customer dissatisfaction
- c. 法规要求 regulatory requirements
- d. 经济风险 economic risk
- e. 过程的有效性和效率 effectiveness and efficiency

当组织明确需要对某一过程进行文件化时，可采用各种不同的方法，如图示法、文字描述、检查表、流程图、示样或电子媒体等。Where it is found necessary to document processes, a number of different methods can be used, such as graphical representations, written instructions, checklists, flow charts, visual media, or electronic methods.

有关部门 ISO 9001:2000 标准对文件的要求，可参考指南第二部分“文件指南”。Further guidance on the documentation requirements of ISO 9001:2000 is given in Guidance on the Documentation Requirements of ISO 9001:2000