

The PDCA cycle and Management System Standards

ISO uses a very simple but powerful tool for quality system standards. This tool is the Plan-Do-Check-Act (PDCA) cycle shown in the figure below. It is also known as the Deming cycle after J.W. Deming, who proposed the concept in the 50s. The entire logic, structure, and sequence of standards like ISO 9001 and ISO 13485 are based on this cycle. Every process or activity needs to pass through these four phases.

Plan Phase

Perhaps, planning tasks are the most important ones in a management system. ISO recognizes this fact, as well as the fact that the plan phase should be the very first thing we do. To better understand this phase, activities like “establish” and “determine” should be associated to planning. Other words we can use instead are “identify” or “define”. Let’s see what an organization needs to plan.

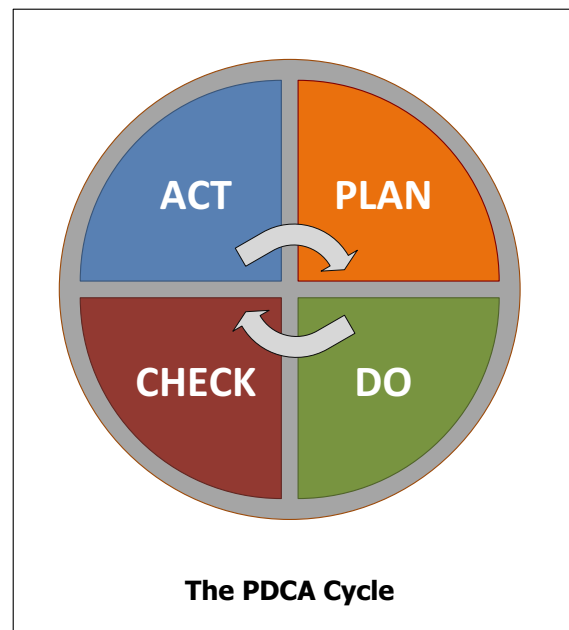
First, the organization needs to establish its high-level planning. This will set direction and provide a framework for the entire system. We are talking about the organization’s purpose. And also, in terms of quality, about: policy, system’s scope, and objectives.

The output of the high-level planning process will provide the necessary guide to the next step. Next the organization needs to identify the processes that will be part of the quality system.

It also needs to define how to apply or operate these processes, their sequence and how they interact. Also, the organization must identify risks related to the processes and how to control them according to those risks.

Then, the organization needs to make the high-detail planning for each process. This planning includes:

- Determine activities, information and criteria to operate the processes
- Determine activities, information and criteria to control the processes, including the desired results that each process should have
- Identify and provide resources and information to operate and control the processes.



- Identify the necessary records to prove compliance with the standards.

Once the organization has set plans and has provided the necessary resources, it is ready to move to the Do Phase.

Do Phase

To operate each process of the system, the organization has to provide the needed inputs. There are two types of inputs: tangible and intangible. Some tangible inputs are: components, raw and production materials. We can mention data, information, and documents as examples of intangible inputs. Skilled human resources follow procedures to convert inputs into outputs. They also use infrastructure like buildings, and process equipment to produce results. Tasks have to be performed in adequate environments, as well.

Processes not only include production and service activities, but all activities of the system. Let's see some examples.

An example is the production of a device. Operators follow work instructions to perform the various production operations. They use inputs like wires, plastic and metallic parts. They could also use adhesives or other type of chemicals. They may use process equipment, like machines, welders, and cutters. Operations may be performed in buildings with clean rooms, because the final product may be sterilized. Thus, cleanliness and bioburden controls are important. The main output of the process will be a finished device ready to the market. The main inputs and outputs of the process are tangible.

Management review is also a process. The interesting thing about Management Review is that it deals with intangible inputs and outputs. Processes like audits and production generate information. Information is the input of the process. Top managers analyze this information to convert it into decisions and actions, which would be the outputs.

Check Phase

H. James Harrington, a quality guru, stated:

“Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it.”

Mr. Harrington explains very well the basic principle behind the check and act phases of the PDCA cycle.

During the plan phase, the organization determined the results that each process needs to achieve. During the do phase, it produced results (or products). But now, it needs to evaluate achieved results to determine if they meet the expected ones.

With that in mind, the organization has to identify, collect, and process data generated by the processes. Then, it converts the data into information that is useful to make decisions. It studies the results and compares actual versus expected results. The closer the actual results are to the expected results the more effective the process is.

One of the most effective ways to perform the check phase is by creating a set of indicators. Many organizations call them key process indicators (KPIs). Some of the requirements of good process indicators are:

- They are aligned with the quality policy and objectives.
- They represent critical or key results of the processes.
- They measure critical results in a direct way.
- They are quantitative and express a measure or a scale.
- They are easy to process and maintain.

When the organization compares actual versus planned results, it needs to take action. In other words, it passes to the act phase.

Act Phase

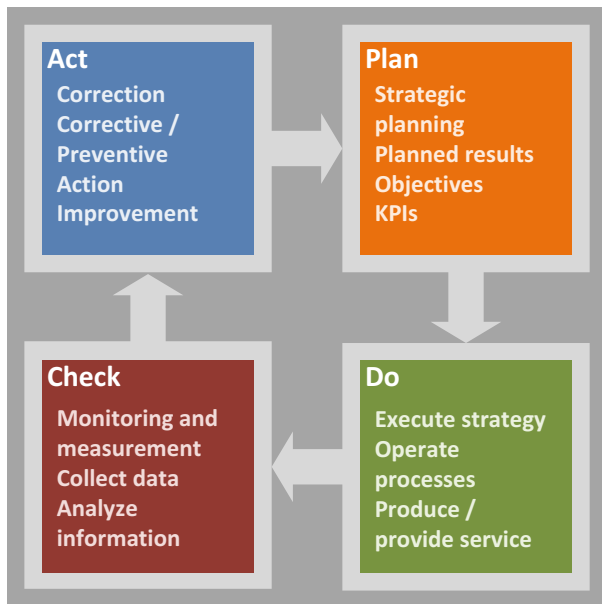
During the check phase, the organization evaluates the actual results against the desired (planned) ones. It might use KPIs or other means to do it. But at the end of the day, the organization needs to draw conclusions on whether a particular result is acceptable or not. With those conclusions, the organization will make decisions and take needed actions.

If the organization had good results, it may decide to either do nothing or take improvement actions. It means to start over the PDCA cycle by planning a better desired result, make the necessary operational changes and continue with the rest of the cycle.

For example if the desired result of the process was to have a maximum scrap rate of 5%, and 5% was actually reached, the organization may decide to maintain the status quo. A result of 5% is good enough. But management may decide to improve. So, they may set a new goal of 3%. But improvement will not fall from the sky. They will need to identify what actions are necessary to achieve the new goal. They may be to improve raw materials quality, operators' skills, or fine-tune assembly operations or process equipment. After changes are in place, the organization may operate the process, evaluate the achieved

results and may take needed actions. It means that the PDCA cycle may be repeated indefinitely.

On the other hand, if the organization had bad results, it will always need to take action. There are three different types of actions: corrections, corrective actions and preventive actions. Depending on the situation, the organization would take a combination of them.



Activities of the PDCA Cycle

Let's go back to our example and imagine that the scrap rate was 8%. In that case, the organization may take corrections or corrective actions to be on track again. If the bad result is not achieved yet, but trending analysis says that it may occur, then the organization may take preventive actions. In all cases the examples of actions mentioned above, may also apply.

Summary

The PDCA cycle has proven to be a very effective management tool. It is so powerful, that ISO chose it as one of the basic pillars of

standards like ISO 9001 and ISO 13485.

In the plan phase the organization sets its strategic planning, desired results, objectives and the way to evaluate results.

Next, in the do phase, the organization fulfills strategy, processes, products and services.

Then, in the check phase, the organization monitors and measures its processes, collect key data, and analyze information. Then it compares actual versus planned results. A key process indicator system is a good way to evaluate results.

Finally, in the act phase, the organization takes the necessary actions to get on track when planned results are not obtained or to improve if it decides to do so.

Let me have a final word about the PDCA cycle. A management system may not only have one cycle. On the contrary, it may have as many cycles as processes or activities its management system has. Each cycle may also be in a different phase, and as I mentioned before, each cycle may be repeated an undefined number of times.

References

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