TECHNICAL BULLETIN - ISO 9001 2008 TO 2015 CHANGES FOR PLASTIC INDUSTRY

1 Preface

Around the world, packaging and manufactured plastic packaging industries have been positively influenced by the introduction of an efficient quality management system (as described in ISO 9001 reference), because companies are constantly growing through specialization in applications and service improvement, to obtain customer's satisfaction.

Past year ISO 9001 presents a framework for the management system and introduced several changes to be considered.

2 Advantages of becoming ISO 9001

Manage quality with a worldwide recognized standard, whatever the size of the company, has three (3) main advantages:

- Stand out the company from its competition and get more sales.
- Comply systematically with customer expectations.
- Improve business performance.

Successful businesses understand that the value of an effective QMS (Quality Management System) is because it ensures the organization to be focused on meeting customer requirements, so they are always compensated with the products and services they receive. The standard also allows:

- Turning companies to stronger competitors in their market, keeping a better QMS to help them meet customers' needs.
- Improve operational performance, by reducing errors and increasing benefits to engage staff with more efficient internal processes.
- Get more customers satisfied with the service received, which expands business opportunities by demonstrating compliance with the agreements.

A certificate according to the ISO 9000 family of standards (such as ISO 9001), means a high degree of confidence for customers (Figure 1).

Figure 1 Benefits of ISO 9001.

3 Changes near to ISO 9001:2015

ISO technical committee decided to make the review of ISO 9001 in 2015, and defined the following objectives to maintain its relevance in the current and future market:

- Possibility to integrate with other management systems.
- Provide an approach to organizational management.
- Reflect environments, generally complex, in which organizations operate.
- Improve the capability of organizations to satisfy their clients.

3.1 ISO new clauses

ISO 9001:2015 is based on the development of the "SL Annex", which provides a common framework for all ISO management systems. It helps maintaining consistency, aligning different management system standards and it has some sub-clauses that are combined with the high-level structure and a common language that applies to all new standards.

With this structure, the reference will be easier for organizations to incorporate their QMS within business processes, while achieving greater involvement of senior management.

ISO 9001:2015:

3.1.1 Clause 4: Organization's context:

The organization must determine the external and internal "issues" that are relevant for its purpose, like those that have an impact on what the organization does, or could affect its ability to achieve any result expected in the QMS. This issue is also known as "risk management" and refers to all social, legal, environmental, safety, financial or close aspects that can impact directly or indirectly to the organization.

- Possible consequences of failures in context:

In general, failures in context can cause information to be expressed poorly within an organization, or loss of important information occurring by the location of it in a single unity, which can cause changes to be executed in an incorrect moment. A waste of talent or a poor understanding of customer needs may happen. Early identification allows correcting mistakes before they impact organization's results.

3.1.2 Clause 5: Leadership:

This clause establishes requirements for the "top management", i.e., the person or group of people who direct and control the organization at the highest level.

Management system now has a greater involvement in system's organization and should ensure the integration of the requirements thereof in the processes of the organization, and that the policy and objectives are consistent with the planned direction of the organization. In the same context, it must be understood the internal strengths and weaknesses of the organization and how they could impact on the ability to offer its products or services. Finally, it establishes requirements to senior management, who assigns responsibilities and authorities of the QMS, but must remain responsible for the effectiveness thereof; in the previous version, this was handled more like a delegation to people responsible for the QMS.

3.1.3 Clause 6: Planning:

The organization should plan actions to treat both risks and opportunities, how to integrate and implement the actions in their processes management system and evaluate the effectiveness of these actions.

- Planning Model:

In a well-planned organization, this reference helps to carry out orderly and purposeful activities. All efforts should be targeted toward the desired results. Nonproductive work is minimized.

For a production company (such as a plastics factory one), monetary losses associated with production time and investment in raw material would be reduced, if the manufacturing process can be effectively controlled, ensuring proper functioning of the machinery, and using procedures supported and described in the corresponding QMS. In the estimation of effectiveness, the implementation of preventive maintenance checks and other metrological checks of the equipment at precise intervals minimizes product loss and downtime with minimal costs.

3.1.4 Clause 7: Support:

This clause begins with the requirement that organizations must determine and provide previous studies for the establishment, implementation, maintenance and continuous improvement of the QMS. Requirements for "documented information" are new terms at ISO 9001:2015, which replace the references to documents and records used in the 2008's standard.

3.1.5 Clause 8: Operation:

This clause refers to the implementation of plans and processes that enable the organization to meet customer requirements and design of products and services.

3.1.6 Clause 9: Performance evaluation:

The organization is supposed to consider what should be measured, methods to use, when to analyze and report data (with its intervals) to ensure control over the processes and products delivered to the customer.

Internal audits should be conducted at planned time intervals, with management reviews to examine the management system of the organization and ensure its continuing suitability, adequacy and effectiveness.

3.1.7 Clause 10: Improvement:

There are new requirements for corrective action. The first is to react to nonconformities and take measures as appropriate, to check and correct the nonconformity and deal with the consequences. The second is to determine whether there are similar nonconformities, or if some could potentially occur. The requirement of continuous improvement has been expanded to cover both the fit and adequacy of the QMS, and its value.

- Improvement model:

Continuous improvement positively influences the quality of products and services, reduces costs, improves working methods, facilitates meeting the needs of both customers and the organization, as well as decreases the times of the whole process (reducing errors, defects, and controlling them). In addition, the development of programs for corrective and preventive action is also essential for the constant improvement of the system.

It is recommended for any organization, to build a corrective actions system to determine the causes of nonconformities. Once determined, it should be evaluated what can be done to prevent the problem from happening again, ensuring its effectiveness.

Figure 2 Shows how within the PDCA cycle (Plan/Do/Check/Act); these clauses can be included on the new high-level structure.

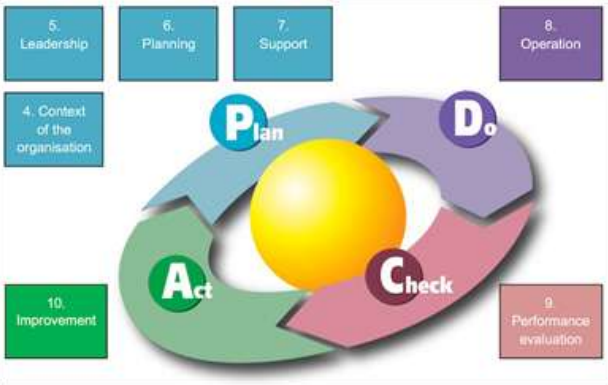

Figure 2 PDCA cycle and clauses (organization's context).

3.2 Differences between clauses of ISO 9001: 2015 and 2008.

3.2.1 About "preventive actions" within the context of the organization.

In previous ISO 9001 reference, the term context of the organization is not mentioned, but in 2015 it were used to describe some operations, such as preventive actions.

In addition:

- In the context of the organization, ISO 2015 indicates that the user must determine the "external and internal issues". Understanding the external context of the organization can be easy when considering issues arising from cultural, social, economic, legal, technological, competitive environment, market, whether international, national, regional or local level, that may affect companies' business.
- Because of the effect it may have on the capabilities of the organization to regularly provide products and services that meet customer requirements, the organization must determine who are the "stakeholders" and what are the relevant requirements thereof.
- Each organization should determine their limits and applicability of the QMS, to set efficient levels that can be covered to the customers.

It's important to know:

For any local company, having an international certification has the potential to maximize their opportunities to compete at the same level as other companies, whatever its size, age or the level of infrastructure that owns. This is how a number of companies considered "small", were able to take the plunge and start their successful participation in the global market, successfully competing against international companies and larger corporations.

3.2.1.1 Transitional measures for preventive actions.

- Define the context of the organization and determine why the organization is where it is. This definition is the heading point and the basis for the adjustment and / or creation of the QMS.
- Document the scope of the organization: considering all the elements that can influence the performance of the QMS, including external, internal, cultural, social, economic, technological, and legal factors.
- Define stakeholders: those people that can affect, be affected by, or perceived to be affected by a decision or activity of the organization. You should also determine the relevant requirements of each stakeholder.
- Determine and document the applicability of each requirement. An organization can review the applicability of the requirements depending on its size or complexity, the model that management uses to adopt the range of proper activities of the organization and the nature of the risks and opportunities taken.
- Strengthen the focus on processes, identifying inputs and outputs thereof and establishing criteria and methods needed to make sure effective operation and control of those processes are defined in the QMS.

3.2.2 About customer focus within Clause 5 "Leadership":

ISO 9001:2015:

- Top management must demonstrate leadership and commitment to customer focus, making sure to determine and meet their requirements, in addition to legal requirements that apply.
- It should identify and consider permanently risks and opportunities that may affect the conformity of services, to increase customer satisfaction.

3.2.2.1 Transitional measures for customer focus.

- Ensure that the objectives of organization improvement fit needs and expectations of customers.
- Analyze and study these expectations.
- Measure customer satisfaction and act accordingly to the results.
- It is imperative that every member of the company knows how their work affects customer satisfaction, developing a systematic management of customer relationship.

3.2.3 About actions to address risks and opportunities.

- First, the organization must consider the understanding of information and context by its members, as well as the diverse needs of stakeholders, to find possible risks and opportunities and ensure that the QMS achieve expected results.
- The "based on risk thought" requires the organization to determine the factors that could cause the processes in the QMS to deviate from planned results, to implement preventive controls that minimize negative effects and maximize the use of the opportunities that are been arised.

3.2.3.1 Transitional measures for Risks and Opportunities.

Actions taken to address risks and opportunities should be proportional to the potential impact on the conformity of products and services.

- Options for risks may include: avoiding or taking risks to pursue an opportunity, eliminate sources of risk, change the probability or consequences of a risk, share risk or risks by keeping informed decisions.
- Opportunities may lead to the adoption of new practices, launching new products, opening new markets, contacting new customers, partnerships, use of new technologies and other desirable and viable options to address the needs of the organization or those of their clients.

3.2.4 About support:

All about support resources (people, infrastructure, ambient, monitoring and measurement, in addition to the knowledge of the organization by its staff) is included at ISO 9001:2015. The term "documented information" replaces previous terms used like documents, documentation and records.

3.2.4.1 Transitional measures for support.

- Consider the capabilities and limitations of existing internal resources and what the company would need to obtain from external suppliers.
- Ensure that organized staff is aware of the quality policy, relevant objectives of quality, its particular contribution to the effectiveness of the quality management system, including benefits caused by their personal performance.
- The quality management system of the organization must include the information required by the relevant legislation and the organization determines are necessary for the effectiveness of the QMS.

3.2.5 About the operation:

Clause 8 - Operation in ISO 2015 includes the planning and operational control, requirements, design and development of products and services, control of processes, products and services externally supplied (purchases), providing products and services (production and delivery), the release thereof, and control of non-conforming outputs.

3.2.4.2 Transitional measures for the operation.

- Determine all requirements for products and services, and establish criteria for acceptance of such processes and products, identifying the resources needed to achieve compliance with the requirements.
- Keep documented information to be confident that the processes have been carried out as planned and to show compliance of products and services.
- Get information related to the view and opinion of the client, organizing its products and services.

3.2.6 About performance evaluation:

Organizations should determine what, how and when its QMS has to be monitored, measured, analyzed and evaluated. Internal audit is also a part of this process, to ensure that the management system meets with its requirements as well as those of the standard, and that it has been implemented and successfully maintained. The management review should analyze the system to verify if it is appropriate, adequate and efficient.

3.2.6.1 Transitional measures for performance evaluation.

- The organization should review what is necessary to monitor and measure, and set the frequency of the monitoring, measuring and evaluation.
- Planning strengthens and implementing the monitoring, measurement, analysis and improvement to demonstrate the ability to meet the requirements agreed with customers.
- Monitor customer perception, regarding compliance with its requirements.
- Review the characteristics and trends of processes and products, including the opportunity to run preventive actions.

3.2.7 About improvement:

Improvement is analyzed in how to deal whit nonconformities and how they become appropriate corrective actions (preventive actions are not in this clause but are mentioned in context - see 3.2.1).

3.2.6.2 Transitional measures for improvement.

- It is necessary to react to any not-conformity, and as applicable take actions to control and correct consequences, evaluating the need for action to eliminate the causes of nonconformity, so that it does not recur or occur elsewhere, using keys offered by ISO 9001:2015.
- Determine if there are similar nonconformities, or some could potentially occur, to implement any necessary preventive action, reviewing the effectiveness of corrective ones and if required, make changes to the QMS.

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4 ISO 9001:2008 - ISO 9001: 2015.

In Figure 3, a correlation matrix is shown between many points of ISO 9001:2015, with the equivalents used in 2008, and in Figure 4 the new structure of Annex SL currently used. This is now used in all references management systems.

ISO 9001:2008		ISO/FDIS 9001	
4	Quality management system	4	Context of the organization
4.1	General requirements	4.4	Quality management system and its processes
4.2	Documentation requirements	7.5	Documented information
4.2.1	General	7.5.1	General
4.2.2	Quality manual	4.3	Determining the scope of the quality management system
		7.5.1	General
		4.4	Quality management system and its Processes
4.2.3	Control of documents	7.5.2	Creating and updating
		7.5.3	Control of documented information
4.2.4	Control of records	7.5.2	Creating and updating
		7.5.3	Control of documented information
5	Management responsibility	5	Leadership
5.1	Management commitment	5.1	Leadership and commitment
		5.1.1	General
5.2	Customer focus	5.1.2	Customer focus
5.3	Quality policy	5.2	Policy
		5.2.1	Developing the quality policy
		5.2.2	Communication the quality policy
5.4	Planning	6	Planning
5.4.1	Quality objectives	6.2	Quality objectives and planning to achieve them
5.4.2	Quality management system planning	6	Planning
		6.1	Actions to address risks and opportunities
		6.3	Planning of changes
5.5	Responsibility, authority and communication	5	Leadership
5.5.1	Responsibility and authority	5.3	Organizational roles, responsibilities and authorities

Figure 3 ISO/FDIS 9001:2015. Ratio ISO 9001 clauses between previous and actual standard.

Figure 4 Annex SL for all references.

5 Other features of the SGC.

5.1 Establishment of quality policy.

The 2008 version stated that the policy quality should be directed towards increasing the effectiveness of the organization, being adapted to its purpose and providing a framework where the quality objectives could be established and reviewed.

The 2015's document states that the high direction shall establish, implement and maintain a quality policy appropriate for both the purpose as to the context of the organization and should support its strategic direction, taking care to provide a framework for the establishment of quality objectives as in the previous case, plus to include a commitment to meet both applicable requirements, and continuous improvement of the system.

5.2 Terminology changes.

In Figure 5, there are some changes found in terminology.

ISO 9001:2008 Structure	ISO 9001:2015 Structure
1. Scope	1. Scope
2. Normative reference	2. Normative reference
3. Terms and definitions	3. Terms and definitions
4. Quality management system	4. Context of the organisation
5. Management responsibility	5. Leadership
6. Resource management	6. Planning
7. Product realisation	7. Support
8. Measurement, analysis and improvement	8. Operation
	9. Performance evaluation
	10.Improvement

Figure 5 Terminology big changes.

5.2 Transition period.

In September 2015 ISO 9001:2015 standard was published, and companies who are currently certified will have a period of three (3) years to adapt to changes presented in vision. Figure 6 shows the schedule.

Figure 6 Transition Schedule.

6 Changes for plastic companies.

- Processors of plastic in Venezuela, based on the creation and/or updating of its QMS, must carry out personnel training to help to review new ideas and the language that should be learned or adapted to each case.
- They must carry out comprehensive control from the start of production, through delivery of products, and even in the review or design of the "post-sale" services to strengthen the customer focus that emphasizes the new ISO 9001: 2015. Within this approach, it will be ensured that every worker is aware of how their sub-processes contribute to meet the requirements agreed upon with customers, which aim to minimize the most common errors that arise in daily work of companies.
- Through customer focus each worker that makes "special quality controls", as long as they are in line with expected requirements they will improve the process performance and get used to self-evaluation.
- Transforming processes and suppliers (for inks, packaging, spare parts, etc.) should be revised to implement improvements that reflect in higher quality end product with greater customer satisfaction.
- "Risk-based" thought will allow determining the factors that could cause deviations from planned processes, and implement improvements and optimization to reduce waste, minimize the environmental impact and take advantage of business opportunities.
- Documented information, that can be associated with records, must allows to have confidence that the processes have been carried out as planned and to demonstrate the conformity of the products and services. The quality manual and records are not mandatory in ISO 9001:2015.
- The standard does not requires filling procedures and work instructions, but initially each company can develop internal procedures, stated in his system, and it would serve to have references or to maintain documents of their working methods so they are performed without error. In this way, everybody can make comparisons when improvements arising out of or deviations are detected.
- During the analysis of the data obtained by each company, through the need to review the information gathered in measuring customer satisfaction, conformity to product requirements are included, as well as the characteristics and trends of processes and products, and the need to carry out the planned preventive actions.

7 Summary

- Management systems ISO 9001 for all companies and plastic sector in particular must be reformulated from 2008 to 2015, toward strengthen the ongoing monitor of their activities, and achieve good performance and continuous service for customers, taking the additional advantage of keeping in line with the inclusion of improvements for the industry.
- Some specific cases were presented that allowed demonstrating the advantages that an ISO 9001 certification would have in companies, as it has the potential to maximize on every opportunity to compete at the same level as other organizations, often regardless of size or infrastructure that they own.

- The transition period of three years should be take in advantage to adapt to the new 2015 version, through training and mindset change in personnel as well as the development of risk management.
- Processing plastic companies can be viewed positively influenced by new clauses in the ISO 9001:2015 like the risk-based thinking, because it would allow them to identify factors that may cause deviation in the results of their planned processes, which will in turn influence the acceptance of its products by customers.

8 References.

8.1 ISO 9001 Transition Guide of BSI[1].

8.2 ISO 9001:2015 standard (Requirements).

8.3 ISO 9001:2008 standard (Requirements).

8.4 British Standard Institute (BSI): "Introduction to Annex SL".

[1] BSI is A British business Standards Company that helps organizations all over the world make excellence a habit.

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