CONFORMITY ASSESSMENT
Policy Issues regarding Quality Assurance

This paper on the importance of quality management systems for small and medium enterprises has been submitted by the United Nations Industrial Development Organization (UNIDO).

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BENEFITS OF QUALITY MANAGEMENT SYSTEMS
FOR SMALL AND MEDIUM ENTERPRISES

When comparing Small and Medium Enterprises (SMEs) with big companies the evident advantage of the SMEs is that quite often the SME is a family-related company with a Director on the top, who is the owner of the company - together with relatives and friends - working together for the company’s success. They are all directly motivated in the prosperity of the business satisfying and attracting their Clients/Customers.

A further advantage is that the management of such a business is very much informal. The “system” is that the Director (owner) like a Matriarch/Patriarch gives oral indications: who does what and how. The others follow those indications under her/his constant guidance, checking and controlling the quality of the product/service.

Small businesses need only a small amount of documentation: mostly of financial nature like bills, receipts, orders, contracts, etc.

A Director of a small Company usually has broad experience in the business and is appreciated by the personnel for her/his skilfulness, understanding and wisdom. Such a Director takes care of employees like loved family members and, no wonder: all have the devotion and motivation for “their” Company.

In general, such businesses have an established way or system of doing business successfully. If, in addition, the customer satisfaction is a value to the enterprise and delivery times and costs are convenient to clients then the system established in a small business is quite effective, however, it is informal and rarely documented.

Beyond the private business practices, governments and public sector organizations do have established ways of operating. The legal framework of a country or a region is the basis for such systems and is in general well documented, but the application and effectiveness is difficult to assess.

Quality management system standards like ISO 9001:2000 *Quality management systems. Requirements* identify those features that can help a private or public business consistently meet its customers’ satisfactions.
Quality systems are about evaluating how and why things are done, writing down how things are done and recording the results to show they were done properly. The underlined words indicate documentation tasks - and these may often be new for SMEs.

Users, Clients and Customers are looking for confidence that can be given by a business having a quality management system (QMS). They will happily remain loyal, constant partners.

It is not the intent of ISO 9001:2000 to imply uniformity in structure of quality management systems or uniformity of documentation. Furthermore, the QMS requirements specified in ISO 9001:2000 are complementary to requirements for products.

In this International Standard a very simple and efficient methodology is followed:

“Plan-Do-Check-Act” PDCA—developed by Shewhart and Deming and is known as the Deming-circle.

PDCA means

**Plan**: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.

**Do**: implement the process.

**Check**: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

**Act**: take actions to continually improve process performance and focusing on the quality of product/service.

This circle will mean different processes for different organizations, however, within one (sub-) sector there will be strong similarities. For instance a textile production plant in a country will have many common features in the processes and also in their documentation. Consequently their QMS will have a considerable proportion of identical elements. Experience shows that SMEs in the same sector (like suppliers of auto parts, electric and electronic supply chains, small shoe production factories) may have almost identical procedures and QMS. Well-known global chains went very far in standardization of their processes (this is the main reason for their success) and they indeed do have identical QMS as well. An example could be the franchiser chains of fast food restaurants all over the world.
ISO 9001:2000 specifies \textit{requirements} for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the QMS in meeting \textit{customer requirements and customer satisfaction}.

It specifies \textit{requirements} for a QMS where an organization (Company, SME, etc.)

\begin{itemize}
  \item[a)] needs to demonstrate its ability to consistently provide product/service that meets customer and applicable regulatory requirements, and
  \item[b)] aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.
\end{itemize}

All requirements of ISO 9001:2000 are generic and are intended to be applicable to all organizations, regardless of type, size and product/service provided. In cases where due to the nature of an organization (SME) and of its products/services any requirement(s) of ISO 9001:2000 cannot be applied: this can be considered for exclusion.

Customers are looking for the confidence that can be given by a business having QMS. While meeting these expectations is one reason for having a QMS, there may be others, which could include the following:

\begin{enumerate}
  \item Improvement of performance, coordination and productivity.
  \item Greater focus on business objectives and customers’ expectations.
  \item Continuous improvement of the quality of products/services to achieve customer’s satisfaction.
  \item Management confidence that the intended/planned continuous improvement of the quality of products/services is being achieved.
  \item Evidence to customers and potential customers of the organization’s (SME’s) capabilities and performance.
  \item Opening up new market opportunities while keeping satisfied existing customers.
  \item Certification/Registration.
  \item Opportunity for SMEs to compete on the same basis as larger organizations.
\end{enumerate}

Documentation should not mean bureaucracy and excessive paperwork or lack of flexibility.

It is true that quality assurance/management standards were invented for big companies having mass production. However, with refining them throughout the years they have been made apt for SMEs as well. The consecutive editions of the ISO 9000 series of standards (1987, 1994, 2000) have been
revised to incorporate proposed extensions and improvements. The most important improvements are: Growing importance of involvement and dedication of senior managers, employee participation and continuous improvement of the processes.

Quality should be made TOP PRIORITY. Business plans should begin with QUALITY goal, quality planning. Companies used to have financial goals, sales goals, and goals for new product development. Quality goals, if existed at all, were somewhere down in the lower levels of the organization or not a priority at all. Now, it has been reinforced that real, (preferably measurable) quality goals need to be at the top of the business plan. Quality planning needs to include a deployment process, which identifies that must be done in order to meet quality goals and who is responsible for performing the tasks, and which ensures that they are given the resources and training to enable them to do these deeds. Not only do the chief executive have to participate in the deployment process – because it involves providing resources and she/he is the only one who can do that – there is also a need for a PERSONAL review of progress.

A further very efficient methodology is also followed in this regard: INTERNAL QUALITY AUDITS. Management and financial audits in general were a best practice well before Quality Management Systems were introduced. While external quality audits, specifically third party audits, are key to obtain a certification by an accredited certification body, internal audits are important to determine whether the established quality management system conforms to the planned arrangements and requirements established by the enterprise as well as is effectively implemented and maintained.

A modified PDCA-circle can be applied to the internal audit process to better understand the synergetic effects of the ISO 9001:2000 requirements with regard to the continual improvement process through corrective or preventive actions:

**Plan:** plan and conduct an impartial audit programme according to the relevance of products and importance of the processes to be audited.

**Do:** determine causes for identified or potential non-conformities.

**Check:** monitor and measure processes and product against actions taken as results of treatment of detected non-conformities.

**Act:** provide results of audits as inputs to management review and take actions to continually improve process performance and adjust the quality management system to the quality of the product / service.
At this point we should think of the situation of big companies versus small companies. Big companies have the disadvantage of bureaucracy, slow reaction, red tapes – partly created by them forcing on themselves EXCESSIVE rules and prescribing unnecessary documentation.

Internal audits are specifically important if the business needs to demonstrate its ability to consistently provide product / service that meets applicable regulatory requirements. It was demonstrated by an example of a small soap factory with an 80% level of exports. To comply with relevant FDA requirements, this business introduced a quality management system following basically the ISO 9001 requirements within four months, because they would have to stop exports if actions were not taken within six months after an audit. To implement the quality management system, one of the managers was appointed by the top management as the quality manager, a quality board was created and the documentation generated within three months and internal audits were carried out during the following months to ensure effective implementation and maintenance of the system. In this particular case, a certification by a third party was not relevant and the business has to rely on the quality audits performed internally. On this occasion, the soap factory won the price “Exporter of the year”.

Specifically those organizations belonging to the public sector that are fully or partly state-owned are at a disadvantage. Although there are examples of customs departments in small economies, which obtained certification for suppliers of governmental bodies, which are to be certified to apply for public tenders, one of the first entities of the public sector to obtain a certification according to the new version of ISO 9001 is the Municipality of Itamaracá in Brazil.

The mayor of Itamaracá elaborated together with a Total Quality Manager (the Secretary of Health) and a team (Total Quality Management Board) a model following Total Quality Management principles. The first step in this endeavour was to introduce a QMS according to ISO 9001:2000 and to obtain its certification with a view to promote the social, economical and cultural development of the city, interacting with businesses and entities with national and international context with the objective of establishing and spreading values related to human dignity, to sustainable development and the legitimacy of the organization.

The implementation of the QMS took place in six months. An internationally recognized certification body has audited the system one month later and the certificate was issued after the causes of detected non-conformities were eliminated. Benefits of the introduction of a QMS are the better coordination in the municipality, better waste collection mechanisms as well as more transparency.
This example shows that although such organizations have different priorities, are used to be static (at the best) for quality, usually do not appreciate innovation, creativity and abhor of any revolutionary rate of improvement and all that this entails, the implementation of a QMS may introduce developments and opportunities of improvement, thus benefiting the stakeholders: in this case the society.

In conclusion, at SMEs - contrary to big organizations/companies - in most cases there is a transparent ownership, thus, it is always evident: who is the boss, who has in hand the resources, who could decide on immediate purchase of something that are needed to satisfy the clients. Decisions at big companies need to do their elaborated course. This may require sometimes so much time that the actions upon it come too late, resulting in the loss of clients, customers.

The most important benefit of ISO 9001 for SMEs is that it gives them the best tool to make the necessary overhauling of the company to win in the competition with the big ones.

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Paper prepared by Dr. Otto Loesener Díaz, Industrial Development Officer, Quality, Technology and Investment Branch, UNIDO, and Dr. Michael Parkany, DIGART, Ltd.

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