Quality Management Standards – Do They Fill Their Purpose?

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Preface

ISO is the main world organization in establishing and publishing standards of Quality Management Systems. Those standards are known well to every organization that manage its Quality Management Systems according to ISO standards and are certified according to relevant standards by authorized organizations.

The aim of any international standard and ISO quality standards in this matter, is to establish general procedures and guidelines that are defined as standards for intended uses, and users and they should be acceptable and understood everywhere, meaning by every organization in any country all over the world. ISO quality standards are written in English and directed to different interested bodies and organizations in all countries. All standards should be written in a language that is easy to read and understand, for anyone who needs them and even to those whose English language is not their mother language!

Quality standards are not mandatory by law, meaning, adopting them by organizations is made voluntarily or mainly due to customers' demand for doing business.

Quality standards are important. They create a technical language and guidelines for the users, intending organizations and their customers. So, when this language is clear and simple to understand and translated to requirements stated in relevant procedures or specifications, they can be easy to understood anywhere in the world, by any user.

The leading ISO Quality Standard is the **ISO 9001 "Quality management systems - Requirements"** and its last version was published in **2015**. It can be used by any size organization in any field of activity. This standard is based on a number of Quality Management principles including focus on customer, commitment of top management, process approach, continual improvement and other important principles. The outcome of adopting the **ISO 9001** standard should help to ensure customer satisfaction, good quality products and services, improvements and profit to the organization.

Additional standards that are connected to the leading ISO 9001 standard are:

ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary
ISO 9004:2018 - Quality management systems - Guidelines for performance improvements
ISO 14001:2015 - Environmental management systems - Requirements with guidance for use
ISO 45001:2018 - Occupational health and safety management systems - requirements
ISO 19011:2018 - Guidelines for quality and/or environmental management systems auditing

Additional standards based on the ISO 9001 standards with additional requirements and directed to specific industries are:

ISO 13485 (2016) – Medical devices - Quality Management Systems - Requirements for regulatory purposes

IATF 16949:2016 - Quality Management System requirements for automotive production and relevant service parts organizations
TL 9000 (2016) - Quality Management System Requirements for Suppliers of Telecommunication
AS 9100D (2016) - Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

Glossary

ISO - International Organization for Standardization. ISO is an independent, non-governmental international organization with a membership of 164 national standards bodies (including ANSI with about 585 participants). Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.
(From: https://www.iso.org/about-us.html).

Standard - An established norm or requirement in regard to technical or administrative systems. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes, and practices. A technical standard may be developed privately or unilaterally, for example by a corporation, regulatory body, military, etc. Standards can also be developed by groups such as trade unions and trade associations. **(**From Wikipedia, the free encyclopedia).

IATF - International Automotive Task Force - The IATF is an "ad hoc" (for a specific purpose) group of automotive manufacturers and their respective trade associations, formed to provide improved quality products to automotive customers worldwide.

TL – Telecom Leadership. When the TL 9000 started developing, TS for Telecom Systems been used. Later it was changed by QuEST Forum to TL for the TL 9000. [QuEST Forum is a global association of companies dedicated to impacting the quality and sustainability of products and services in the ICT industry. (ICT - Information and Communications Technology) industry)].

AS – Aerospace Standard

Purpose of this Report

Each time a new Quality standard or new version of an old standard is published, many articles followed by explanations about using them are published. Why? From my point of view, one reason is to explain to the intending user how to apply the standards, but the second reason from my point of view is because those standards are not clear enough, sometimes complicated and difficult to understand and use. They are written in some kind of legal language that does not serve well all intending users in every country and organizations all over the world.

So, in this report, I will explain from my point of view why the ISO Quality standards do not serve well enough the intending users and what should be done for improving them for easier use and with much more satisfaction. These are my point of view, but many people in the industry I was talking with agree with what I'm going to write about. I shall refer only to some main points but I'm sure that there are more.

Straight to the Point

According to the ISO website: https://www.iso.org/about-us.html, ISO is an **independent**, non-governmental international organization with a membership of 164 national standards bodies. But, how much are the 164 national standard bodies independent? In Israel, The government, through the Industry and Trade Office, is responsible for the SII (Standards Institution of Israel). The same or similar dependence may exist in other countries as well. In Israel there is also very often a strong connection between the national standard body and big and strong organizations that might hurt the "independency".

In addition we should be aware of the fact that the standards that are established by ISO or by national standard bodies are sold (and they are not cheap!) and not free to use for any intending user. According to ISO, over one million companies and organizations certified themselves to ISO 9001. The last version of ISO 9001, the 2015 version cost 162 American dollars which means that if more than million bodies bought the new standard, ISO received more than 162 million American dollars, a lot of money. A previous version was in 2008 and next one will be somewhere in the 2020's and for each version, another 162 million American dollars will be spent. We must not forget ISO profits from other quality standards (ISO 14001, ISO 19011 and others). What is done with all this money?

What is the real aim (destination or quest) of ISO? Is it to improve the quality of the outcome of the organizations activities and their profits by quality management aspects or to maintain its standards, to change versions every several years and collect the profit by selling the standards?

Each time a new version of Quality standard is published many articles and reports dealing with the new version (explanations, highlights) are published. Most published articles support the changes. It's fine but I'm asking myself, isn't there anyone in the Quality area (Quality Managers, Quality Auditors, Quality Engineers or other Quality Experts) that might think differently? Maybe the changes in the new versions are not so urgently needed or critical? Maybe the organizations that operated under the requirements of the previous version can continue the same good Quality activity without the new requirements and without spending additional money for the new changes and the new standard? Did anyone in ISO or anyone of the 164 national standard representative bodies survey the certified organizations for their opinions about the different aspects of the Quality standards and their frequent changes? I'd like to know if during the discussion on the change of the standard version in ISO, were there any national representatives that rejected the changes and if so, what the reasons for refusal was? Are the 164 national standards bodies and the 585 participants in ISO independent?

In some weak countries, when the leader say yes, all the follower say yes. When the leader say no, all the follower say no. ISO organization shouldn't be like those weak leaders and should be completely transparent in its activities and especially in its Quality activities!

Lately I found some important reports criticizing the ISO 9001 standard (see in references). Did anyone in ISO or in the 164 national standard bodies refer to these reports? I will read them after I will write mine.

ISO 9001 standard is a major and leading standard in QMS (Quality Management System). So, the reasons for revising it should be somehow critical and very important for the organizations' activities, improvements and profits. But the changes in the 2015 version do not address those matters, and they will not make any changes that will make the organizations' QMS better than when being managed under the 2008 version. The only organization that wins in those changes is ISO!

Some of the changes in the 2015 version that most commentators praised were:

- **Greater focus on the customer**. The customer is a primary focus sense the first ISO 9001 standard (1987). Even before the first version, Quality Gurus focused on customer in their quality system publications. So, any improvement in increasing the focus on the customer doesn't seems to be of any help. We've been there already.
- **Risk-based thinking**. Risk-based thinking replaces "preventative action". Risk thinking is not new. It has been always taken into account during planning, purchasing, contract reviews and many other activities in the organization, although it wasn't highlighted directly and intentionally in the standard. Risks in organization activities are always taken into account and planned by the top management while the "preventative action" is being taken by all levels in the organization, and mostly by employees at lower levels during routine action of production, servicing and audits. The idea is that true Risk-based thinking will automatically lead to preventative action is wrong. Adding the Risk-based thinking, is o.k., but replacing the "preventative action" is a big mistake!
- **Greater flexibility in regards to documentation**. For years organizations created and maintained Quality Manuals and procedures supporting their activities and then, periodically having their Quality Managing System (QMS) certified by local certification authorities. So why change a system that worked well? The flexibility can be achieved by the certification auditors without any change in the standard!
- **Terminology changes**. The term "products" has been changed to "outputs". Since the first ISO 9001 standard (1987) we knew and trained others that "product" refer to physical products as well as services and everyone knows it. The change of this terminology doesn't serve at the organization!

ISO 9004. Good preparation and consideration could have integrated ISO 9004, the standard for performance improvement into ISO 9001. Improvement (Continuous Improvement) was always a key issue in Quality Management and in every Quality training. So why require a special standard for it? Performance Improvement – yes, but it should be an integral part of the ISO 9001.

ISO 14001. This standard whose Quality Management System is based on ISO 9001 standard is revisited every time that ISO 9001 is being revisited. It should be a part of the ISO 9001 standard as an additional Chapter with fewer pages. Therefore, the organization that would like to adopt and implement this environmental Chapter in its Quality Management System would not need to buy the additional standard, which will not exist anymore. It only needs to add some procedures to its existing Quality Management System. Many of the subjects in ISO 14001 are the same to those of ISO 9001, so why to repeat them? The review and certification by the appropriate body would be easier and quicker for any organization. This can be a great improvement!
And moreover: there are in addition to ISO 14001, 14 (maybe more) additional standards dealing with Environmental Management (ISO 14004, IS0 14005, ISO 14006, ISO/AWI 14015, ISO/WD 14020, ISO/DIS 14030-1, ISO 14031, ISO 14040, ISO 14044, ISO 14046, ISO/TR 14047, ISO/TS 14048, ISO/TR 14049 and ISO/TR 14062) and 2 standards under development (ISO/CD 14030-2 and ISO/DIS 14030-3). Why have so many non-mandatory standards dealing basically with the same matter? Isn't a single one enough?

ISO 45001. The structure of this standard is also based on ISO 9001, but of course is dealing with different matters, Occupational Health and Safety. A very important issue for every employee at any workplace. But as the structure of the standard is based on ISO 9001, the ISO 45001 should also be a Chapter of the ISO 9001, with much less paper work. Every organization that want to adopt Occupational Health and Safety matters into its Quality Management System will only need to add a few procedures dealing with those matters. There is no place for this independent standard!

ISO 50001. Lately I discovered a new ISO standard, the **ISO 50001:2018** "Energy management systems – Requirements with guidance for use". According to ISO website (https://www.iso.org/iso-50001-energy-management.html), ISO 50001 is based on the management system model of continual improvement also used for other well-known standards such as ISO 9001 or ISO 14001. These standards doesn't stand alone, as there are 5 additional connected standards (!):

ISO 50002:2014 "Energy audits - Requirements with guidance for use"
ISO 50003:2014 "Energy management systems - Requirements for bodies providing audit and certification of energy management systems"
ISO 50004:2014 "Energy management systems - Guidance for the implementation, maintenance and improvement of an energy management system"
ISO 50005 "Energy management systems - Modular implementation of the energy management system ISO 50001 including the use of energy performance evaluation techniques" – **under development**
ISO 50006:2014 "Energy management systems - Measuring energy performance using Energy Baselines (EnB) and Energy Performance Indicators (EnPI) - General principles and guidance"

How ludicrous! ISO 50001 ÷ ISO 50006 standards should be under one and only one standard! And then be integrated with ISO 9001!

There are 4 sectorial Quality Management System standards:

ISO 13485 (2016) - **Medical** devices - Quality Management System - Requirements for regulatory purposes
IATF 16949 (2016) - Quality Management System for organizations in the **Automotive** industry
TL 9000 (2016) - Quality Management System Requirements for Suppliers of **Telecommunication**
AS 9100D (2016) - Quality Management System - Requirements for **Aviation, Space, and Defense** Organizations

All above sectorial standards structures are based on ISO 9001 and each time ISO 9001 is being revised they follow and make the appropriate changes as well. Each organization of course can create for its sector any needed standard but is it really required? And what about Quality Management System marine, toys, clothes, food and other sectors?
Organizations that supply products or services to difference sectors need to be certified to different standards. It would be much easier and logical to be certified to one standard that include different referenced Chapters for different sectors!!!
ISO 13485 belongs to ISO and should be integrated into **ISO 9001** as a Chapter, with basic requirements for medical devices sector's needs.
Organizations that are responsible to **IATF 16497**, **TL 9000** and **AS 9100D** should consider changing their attitudes and thoughts about the need for those spreads in the standards. It will be better for their users.

IATF 16497 is leading by International Automotive Task Force, **TL 9000** is leading by TIA (Telecommunication Industry Association) and by BPC (Business Performance Community) and **AS 9100D** is leading by the Society of Automotive Engineers and the European Association of Aerospace Industries.

ISO 19011. In Quality, improvement is a critical issue for an organization's status. There are many systems for improving quality (First Seven Tools, Second Seven Tools, SPC, Lean Manufacturing, FRACAS and others) and the important one is the **ISO 19011** stands for: auditing the organization's Quality Management Systems for conforming to the organization's obligations as stated in its Quality Manual and/or referred procedures. One of the outcomes of the audit is to point to possible improvements of the QMS. This standard, according to its name, directed to quality and/or environmental management systems. The standard should not be directed only to Quality Management System and Environmental Management Systems because there are additional management systems and the standard should refer to all of them: **ISO 45001**, **ISO 50001, ISO 13485, IATF 16949**, **TL 9000** and **AS 9100D** and of course **ISO 14001**.

About the content of the standard, too complicated and detailed, as if the organizations exist through it. The standard should be simplified and may be added to the modified ISO 9001 as a Chapter.

Why change the title of the standard each time? The title of **ISO 19011:2011** version (Guidelines for auditing management systems) was the best. This title should remain.

ISO 9000. Each Quality standard has its own Fundamentals and Vocabulary so if you collect all of them you'll get almost the entire Fundamentals and Vocabulary of **ISO 9000**. So, adding the Fundamentals and Vocabulary of **ISO 9000** as a Chapter to modified **ISO 9001** makes a lot of logic. Please consider this.

On the last minute

Just before finishing writing the report I looked at the Bibliography of **ISO 9004:2018** and discovered new bizarre standards:

ISO/TS 9002 - Quality management systems - Guidelines for the application of **ISO 9001:2015**. Seems that this standard corrected the mistakes of **ISO 9001**. What a shame!

ISO 10001, **ISO 10002**, **ISO 10003**, **ISO 10004** and **ISO 10008** - Quality management for customers. If customers will know that there are so many standards for their satisfaction, they will be satisfied just by knowing it. "Well done"!

ISO/IEC 27000, **ISO/IEC 27001** and **ISO/IEC 27002** – Information technology for Security techniques. One complete and well done standard wasn't enough?

And there are many more bizarre standards in the Bibliography list. Well, there is a lot of work to **ISO Independent Members** in establishing new standards for new subjects. What about standard for dealing with Aliens when they will arrive?

My Summary

So, do we need the Quality standards? Yes, they create a Quality Management System that, in most cases is the Management System of organizations and it makes order in managing the organization and helps its customers as well to understand the organization they do business with.

But, Changes should be made in all ISO Quality standards and in Quality standards based on ISO standards. Improvement and listening to customers are Quality important points. Quality standard's users are customers (I use them so I am a customer too). So, ISO should improve its standards and listen to its customers!

References – additional reading

As I mentioned earlier, I didn't read any of the following reports so as not to be influenced in my own report. My decision to add the following reports is based only on their title and I hope that I didn't make a mistake by it. I'm going to read the following reports soon.

- "Is ISO the way to go? Some say, Not So" by Ian Wilson, Consultant Clinical Microbiologist (June 4, 2010), https://james.westgard.com/the_westgard_rules/2010/06/iso-not-so.html
- ''So many standards to follow, so little payoff'' (Companies have spent a lot of money to comply with ISO's popular management standards. Now, many wonder why they bothered), by Stephanie Clifford@stephcliff (May 1,2005), https://www.inc.com/magazine/20050501/management.html
- "The 'quality' you can't feel". The universally used ISO 9000 standard is failing to improve business. John Seddon on why bosses need to regain control from assessors, by John Seddon (Nov 19, 2000), https://www.theguardian.com/money/2000/nov/19/workandcareers.madeleinebunting
- 'The Case Against ISO 9000', Oak Tree Press (Dec 4, 1998) by John Seddon
- "A Brief History of ISO 9000 - Where did we go wrong?" John Seddon
- "Problems" by Adrian Murray. https://sites.google.com/site/a3nmurray/pages-of-interest/iso-9000
- "The Top Five Things that Can Go Wrong with ISO 9001:2015" by Cavendish Scott, Inc. 984 South Vine Street, Denver, CO 80209, http://www.cavendishscott.com/articles-news/iso-90012015/the-top-five-things-that-can-go-wrong-with-iso-90012015/
- "Biggest Mistakes with ISO" by Cavendish Scott, Inc. 984 South Vine Street, Denver, CO 80209, http://www.cavendishscott.com/articles-news/iso-9001-articles/biggest-mistakes-with-iso/
- "ISO 9001:2015 Implementation: The Good, the Bad and the Trending - The future for ISO 9001 is strong" by Penny Ouellette (Nov 8, 2018), https://www.qualitymag.com/articles/95098-iso-90012015-implementation-the-good-the-bad-and-the-trending
- "Annual Analysis of the ISO Survey for 2019" by Christopher Paris (Sep 15, 2019) https://www.oxebridge.com/emma/iso-survey-2018-analysis-facing-20-loss-of-iso-9001-certs-worldwide-iso-dismantles-data-trending/
- ''2019 Analysis of Worldwide AS9100, AS9100 & AS9120 Certifications'' by Christopher Paris (Sep 25, 2019), https://www.oxebridge.com/emma/2019-analysis-of-worldwide-as9100-as9100-as9120-certifications/

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