

**TRINIDAD AND TOBAGO BUREAU OF STANDARDS
CERTIFICATION DIVISION**

**ISO 9001:2015
TRANSITION AUDITS**

INFORMATIVE DOCUMENT



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1 INTRODUCTION

At the Trinidad and Tobago Bureau of Standards (TTBS), the process to transition an organization's certification from ISO 9001:2008 to ISO 9001:2015 includes a "**transition audit**".

The transition audit is a special evaluation that must be performed in addition to the normally scheduled ISO 9001:2008 surveillance and recertification audits in order to confirm that the organization has implemented systems that will allow it to conform to the additional requirements listed in ISO 9001:2015. It provides an advantage, in that if the organization were found to be noncompliant with ISO 9001:2015 it could still maintain its certification to ISO 9001:2008 up until the end of the transition period on 2018-Sep-21. This approach would minimize the risk to the certified organization in case they are unsuccessful in their transition attempts.

The intent of this document is to make, (i) our certified clients (ii) the consultants of our certified clients and (iii) our auditors, aware of our approach and requirements for the transition audit. This includes the areas to be assessed, as well as the minimum additional evidence that must be verified at the audit.

Where desirable the transition audit may be scheduled to coincide with surveillance and/or re-certification audits. The duration of the transition audit is typically consistent with the duration of a surveillance audit but will not be less than one audit man day. All transition audits (including all sub-components) must be completed by 2018-May-22, after which certification to ISO 9001:2015 will require a certification audit.

All nonconformities that require client action for compliance with the new requirements will be documented in the transition audit report. The organization can only be certified to ISO 9001:2015 after all identified nonconformities have been appropriately addressed and the effectiveness of the management system demonstrated. Major nonconformities must be corrected before certification can be recommended; however corrective action plans may be accepted for Minor Nonconformities.

2 BACKGROUND

The ISO 9001 standard was revised on 2015-Sep-22. The new publication introduces significant changes to the standard. As a result organizations that were previously certified to ISO 9001:2008 must demonstrate conformance to the additional requirements listed in ISO 9001:2015 prior to being transitioned to the new revision of the standard (i.e. obtaining an ISO 9001:2015 certificate)

The standard is now based on Annex SL of the ISO Directives, a high-level structure (HLS) which standardizes sub-clause titles, core text, common terms and core definitions to enhance compatibility and alignment with other ISO management system standards.

The main changes in the new version of ISO 9001:2015 are:

- i. The adoption of the HLS as set out in Annex SL of ISO Directives Part 1.
- ii. An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- iii. Fewer prescribed requirements.
- iv. Less emphasis on documents.
- v. Improved applicability for services.
- vi. A requirement to define the boundaries of the QMS.
- vii. Increased emphasis on organizational context.
- viii. Increased leadership requirements.
- ix. Greater emphasis on achieving desired outcomes to improve customer satisfaction.

3 SCOPE OF THE TRANSITION AUDIT

The transition audit is applicable to all organizations, regardless of the maturity of their QMS. It includes all areas where there have been significant changes to the standard, whether those changes are major (i.e. the introduction of new requirements) or minor (i.e. amendments to old requirements). It does not include insignificant changes (i.e. changes to wording, phrases and/or terminology which do not change the meaning or intent of the requirements).

Table 1 (Correlation Matrix) below identifies:

- the clauses of ISO 9001:2015 (column 1)
- the corresponding clauses in ISO 9001:2008 (column 2)
- the severity of the change, i.e. major, minor and insignificant (column 3)
- areas to be included in the transition audit, i.e. areas with significant changes (column 4)

TABLE 1 – Correlation Matrix

| ISO 9001:2015 | | ISO 9001:2008 | | Severity of Change | Included in Transition Audit |
|---------------|--|-------------------|--|--------------------|-------------------------------------|
| 4 | Context of the organization | 1.0 | Scope | ----- | |
| 4.1 | Understanding the organization and its context | 1.1 | General | Major | <input checked="" type="checkbox"/> |
| 4.2 | Understanding the needs and expectations of interested parties | 1.1 | General | Major | <input checked="" type="checkbox"/> |
| 4.3 | Determining the scope of the quality management system | 1.2 4.2.2 | Application Quality manual | Major | <input checked="" type="checkbox"/> |
| 4.4 | Quality management system and its processes | 4 4.1 8.2.3 | Quality management system General requirements Monitoring and measurement of processes | Minor | <input checked="" type="checkbox"/> |
| 5 | Leadership | 5 | Management responsibility | ----- | |
| 5.1 | Leadership and commitment | 5.1 | Management commitment | ----- | |
| 5.1.1 | General | 5.1 | Management commitment | Minor | <input checked="" type="checkbox"/> |
| 5.1.2 | Customer focus | 5.2 | Customer focus | Minor | <input checked="" type="checkbox"/> |
| 5.2 | Policy | 5.3 | Quality policy | ----- | |
| 5.2.1 | Establishing the quality policy | 5.3 | Quality policy | Minor | <input checked="" type="checkbox"/> |
| 5.2.2 | Communicating the quality policy | 5.3 | Quality policy | Minor | <input checked="" type="checkbox"/> |
| 5.3 | Organizational roles, responsibilities and authorities | 5.5.1 5.5.2 | Responsibility and authority Management representative | Minor | <input checked="" type="checkbox"/> |
| 6 | Planning | 5.4 | Planning | ----- | |
| 6.1 | Actions to address risks and opportunities | 5.4.2 8.5.3 | Quality management system planning Preventive action | Major | <input checked="" type="checkbox"/> |
| 6.2 | Quality objectives and planning to achieve them | 5.4.1 | Quality objectives | Minor | <input checked="" type="checkbox"/> |
| 6.3 | Planning of changes | 5.4.2 | Quality management system planning | Minor | <input checked="" type="checkbox"/> |

| ISO 9001:2015 | | ISO 9001:2008 | | Severity of Change | Included in Transition Audit |
|---------------|--|---------------|---|--------------------|-------------------------------------|
| 7 | Support | 6 | Resource management | ----- | |
| 7.1 | Resources | 6 | Resource management | ----- | |
| 7.1.1 | General | 6.1 | Provision of resources | Insignificant | |
| 7.1.2 | People | 6.1 | Provision of resources | Insignificant | |
| 7.1.3 | Infrastructure | 6.3 | Infrastructure | Insignificant | |
| 7.1.4 | Environment for the operation of processes | 6.4 | Work environment | Insignificant | |
| 7.1.5 | Monitoring and measuring resources | 7.6 | Control of monitoring and measuring equipment | Minor | <input checked="" type="checkbox"/> |
| 7.1.6 | Organizational knowledge | None | | Major | <input checked="" type="checkbox"/> |
| 7.2 | Competence | 6.2.1 | General | Insignificant | |
| | | 6.2.2 | Competence, training and awareness | | |
| 7.3 | Awareness | 6.2.2 | Competence, training and awareness | Minor | <input checked="" type="checkbox"/> |
| 7.4 | Communication | 5.5.3 | Internal communication | Minor | <input checked="" type="checkbox"/> |
| | | 7.2.3 | Customer communication | | |
| | | 7.4.2 | Purchasing information | | |
| | | 7.4.3 | Verification of purchased product | | |
| 7.5 | Documented information | 4.2 | Documentation requirements | ----- | |
| 7.5.1 | General | 4.2.1 | General | Insignificant | |
| 7.5.2 | Creating and updating | 4.2.3 | Control of documents | Insignificant | |
| | | 4.2.4 | Control of records | | |
| 7.5.3 | Control of documented information | 4.2.3 | Control of documents | Insignificant | |
| | | 4.2.4 | Control of records | | |
| 8 | Operation | 7 | Product realization | ----- | |
| 8.1 | Operational planning and control | 7.1 | Planning of product realization | Insignificant | |
| 8.2 | Requirements for products and services | 7.2 | Customer-related processes | ----- | |
| 8.2.1 | Customer communication | 7.2.3 | Customer communication | Minor | <input checked="" type="checkbox"/> |

| ISO 9001:2015 | | ISO 9001:2008 | | Severity of Change | Included in Transition Audit |
|---------------|---|-------------------------|---|--------------------|-------------------------------------|
| 8.2.2 | Determining of requirements related to products and services | 7.2.1 | Determination of requirements related to the product | Insignificant | |
| 8.2.3 | Review of requirements related to the products and services | 7.2.2 | Review of requirements related to the product | Insignificant | |
| 8.2.4 | Changes to requirements for products and services | 7.2.2 | Review of requirements related to the product | Insignificant | |
| 8.3 | Design and development of products and services | 7.3 | Design and development | ----- | |
| 8.3.1 | General | New | | Insignificant | |
| 8.3.2 | Design and development planning | 7.3.1 | Design and development planning | Minor | <input checked="" type="checkbox"/> |
| 8.3.3 | Design and development inputs | 7.3.2 | Design and development Inputs | Minor | <input checked="" type="checkbox"/> |
| 8.3.4 | Design and development controls | 7.3.4 7.3.5 7.3.6 | Design and development review Design and development verification Design and development validation | Insignificant | |
| 8.3.5 | Design and development outputs | 7.3.3 | Design and development outputs | Minor | <input checked="" type="checkbox"/> |
| 8.3.6 | Design and development changes | 7.3.7 | Control of design and development changes | Insignificant | |
| 8.4 | Control of externally provided processes, products and services | 7.4.1 | Purchasing process | ----- | |
| 8.4.1 | General | 7.4.1 | Purchasing process | Minor | <input checked="" type="checkbox"/> |
| 8.4.2 | Type and extent of control | 4.1 7.4.1 7.4.3 | General requirements Purchasing process Verification of purchased product | Minor | <input checked="" type="checkbox"/> |
| 8.4.3 | Information for external providers | 7.4.2 | Purchasing information | Minor | <input checked="" type="checkbox"/> |

| ISO 9001:2015 | | ISO 9001:2008 | | Severity of Change | Included in Transition Audit |
|---------------|---|----------------|---|--------------------|-------------------------------------|
| 8.5 | Production and service provision | 7.5 | Production and service provision | ----- | |
| 8.5.1 | Control of production and service provision | 7.5.1 | Control of production and service provision | Insignificant | |
| 8.5.2 | Identification and traceability | 7.5.3 | Identification and traceability | Insignificant | |
| 8.5.3 | Property belonging to customers or external providers | 7.5.4 | Customer property | Minor | <input checked="" type="checkbox"/> |
| 8.5.4 | Preservation | 7.5.5 | Preservation of product | Insignificant | |
| 8.5.5 | Post-delivery activities | 7.5.1 | Control of production and service provision | Insignificant | |
| 8.5.6 | Control of changes | 5.4.2 7.3.7 | Quality management system planning Control of design and development changes | Minor | <input checked="" type="checkbox"/> |
| 8.6 | Release of products and services | 7.4.3 8.2.4 | Verification of purchased product Monitoring and measurement of processes | Insignificant | |
| 8.7 | Control of nonconforming outputs | 8.3 | Control of nonconforming product | Insignificant | <input checked="" type="checkbox"/> |
| 9 | Performance evaluation | New | | ----- | |
| 9.1 | Monitoring, measurement, analysis and evaluation | 8 | Measurement, analysis and improvement | ----- | |
| 9.1.1 | General | 8.1 | General | Insignificant | |
| 9.1.2 | Customer satisfaction | 8.2.1 | Customer satisfaction | Insignificant | |
| 9.1.3 | Analysis and evaluation | 8.4 | Analysis of data | Minor | <input checked="" type="checkbox"/> |
| 9.2 | Internal audit | 8.2.2 | Internal audit | Insignificant | |
| 9.3 | Management review | 5.6 | Management review | ----- | |
| 9.3.1 | General | 5.6.1 | General | Insignificant | |
| 9.3.2 | Management review Inputs | 5.6.2 | Review Input | Minor | <input checked="" type="checkbox"/> |
| 9.3.3 | Management review Outputs | 5.6.3 | Review Output | Insignificant | |
| 10 | Improvement | 8.5 | Improvement | ----- | |

| ISO 9001:2015 | | ISO 9001:2008 | | Severity of Change | Included in Transition Audit |
|---------------|-------------------------------------|---------------|----------------------------------|--------------------|-------------------------------------|
| 10.1 | General | 8.5.1 | Continual improvement | Minor | <input checked="" type="checkbox"/> |
| 10.2 | Nonconformity and corrective action | 8.3 | Control of nonconforming product | Minor | <input checked="" type="checkbox"/> |
| | | 8.5.2 | Corrective action | | |
| 10.3 | Continual improvement | 8.5.1 | Continual improvement | Insignificant | |

4 ADDITIONAL REQUIREMENTS & RULES ON THEIR APPLICATION (CLAUSE BY CLAUSE)

Clause 4 - Context of the organization

Clause 4.1 – Understanding the organization and its context (Major Change)

- The organization must provide evidence:
 - that external and internal issues have been identified
 - that the organization is monitoring and reviewing information on these issues on a regular basis
 - to demonstrate how it will continuously identify new issues as they become relevant
 - that the process to identify issues has considered at the least, and as applicable:
 - Internal Issues
 - overall performance including financial results
 - operational factors including:
 - process performance,
 - the validity of measuring equipment used and the need for traceability to provide confidence in the validity of the measurement results,
 - production and delivery capabilities and
 - customer perception
 - resource factors including infrastructure and environment
 - human aspects including competence of persons and relationships with unions
 - External Issues
 - legal and statutory requirements
 - technological factors (including changes in technology, patents)
 - competitive and market (including market share; similar or substitute products)

Clause 4.2 – Understanding the needs and expectations of interested parties (Major Change)

- The organization must provide evidence:
 - that relevant interested parties have been determined
 - that the relevant requirements of these interested parties have been determined
 - that the organization is monitoring and reviewing information on these interested parties and their relevant requirements
 - to demonstrate how it will continuously identify new interested parties as applicable
 - that the process to determine which interested parties are relevant has **considered:**
 - at the least the following parties:
 - customers,
 - employees and others working on behalf of the organization (e.g., subcontractors),
 - regulators, legal and regulatory authorities,
 - owners, shareholders / joint venture partners / franchisors / parent and subsidiary organizations

- trade and professional associations.
- at the least the following criteria for evaluating the relevance of parties:
 - possible influence or impact on the organization's performance or decisions
 - ability to generate risks and opportunities
 - ability to be affected by the decisions or activities of the organization

Clause 4.3 Determining the scope of the QMS (Major Change)

- The organization must provide evidence that the following have been considered in the development and/or the review of the scope of the QMS:
 - that external and internal issues (clause 4.1 of 9001: 2015)
 - requirements of relevant interested parties (clause 4.2 of 9001:2015)
 - the products and services of the organization
- Noting that from time to time there may be changes in (i) external and internal issues (ii) relevant interested parties and/or their requirements and (iii) the products and services of the organization; the organization must demonstrate what process or system it will institute to ensure that the scope is reviewed following such changes. Also, plans for such changes shall conform with the requirements in clause 6.3.
- Where the organization has identified additional exemptions, not previously covered under their existing ISO 9001:2008 certifications:
 - the organization must provide suitable justifications (Note: these exclusions shall not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction).
 - these justifications must be included in the documented scope

Clause 4.4 Quality management system and its processes (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, the organization must provide evidence that the following has been determined for each process:

- a) inputs required and outputs expected
- b) established performance indicators and related criteria to determine if the level of performance is acceptable, as well as, supporting monitoring & measuring activities and documented results
- c) assigned responsibilities and authorities (aka process owners)

Note:

An acceptable method of demonstrating that ISO 9001:2015 - Clause 4.4.1 a) to h) has been addressed, is by developing and documenting process diagrams and process maps which address those requirements, however other methods may be acceptable

Clause 5 Leadership

Clause 5.1 Leadership and Commitment

Clause 5.1.1 General (Minor Change)

- Top management must demonstrate how they take accountability for the effectiveness of the QMS. Acceptable methods of demonstrating this must include but are not limited to:
 - identification of persons who have the ultimate responsibility for the performance of processes and projects and the authority and ability to make necessary changes (aka process owners)
 - implementation of continual performance monitoring and reporting on activities and planned results (through performance indicators, related criteria to determine if the level of performance is acceptable and objectives)
- Top management must demonstrate that policy and objectives
 - are aligned to the strategic direction of the organization
 - have been developed considering:
 - the organization and its context including internal and external issues
 - the needs and expectations of relevant interested parties
 - process capabilities (including the sequence and interaction of processes)
- Top management must demonstrate how it promotes the use of the process approach and risk-based thinking.
- Top management must demonstrate how it communicates the importance of effective quality management and of conformity to QMS requirements.
- Top management must demonstrate how it ensures that the quality management system achieves its intended results. In addition to the implementation of the other clauses of ISO 9001:2015, acceptable methods of demonstrating this must include but are not limited to taking corrective actions where criteria related to performance indicators and objectives are not achieved.

Clause 5.1.2 Customer Focus (Minor Change)

The organization shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

Clause 5.2 Policy

Clause 5.2.1 Establishing the quality policy (Minor Change)

- The policy must be reviewed to ensure that it is appropriate to the context of the organization and supports its strategic direction. In this regard, alignment with the following should be reviewed as applicable: strategic plans, mission, vision, guiding principles and core values
- Noting that from time to time there may be changes in (i) external and internal issues (ii) relevant interested parties and/or their requirements; the organization must demonstrate what process or system it will institute to ensure that the policy is reviewed following such changes.

Clause 5.2.2 Communicating the quality policy (Minor Change)

The organization must demonstrate what mechanism it has put in place to make the Quality Policy available to relevant interested parties identified.

Clause 5.3 Organizational roles, responsibilities and authorities (Minor Change)

The organization must demonstrate that persons who have been assigned with responsibilities and authorities for processes (aka process owners) are familiar with the requirements of the QMS as it relates to the processes under their purview and can readily retrieve information on these processes (including information, as applicable, on process performance, achievement of objectives, internal audit findings, customer satisfaction, the status of nonconformities and corrective actions, and decisions and actions arising from management reviews).

Note: this is consistent with the following:

- 4.4.1 “The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall ... e) assign the responsibilities and authorities for these processes, and
- 5.1.1 “Top management shall demonstrate leadership and commitment with respect to the quality management system by ... a) taking accountability for the effectiveness of the quality management system ... c) ensuring the integration of the quality management system requirements into the organization’s business processes; g) ensuring that the quality management system achieves its intended results and h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system

Clause 6 Planning

Clause 6.1 Actions to address risks and opportunities (Major Change)

- The organization must demonstrate that it has a methodology in place that enables them to effectively identify risks and opportunities that need to be addressed to achieve intended results (including quality objectives, process performance and conformance of products and services); enhance desirable effects; prevent or reduce undesirable effects and achieve improvement.

- The organization must demonstrate, that at a minimum, it has examined:
 - the issues referred to in section 4.1 of ISO 9001:2015 and
 - the requirements referred to in section 4.2 of ISO 9001:2015.
 - the results of the examination must be documented

This could be demonstrated by, but is not limited to, documenting the results of the examination; this may be done as a part of a wider and documented risk assessment.

- Noting that from time to time there may be changes in (i) external and internal issues (ii) relevant interested parties and/or their requirements (iii) the products and services of the organization; the organization must demonstrate what process or system it will institute to identify new risks following such changes.
- The organization must demonstrate that it is taking a planned approach to addressing risks and realizing opportunities. It must also demonstrate that actions taken are proportionate, and that for those actions that have been completed, that each action's effectiveness has subsequently been assessed.

This could be demonstrated by, but is not limited to:

- Identification and documentation of the causes and sources of risks and opportunities via the use of consistent and suitable tools and methodologies.
- Identification and documentation of suitable actions to
 - address the causes and sources of risk,
 - share or transfer the risk and
 - pursue opportunities

- Determining and documenting the impact (severity) and likelihood of occurrence of the identified risks and opportunities, via qualitative and/or quantitative methods prior and subsequent to taking actions to address the risks and opportunities, in order to:
 - determine whether the actions taken are proportionate, as well as, to assess their effectiveness in:
 - avoiding risks or eliminating the sources of the risk
 - changing the consequence of the risk
 - changing the likelihood of occurrence
 - suitably justify any cases where the organization chooses to retain the risk

Notes:

- 1) *In section 4.4.1 of ISO 9001:2015 the organization is required to establish, implement, maintain and continually improve QMS processes, including the process to address risks and opportunities.*
- 2) *In section 4.4.2 of ISO 9001:2015 the organization is required to maintain documented information to support the operation of these processes and retain sufficient documented information to have confidence that processes are carried out as planned.*

Clause 6.2 Quality Objectives and planning to achieve them (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, and consistent with the requirement of section 4.4.1 c) of ISO 9001:2015 for process performance indicators; the organization must demonstrate that:

- it has established quality objectives for all relevant processes.
- for each objective it has determined a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed; e) how the results will be evaluated.

Clause 6.3 Planning of changes (Minor Change)

The organization shall demonstrate that it has established a formal process to carry out changes in a planned manner, and that the process takes into consideration a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources and d) the allocation or reallocation of responsibilities and authorities.

Clause 7 Support

7.1 Resources

7.1.1 General (Insignificant Change)

No additional requirements & rules on their application

7.1.2 People (Insignificant Change)

Note:

There is now an explicit requirement to provide persons needed to implement the QMS. While this was partly addressed by the requirement to appoint a Management Representative in the 2008 version, the organization must now consider the other persons needed for implementation of the QMS and ongoing maintenance.

7.1.3 Infrastructure (Insignificant Change)

No additional requirements & rules on their application

7.1.4 Environment (Insignificant Change)

No additional requirements & rules on their application

7.1.5 Monitoring and measuring resources - 7.1.5.2 Measurement traceability (Minor Change)

Where there is no requirement for measurement traceability, in order to determine whether calibration and verification are essential in providing confidence in the validity of measurement results, and consistent with section 4 and 6.1 of ISO 9001:2015, the organization shall examine the associated risks of using un-calibrated or un-verified measuring instruments.

Note:

TTBS recommends the use of calibration labs which are accredited for the specific parameters and calibration ranges relevant to measuring equipment

7.1.6 Organizational Knowledge (Major Change)

- The organization shall demonstrate that it has taken steps to identify the organizational knowledge necessary to establish the continuing conformity of their products and services.
- The organization shall demonstrate how the knowledge is being maintained.
- The organization shall demonstrate that an assessment of organizational knowledge has taken place prior to any changes made to the quality management system in response to changing needs or trends
- The organization shall demonstrate how it maintains awareness of changes in relevant technical, industry and/or market knowledge

7.2 Competence (Insignificant Change)

No additional requirements & rules on their application

7.3 Awareness (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, the organization must now demonstrate that external providers (including contractors and outsourced providers of services) are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the quality management system and the implications of not conforming to quality management system requirements.

7.4 Communication (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, the organization must now demonstrate that it has determined the external communications relevant to the QMS including what it will communicate, when to communicate, with whom to communicate, how to communicate and who communicates.

7.5 Documented Information

Note: Where procedures are maintained for documented information, the organization should ensure that it is revised and updated to reflect the updated terminology.

7.5.1 General (Insignificant Change)

No additional requirements & rules on their application

7.5.2 Creating and updating (Insignificant Change)

No additional requirements & rules on their application

7.5.3 Control of documented information (Insignificant Change)

No additional requirements & rules on their application

Clause 8 Operation

8.1 Operational planning and control (Insignificant Change)

No additional requirements & rules on their application

8.2 Requirements for products and services

8.2.1 Customer Communication (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, and consistent with clause 8.5.3 of ISO 9001:2015, the organization must now demonstrate that:

- it has informed the customer of how it intends to handle and control customer property and that any issues raised by the customer are addressed; and
- where contingency actions are required, that customer communications include establishing specific requirements for contingency actions, where relevant.

8.2.2 Determining the requirements for products and services (Insignificant Change)

No additional requirements & rules on their application

8.2.3 Review of the requirements for products and services (Insignificant Change)

No additional requirements & rules on their application

8.2.4 Changes to requirements for products and series (Insignificant Change)

No additional requirements & rules on their application

8.3 Design and development of products and services

8.3.1 General (Insignificant Change)

No additional requirements & rules on their application

8.3.2 Design and Development Planning (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system, the organization shall demonstrate that the planning for the design and development activities has considered the internal and external resources needed, the need for involvement of customers and users in the process, the requirements for subsequent provision of products and services, the level of control expected by customers and other relevant parties.

8.3.3 Design and development Inputs (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system; the organization shall demonstrate that in developing the design and development inputs that it has considered regulations, standards or codes of practice that the organization has committed to implement and the potential consequences of failure due to the nature of the products and services.

8.3.4 Design and development controls (Insignificant Change)

No additional requirements & rules on their application

8.3.5 Design and development outputs (Minor Change)

The organization shall demonstrate that it is retaining documented information on the outputs.

8.3.6 Design and development changes (Insignificant Change)

No additional requirements & rules on their application

8.4 Control of externally provided processes, products and services

8.4.1 General (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system (Section 4.1 General Requirements & 7.4.1 Purchasing Process), the organization shall demonstrate that controls for purchasing:

- have been extended to providers of processes and services
- now includes documented information related to monitoring of performance (to support re-evaluation activities)

The organization shall demonstrate that it has established criteria for monitoring of performance.

8.4.2 Type and Extent of Control (Minor Change)

The organization shall demonstrate that it has

- defined the controls needed for the external provider and the resulting output.
- determined the verification and other activities

8.4.3 Information for external providers (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system (Section 7.4.1 Purchasing Process) the organization shall demonstrate that it communicates its requirements for:

- the external provider's interactions with the organization
- control and monitoring of the external providers' performance to be applied by the organization
- verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises.

8.5 Production and Service Provision

8.5.1 Control of production and service provision (Insignificant Change)

No additional requirements & rules on their application

8.5.2 Identification and traceability (Insignificant Change)

No additional requirements & rules on their application

Note: change from suitability of product to suitability of process outputs.

8.5.3 Property belonging to customers or external providers (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system for property belonging to customers (Clause 7.5.4 Customer Property), the organization must demonstrate that suitable controls have been implemented for property belonging to external providers.

8.5.4 Preservation (Insignificant Change)

No additional requirements & rules on their application

Note:

There has been a change from suitability of product to suitability of process outputs.

8.5.5 Post delivery activities (Insignificant Change)

No additional requirements & rules on their application

8.5.6 Control of changes (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system (5.4.2 Quality Management System Planning) the organization shall demonstrate that it reviews and controls changes related to production and/or service provision including changes to specifications, methods, etc., and retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services (Insignificant Change)

No additional requirements & rules on their application

8.7 Control of nonconforming (Insignificant Change)

No additional requirements & rules on their application

Note:

There has been a change from suitability of product to suitability of process outputs.

Clause 9 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General (Insignificant Change)

No additional requirements & rules on their application

9.1.2 Customer satisfaction (Insignificant Change)

No additional requirements & rules on their application

9.1.3 Analysis and evaluation (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system (8.4 Analysis of data) the organization shall demonstrate that the results of analysis are being used to evaluate

- if planning has been implemented effectively
- the effectiveness of actions taken to address risks and opportunities
- the need for improvements to the quality management system.

9.2 Internal audit (Insignificant Change)

No additional requirements & rules on their application

9.3 Management review

9.3.1 General (Insignificant Change)

No additional requirements & rules on their application

9.3.2 Management review inputs (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system the organization must demonstrate that the following are included in the management review:

- changes in external and internal issues that are relevant to the quality management system;
- information on trends for the following are provided for the management review:
 - customer satisfaction and feedback from relevant interested parties;
 - the extent to which quality objectives have been met;
 - process performance and conformity of products and services;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
 - the performance of external providers;
- the effectiveness of actions taken to address risks and opportunities

9.3.3 Management review outputs (Insignificant Change)

No additional requirements & rules on their application

Clause 10 Improvement

10.1 General (Minor Change)

The organization must demonstrate that it has determined and selected opportunities for improvement and has implemented any necessary actions to meet customer requirements and enhance customer satisfaction, including:

- improving products and services to meet requirements as well as to address future needs and expectations;
- correcting, preventing or reducing undesired effects;
- improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action (Minor Change)

In addition to the applicable requirements currently implemented under the ISO 9001:2008 system (8.5.2 Corrective action), the organization shall demonstrate that:

- it has determined if similar nonconformities exist, or could potentially occur and takes the appropriate action
- updates the risks and opportunities determined during planning, if necessary;

10.3 Continual Improvement (Insignificant Change)

No additional requirements & rules on their application