

Executive responsibility according to ISO 9001:2015

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Abstract

In the current 2008 edition of the ISO 9001 Quality management systems requirements standard there is a requirement for top management of an organization to appoint a management representative to perform certain tasks in establishing and maintaining the Quality Management System (QMS). This position can vary, depending on the understanding of the requirement by senior executives, from that of an administrative position to one of complete control of the QMS. The revised standard now calls for more leadership and commitment from top management. Top management now needs to take accountability for the effectiveness of the QMS. The new standard also requires that top management ensure that the quality policy and objectives for the QMS are compatible with the context and strategic direction of the organization and are integrated into the organization's business processes. Furthermore the new standard also requires that top management engage, direct and support persons in order to contribute to the effectiveness of the QMS. In essence this now means top management need to link strategy and operations in their organizations. A methodology will be discussed in this paper as to how executives can effectively address this issue. The methodology is based on the Focus, Alignment, Integration and Review (FAIR) approach. Focused activities in the form of new strategic goals and objectives need to be aligned across various business processes. Once this has taken place the new activities need to be integrated into the existing operations. Finally executive involvement is recommended in order to review the outcomes of the integration process at the various levels and stages of application.

Keywords

Focus, alignment, integration, review and diagnosis.

Introduction

Leadership and commitment

This paper will look at how the requirements for top management have changed with the publication of the new standard. The new ISO 9001:2015 Quality management systems - Requirements standard specifies that top management shall demonstrate leadership and commitment with respect to the quality management system. This statement is different from the previous requirement in the ISO 9001:2008 Quality management systems version where the standard required of top management to provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness. What is the difference between the new and the previous requirement relating to management responsibility? The main difference identified in the revised standard is the substitution of just management responsibility, which could be delegated to a management representative, for expanded traits of leadership that includes engaging, directing and supporting persons to contribute to the effectiveness of the quality management system. The standard now also calls on top management to ensure that the quality management system achieves its intended results and not just establishing quality objectives as was found in the previous standard.

Customer focus

In the 2008 standard under the heading of Customer focus there was a requirement that top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. This requirement was illustrated through the model of a process-based quality management system found in the standard that is illustrated in figure 1. This model shows that customers play a significant role in defining requirements as inputs into the system. The model also illustrated that management had a responsibility to interact with customers although this responsibility could be delegated to a management representative. This is shown in the model as a two way information flow between management and the potential customer. Once this interaction had taken place, which could be regarded as a pre-planning phase in the Plan, Do, Check, Act (PDCA) cycle, then management could start the planning process through establishing the objectives, resources and finally processes necessary to deliver results in accordance with customer requirements and the organization's policies. The model also shows that customers play a significant role in feeding data back into the system showing their levels of satisfaction or dissatisfaction with the product or service offered.

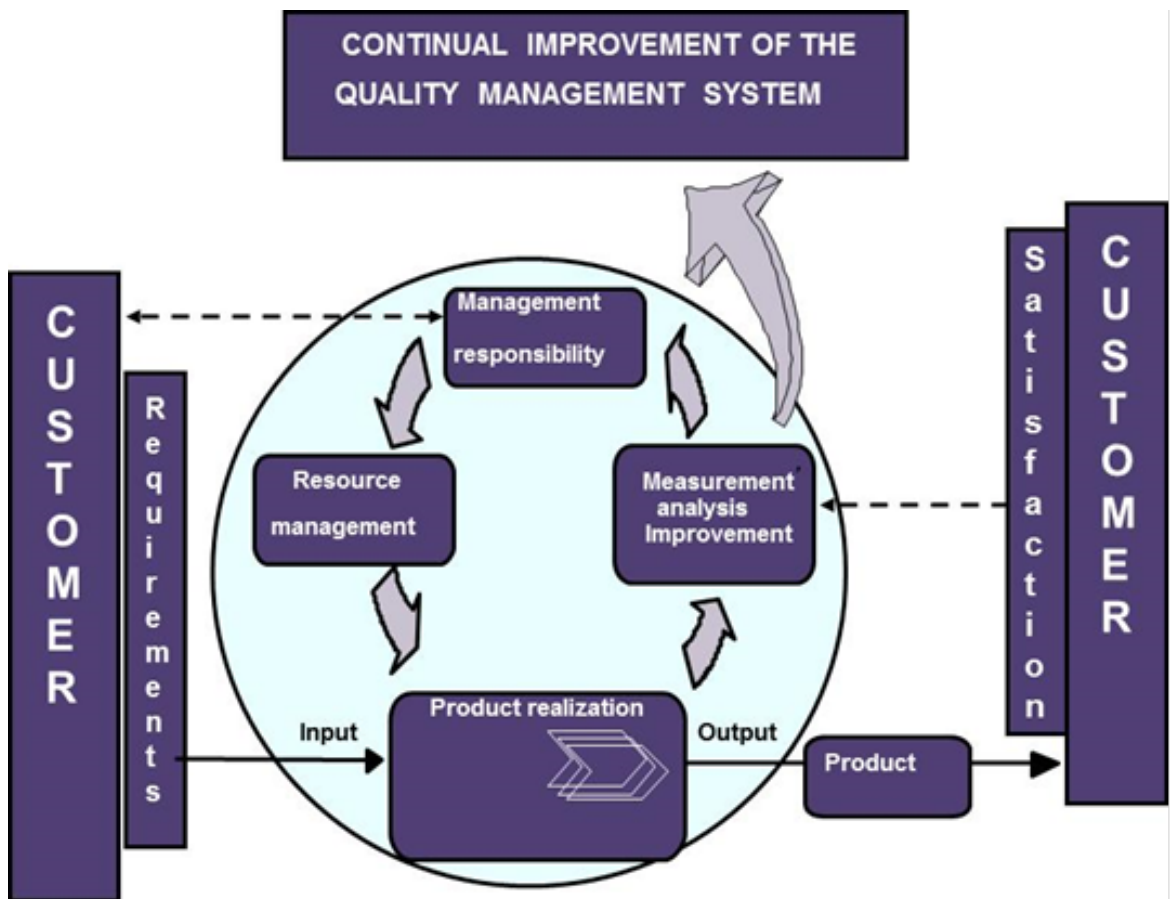


Figure 1 Model of a process-based quality management system taken from ISO 9001:2008

The new ISO 9001:2015 Quality management system requirements standard requires that top management shall demonstrate leadership and commitment with respect to customer focus. Amongst these new requirements top management need to ensure that risks and opportunities that can affect conformity of

products and services and the ability to enhance customer satisfaction are determined and addressed. The new requirement also calls on top management to ensure the focus on enhancing customer satisfaction is maintained.

Change from management responsibility to leadership

There have now been significant changes in the new ISO 9001:2015 Quality management systems – Requirements standard where the requirement for management responsibility has been replaced for a requirement for leadership. How is this change going to affect the application of the requirements to satisfy conformance to the new ISO 9001:2015 standard?

If we follow the definition of leadership found in ISO 9000:2015 Quality management systems – Fundamentals and vocabulary we see that; “Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization’s quality objectives.” This very much follows some of the Deming principles found in his work *Out of Crisis* (Deming WE 1986). ISO 9000:2015 goes on to give a rationale for this statement. “Creation of unity of purpose and direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.” So what are the possible actions that top management of an organization could take to comply with the leadership requirement found in ISO 9001:2015?

According to ISO 9000:2015 these actions could include:

- Communicate the organization’s mission, vision, strategy, policies and processes throughout the organization;
- Create and sustain shared values, fairness and ethical models for behavior at all levels in the organization;
- Establish a culture of trust and integrity;
- Encourage an organization-wide commitment to quality;
- Ensure that leaders at all levels are positive examples to people in the organization;
- Provide people with the required resources, training and authority to act with accountability;
- Inspire, encourage and recognize the contribution of people.

ISO 9000:2015 is not a “requirements” standard; it is only a support document so although the above actions “could” take place these are not mandatory “shall” requirements. If we now revert back to ISO 9001:2015 under the heading of Leadership and commitment we will find that there are ten “shall” requirements that top management have to demonstrate in order to prove their leadership and commitment to the quality management system. One of the ten requirements that stand out is the need to take “accountability” for the effectiveness of the quality management system.

In the 2008 standard responsibility not accountability was required to be delegated to a “Management representative” but often the management representative did not have complete authority for satisfying customer requirements. According to the ISO document N1287 relating to Frequently Asked Questions issued by TC 176, the technical committee that develops the standard, this position of a management representative although no longer mandatory may still be retained. However, in the 2008 standard the management representative was required to have the responsibility and authority to perform tasks in support of the quality management system whereas in the revised standard the leadership now has to take accountability for the effectiveness of the quality management system. This word change could be very significant on how the requirement is interpreted.

According to the revised ISO 9001:2015 standard, top management must also now ensure the quality policy and related quality objectives are established for the quality management system and are also compatible with the context and strategic direction of the organization. So for the first time in the development of the ISO 9001 quality management system requirements ISO are now specifying that the quality management system is linked to the strategic direction of the organization. The new standard also requires the integration of the quality management system requirements into the organization's business processes. The ISO 9000:2015 Quality management systems - fundamentals and vocabulary standard does not give a definition of a "business process" only that of a "process". However, there is a note under leadership in ISO 9001:2015 that says "business" can be interpreted broadly to mean those activities that are core to the purpose of the organization's existence. How have these changed requirements been illustrated in the new standard?

A new model has been developed and has been incorporated into ISO 9001:2015 as illustrated in figure 2.

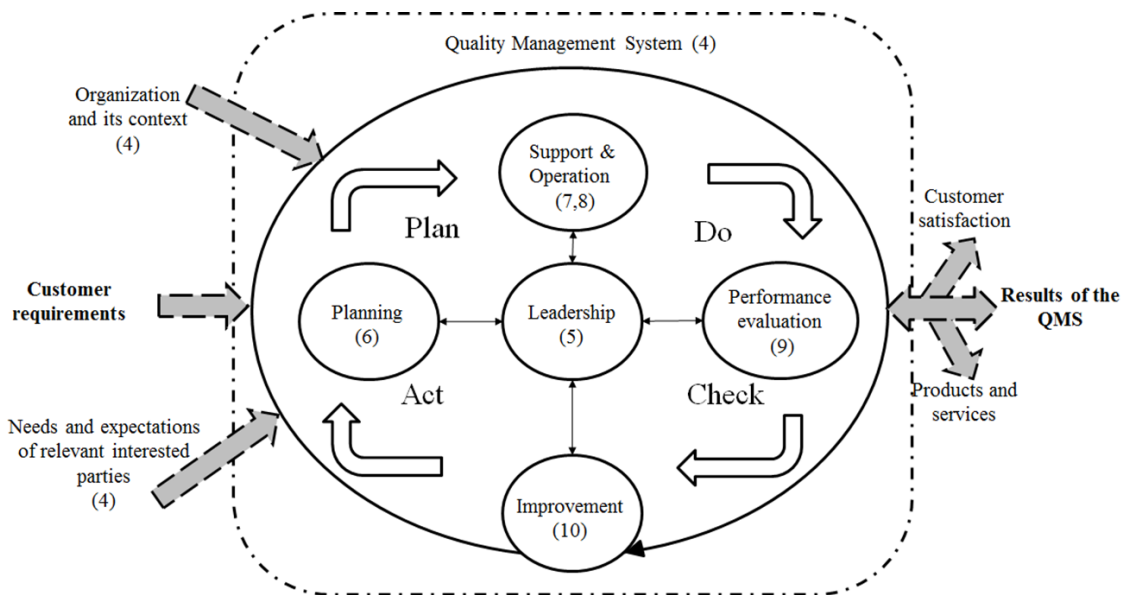


Figure 2 Representation of the structure of this International Standard in the PDCA cycle as found in ISO 9001:2015

It appears from the model in figure 2 that a number of inputs are coming into the Quality Management System that is depicted by the chain line surrounding the PDCA cycle. These include the organization and its context, customer requirements, needs and expectations of interested parties and results of the QMS with respect to customer satisfaction levels relating to products and services. This new model is not as explicit as its predecessor in the 2008 version of the ISO 9001 standard and maybe needs further clarification by the ISO Technical Committee.

The revised model does, however, indicate the various clause numbers 4 - 10 found in the standard and how they are grouped in relation to the PDCA cycle. Although it doesn't explicitly say so in the standard, the PDCA cycle is a fractal that can be applied to all processes found in the system. It appears from the model that leadership is now playing a central role to all the other requirements that are to be found in the revised standard illustrated by two-directional arrows. What is not clear is where the external influences fit into the quality management system. For example there is a requirement for the organization to communicate with customers including information relating to products and services and also a requirement relating to feedback including customer complaints. Unlike the model found in the 2008 version there is no direct link between management responsibility and customer requirements. However,

there is a requirement in the body of the standard under the heading of customer focus that requires top management to demonstrate leadership and commitment to ensure that customers as well as statutory and regulatory requirements are determined, understood and consistently met. Another interesting change found in the new standard is the definition of the Act part of the PDCA cycle that now only requires organizations to improve performance as necessary. The previous definition stated that actions needed to be taken to continually improve process performance. This new definition goes against the established understanding of PDCA that it is a continually rotating cycle.

Linking strategy and operations through Hoshin Kanri

Do executives now need to take a revised approach to their understanding and commitment towards daily management activities as found in the ISO 9001:2015 requirements standard as well as middle management's implementation and execution of strategic and other cross-functional improvement activities? There is a leadership activity practiced in many Japanese organizations referred to as *top shindan* (Witcher, Chau & Harding 2007). The literal translation of this term from the Japanese is Top Executive Diagnosis and this term will be used in this paper. This approach not only supports the Japanese methodology known as *hoshin kanri*, the literal translation of which is policy management or deployment but can also be used as an enabler for showing the leadership traits now expected in ISO 9001:2015. *Hoshin kanri* takes overall strategic goals and objectives and then breaks them down into individual targets that are cascaded down to various levels in the organization. These goals invariably have a focus on improved customer satisfaction leading to increased market share and financial sustainability. Another feature of the new ISO 9001:2015 standard is how to accommodate the changed main heading relating to improvement from "continual improvement" to just "improvement". The rationale behind this move was that improvement can be associated with small improvement, breakthrough improvements, innovation or just corrective actions. However, there is a sub clause under 10.3 that says the organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The *hoshin kanri* activity is more related to break through activity than small gradual improvements or *kaizen* (Imai M 1986). The clause in 6.2 Quality objectives and planning to achieve them found in ISO 9001:2015 opens up the opportunity to use the Top Executive Diagnosis methodology. This paper considers first the place that Top Executive Diagnosis has as a phase in FAIR, the four phases of *hoshin kanri*, and the general significance of this diagnosis. The paper then looks at the big picture on how strategy, objective setting and results fit into the general operations of an organization that may be applying the new leadership requirements found in the revised ISO 9001:2015 standard.

Hoshin Kanri explained

Research indicates that the *hoshin kanri* approach is comprised of four main tasks – focus, alignment, integration, and review (Witcher, 2003).

- Senior management need to *focus* organization-wide attention on strategic objectives, but need to balance these with other incremental diagnostic objectives to set the short-term vital few strategic priorities.
- The organization as a whole must use these priorities to *align* plans and other local priorities and management systems so there are no winners and losers.
- Everybody must *integrate* these priorities into daily management by applying TQM and PDCA principles to the management of work.
- Senior management need to *review* the operational effectiveness of the core organization-wide management processes, including the effectiveness of strategic management (deployment) itself.

This 'FAIR' view is represented figuratively as a strategy management annual cycle, see figure 3. Top Executive Diagnosis applies to the 'review' part of this cycle. It represents an annual in-depth check on how strategy and other cross-functional performance management activities have been managed during

the year. However, in practice the in-depth check may be conducted half yearly or quarterly too. This fits well with the ISO 9001:2015 requirement for management review that now requires the quality management system to be aligned with the strategic direction of the organization. The idea is not for the organization to implement the management review clause just to pass a certification audit that was often the case of introducing ISO 9001:2008. Organizations should stimulate mutual discussion between senior management and the people who implement top management goals in their daily management activities identified in the quality management system. This then creates ways and means to improve the existing quality management system. It is not therefore merely corrective action or diagnostic. Top Management must realize the importance of discussions based on facts that emanate from daily operations supporting the business processes. This aspect of the system is covered under the communication clause of the ISO 9001:2015 standard. Typically a senior management team will provide an initial short report as input, and top-level management will draw up a checklist of subjects to consider. Surveys of the present situation may be conducted and data analyzed. The management team may take part in plant surveillance where employees will be involved with discussion and analysis with senior management. There may also be roundtable discussions and these can be utilized to expand on the typical ISO 9001 internal audit requirement. At the end of the diagnosis period recommendations will be suggested from top management, and these are likely to be considered at the next round of diagnosis that could be linked to the management review requirement.

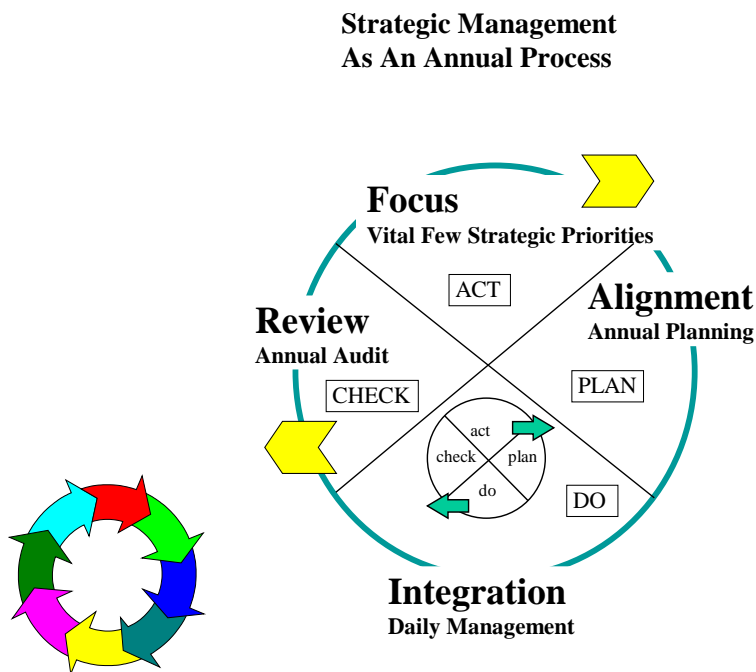


Figure 3 the FAIR model taken from Witcher B 2003 Policy management of strategy

The leadership characteristic of this audit and diagnosis cycle is considerable. The business audit and subsequent diagnosis offers the best chance for top management to engage, direct and support persons to contribute to the effectiveness of the quality management system. This is one of the ten leadership requirements found in the ISO 9001:2015 standard. The employees consulted are also given opportunities to examine and to rearrange their daily work. Moreover, the top level diagnosis contributes to the improvement of mutual understanding and human relations among the employees.

The visible involvement of top management showing leadership traits at operational level sends messages to other employees about top level commitment to strategy and strategic objectives. The involvement of people at other levels also acts to reinforce motivation in regard to company-wide issues. It can also play an important role for the dissemination of knowledge generally across the organization, particularly when results are relayed at large through an organization's communication media, and specialist networks. This approach also reinforces the requirement found in the new standard determining the organizational knowledge necessary for the operation of its processes as well as the requirement for determining communication relevant to the quality management system. This makes it easier for an organization to work together and focus its capabilities on those critical success factors that underpin competitive advantage. This helps to achieve an organization's overall strategic objectives, and enables top management to drive the management of key processes in a way that will improve the effectiveness of the quality management system.

The need to focus on consistency

One of the expected outcomes of the Top Executive Diagnosis is to ensure that there is an alignment of activities in the cascading of strategic objectives that do not have a negative impact on operating processes. It is an important part of Japanese management to be consistent in the application of each task allocated that is supporting the overall organization's strategy. Any variation in any daily management process needs to be controlled and limited. This approach to controlling processes was an important part of the ISO 9001:2008 requirement but to an extent has been overlooked by certain auditors. The first aim in limiting variation is to focus on the consistency of the task being performed. The degree of documented information developed for consistency is dependent on the nature of the task and the skill and experience of the person performing the task. The need for specific procedures to enable product realization in an organization was often abused in the ISO 9001:2008 quality requirements audit with a focus on only the six mandatory procedures found in the standard.

The Top Executive Diagnosis can be used to monitor improvements to all formalized processes and ensure that quality objectives are met. At shop floor level, once the operating system is under control, improvements to the process can be made through *kaizen* activities in line with the continual improvement requirement. The overall purpose of the Top Executive Diagnosis is then to confirm the current status of the *hoshin kanri* methodology and the organization's strategic objectives. It can also check the appropriateness of individual objectives and methodologies to the overall strategic objectives, and to gain the required support from the lower levels of supervision. Top Executive Diagnosis focuses on constancy of purpose by comparing existing and improved methods and results across functional barriers and determining whether they are focused on the broad organizational or other business objectives.

Top Executive Diagnosis as a leadership tool

Learning from experience and developing the competencies to problem solve issues are essential aspects of the learning organization (Senge, 1990). This applies as much to top management as it does to everyone else. The meaning of 'review' typically suggests periodic review when progress is assessed against pre-set milestones or to review critical issues. ISO 9001:2015 calls for a review by top management of the organization's quality management system. According to the standard this must be carried out at planned intervals in order to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. Reviews work most effectively if they are linked together as an organization-wide managed system of review, which delivers an audit trail of how the organization as a whole has been performing to achieve its purpose and longer-term strategic goals. This system provides an essential feedback loop for organization-wide learning and an opportunity for strategic-aligned evaluation, problem-solving, and corrective action. Review is also a social activity that involves participants in a shared evaluation of objectives and facts, which reinforces consensus, especially

for cross-functional management and where individuals from different functional areas may meet only infrequently.

How these periodic reviews are conducted is important and should not be seen just as a paperwork exercise or a witch hunt. The stress is on review as a method for investigating issues and not centered on who is to blame. This fear of being audited has always been one of the negative outcomes of typical ISO 9001 internal audits where often opportunities for improvement are missed. If organizational leaders take accountability for an overall managed system of review, then it is likely that meetings will be held when necessary, that they are prepared, chaired, and followed up effectively. A managed system requires its own administration and staff support, and involve administrative tasks such the managing meetings, agendas, logistics, the provision of advice even training to assist the reporting process, and post-review activities to ensure follow up action happens quickly. This activity relating to the quality management system's effectiveness was previously the responsibility of an appointed management representative and not necessarily that of top management. This previous mandatory requirement of a management representative is no longer a specific mandatory requirement of ISO 9001:2015 although a person may still be appointed in this position to support top management but top management retains accountability.

The *hoshin kanri* FAIR approach uses 'Review' to mean the Top Executive Diagnosis or a business (performance) evaluation, and which will include an appraisal of the annual strategic management process (*hoshin kanri*) itself. It is probably the most important vehicle for driving and facilitating organization-wide learning, especially for strategy and improvement in core organizational cross-functional processes. The participation of top management means that a wide involvement of people is more likely and the relevance of the state of health and the organization's operational effectiveness in relation to best practice will become more understood in the wider organization. Figure 4 illustrates what an inter-linked system of cascaded corporate strategy, objectives and review might look like.

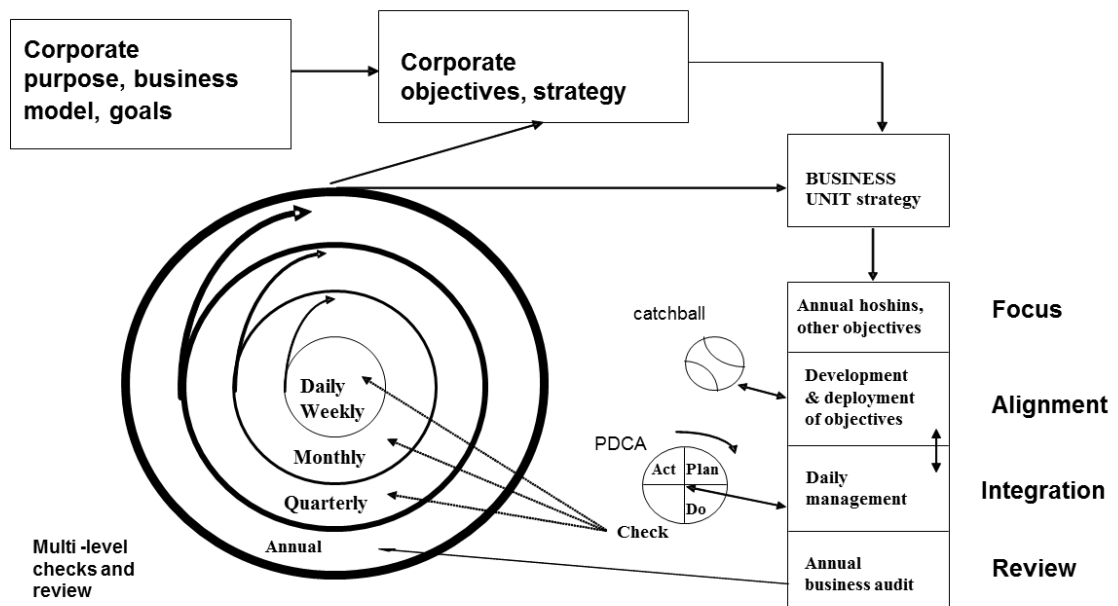


Figure 4 interlinked system of review taken from Witcher B and Chau V (2007)
Balanced Scorecard and Hoshin Kanri (adapted)

The model, shown in figure 4, starts by cascading the breakthrough *hoshins* and other objectives to the various business units as "Focus" items. The next stage of "Alignment" is most important. The figure illustrates this as a *catchball* activity, a term preferred by the Americans. The Japanese would use the term

nemawashi that is far more descriptive and means “digging around the roots” a term used for understanding what is feeding into a system before making quick decisions. The term indicates that it is necessary to look deeply into what is below the surface. The next step is “Integration” and this activity is most important in merging new targets and improvement activities into an existing management system. The PDCA cycle promoted in the ISO 9001:2015 standard is most important in this phase of implementation. Current processes need to be assessed and challenged in order to obtain improved performance.

Information obtained from review is used as part of the strategic management process shown as a sequence of interacting loops that can be used to feed back into the FAIR process. The circles to the left illustrates that data may be rolled upwards from a daily, weekly, monthly or quarterly to an annual level of review. The Top Executive Diagnosis is shown here as an ‘annual business audit’ under ‘Review’. Such Top Executive Diagnosis typically concerns an evaluation of an organization’s effectiveness in managing its core cross-functional processes. One of these enabling processes will be how the deployment of strategy takes place. The importance of this form of annual review is that it should involve top-level management in a way that enhances its understanding of daily management that consists of various processes. This is shown in Deming’s Plan-Do-Check-Act cycle, a business process approach for managing work (Deming, 1986) that is described in the introduction section of the ISO 9001:2015 standard. In fact, PDCA is an essential principle for effective *hoshin kanri*: top management should use a PDCA cycle approach to manage FAIR.

Conclusion

The defined role of leadership has changed considerably the way the 2015 updated version of the ISO 9001 Quality management system Requirements standard should be interpreted. The challenge is going to be how this change can be effectively audited in terms of collecting objective evidence to show top management commitment to the quality management system and identifying inherent risks. The importance of feedback and review in terms of both diagnostic and more open forms of learning has been a major subject in the general management literature (Ackoff, 1971) and more specifically to the strategic planning and strategic control literature (Lorange, *et al.* 1986). Taking a diagnostic approach to consider strategic objectives is in fact fine, but these meetings must consider how progress on one objective is likely to have an impact on others particularly in terms of stated quality objectives. Linking various cross functional process relationships to the success of an organization must be understood. The advantage of deploying *hoshin kanri* and Top Executive Diagnosis activities is that the highest level of management gains this understanding, and top management can then be seen to practice more effective leadership in its implementation and execution of the requirements of ISO 9001:2015.

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