The substantially updated revision of the quality management system (QMS) standard, ISO 9001:2015 has now been published continuing the path that commenced with BS5750 [1]. As with all management system standards, ISO 9001 periodically goes through a comprehensive review process to ensure that the standard continues to meet the needs and demands of interested parties. What is particularly different about the current review is that the new standard will adopt the new high level (HL) structure laid down in Annex SL of the ISO/IEC Directives, Part 1 – Consolidated ISO Supplement – Procedures document.

Understanding and exploiting the ISO 9001:2015 changes

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Despite sharing common elements, previously published ISO management system standards have differed in structure, terminology and requirements, which has inevitably led to confusion and difficulties in implementation particularly when an organisation has opted for an *integrated management system* (IMS) approach. Annex SL (previously known as *ISO Guide 83*) overcomes these difficulties by imposing a *generic management system* structure with a common high level structure, identical core text and common terminology and core definitions for use in *all* MSS (management systems standards). In future ISO MSS will be aligned and the compatibility of these standards and will be enhanced.

For example, many organisations have implemented both ISO 9001[2] and ISO 14001[3] but despite sharing common requirements, these management standards currently differ in terms of definitions and details, which has led to conflicts, duplication, confusion and misunderstanding. The adoption of Annex SL will remedy these issues by aligning future management systems standards so that they will have the same 'look-and-feel'. A major consequence will be the development of integrated management systems that will address multiple disciplines (e.g. quality, environmental, health & safety, etc.).

Individual MSS will also be able to add additional 'discipline-specific' requirements as required provided that these additions do not affect harmonisation or contradict or undermine the intent of the high level structure. Obvious examples will be the AS9100[4] series of standards (aerospace/defence), TS16949[5] (automotive/motorsport), IRIS[6] (rail) and the AQAP[7] standards (military).

This article focuses on the basic ISO 9001:2015 to explain the structure and requirements, compare the existing standards, and set out practical implementation strategies to ensure that organisations are fully exploiting the opportunities offered by the adoption of a modern (and visual) process-based approach[8].

UNDERSTANDING THE NEW MSS STRUCTURE

The structure of ISO 9001:2015 will adopt the Annex SL template mandated for all 'discipline-specific' standards which consists of:

- high level structure
- identical core text
- common terms and core definitions

The HLS (high level structure) consists of the following clause sequence:

0. Introduction
   - 0.1 General
   - 0.2 The ISO standards for quality management
   - 0.3 Process approach
   - 0.4 Plan-do-check-act cycle
   - 0.5 'Risk-based thinking'
   - 0.6 Compatibility with other management system standards
1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organisation
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

- Annex a (informative) clarification of new structure, terminology and concepts
- Annex b (informative) quality management principles
- Annex c (informative) the ISO 10000 portfolio of quality management standards
- Bibliography

The HLS will enhance the consistency and alignment of different management system standards (e.g. ISO 9001 and ISO 14001).

The MSS requirements are contained in clauses four through to ten which include some 45 'shall statements' giving rise to 84 mandatory requirements. These are considered to be the *minimum requirements* so 'the disciplines' (e.g. aerospace/defence, automotive/motorsport, rail, nuclear, etc.) will add in their own needs, which will result in more sector-specific requirements.

QUALITY MANAGEMENT PRINCIPLES

ISO 9001:2015 makes more explicit use of the *quality management principles*. There are now seven - the previous principles *process approach* and *system approach to management* have been combined. Also, the revision of ISO 9001:2015 has led to a change of one of the principles from *continual improvement* to just *improvement*.

P-D-C-A

Because ISO 9001:2015 employs the process approach, the P-D-C-A (plan-do-check-act) cycle applies to all identified processes. P-D-C-A enables an organisation to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined - and acted on!

SUMMARY OF KEY ISO 9001 CHANGES

The following sections address the *key changes* only and provide guidance on implementation strategies. Other approaches may be used provided they meet the requirements of ISO 9001:2015 standard.

RISK-BASED THINKING

ISO 9001:2015 adopts the principle of *risk-based thinking*. The concept of risk-based thinking has always been implicit in ISO 9001 - indeed risk management is already a mandatory clause in the aerospace/defence AS9100 series of standards. Risk-based thinking is now explicit and incorporates requirements for its inclusion in the establishment, implementation, maintenance and ongoing improvement of the quality management system.

Organisations must now determine, consider and, where necessary, take action to address any risks or opportunities that may impact (either positively or negatively) their quality management system's ability to deliver its intended outcomes, or that could adversely affect customer satisfaction.

Preventive action as an explicit requirement has therefore been replaced with *'risk-based thinking'* and the need to understand risk in the context of the management system. Because one of the key purposes of a formal management system is to act as a *preventive tool*, 'preventive action' is addressed *throughout* the development and implementation of the quality management system.

CONTEXT OF THE ORGANISATION

A new clause (clause 4.1) is introduced relating to the *organisation and its context*, which requires organisations to determine the *issues* and *requirements* that can impact on the planning and development of the management system.

This should be a welcomed addition as it provides the opportunity to define *the business* - what is achieved for customers (i.e. the purpose) and the direction in which the organisation is heading (i.e. its strategic direction).

A common approach to defining the purpose of an organisation, is to agree on:

Mission: the organisation's purpose and reason for existing

Vision: where the organisation is going in the medium to long term

Values: what the organisation stands for - its principles and ethics

Mission concentrates on the present. A *mission statement* defines the fundamental purpose of an organisation. It identifies who the organisation is, what it does, and to whom it serves.

The mission statement should communicate the scope and scale of the organisation's operations, in an easily understandable manner. It describes what the organisation does with particular focus on what it does for its customers and other interested parties. It states clearly and concisely the business strategy, and provides personnel with a framework and purpose. Its purpose is to motivate its people, suppliers and other partners.

Vision focuses on the future. A *vision statement* is an aspirational description of the desired mid or long term achievements of an organisation, by those involved or affected by it. It's what the organisation wants to become - how the future will look when the mission is achieved. Its purpose is to motivate external people to work with you. It's the end destination for an organisation's 'roadmap': what it hopes to become; the customer outcome it wants achieve; the market position it wants to assume; the impact it will have; the capabilities it plans to develop; and the activities it plans to pursue.

When developing its vision, an organisation needs to ensure its desired future is consistent with its existing *values*.

Values identify the principles and ethics by which the organisation and its members conduct themselves and their activities. Values underpin policies, procedures, strategies, missions and visions by acting as the foundation and a reference point for every decision made by the organisation's personnel.

It can be seen that the above mission, vision and value statements serve to direct and guide an organisation over a sustained period of time. Collectively they define the purpose of the organisation and should be a high-profile part of the QMS documentation. With the organisation's purpose and strategic direction defined, it is required to determine *external and internal issues* that can impact on their achievement and that also affect its ability to achieve the intended result of its QMS.

A tried and tested approach is to use *SWOT analysis* which is a framework that helps organisations identify all *internal* and *external* issues that might impact their purpose and strategic direction. In a very structured and simple manner, SWOT helps an organisation understand the dynamics of everything related to their unique situation. It's directed brainstorming!

In the SWOT analytical model, *strengths* and *weaknesses* are considered as the internal *issues*, completely controllable by the organisation itself.

On the other hand, *opportunities* and *threats* are regarded as *external issues* that might not be controllable by the organisation.

The SWOT model states that after thoroughly analysing every issue in these four categories, an organisation should work towards:

- exploiting, managing and developing further their strengths and opportunities
- eradicating or considerably reducing their weaknesses and external threats.

The results of SWOT analysis can assist in establishing a *strategic direction* for the organisation. This equates to a conventional business plan, with a span of one to three years.

With the purpose and strategic direction defined, attention must be given to *understanding the needs and expectations of interested parties*, which is addressed in a second new clause (clause 4.2).

The key 'focus' is for the organisation to:

- consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- aim to enhance customer satisfaction

To ensure a 'correct focus', the organisation must determine:

- the *interested parties* that are relevant to the QMS (quality management system)
- the *requirements* of these interested parties that are relevant to the QMS

Interested parties can include customers, owners/shareholders, suppliers and partners, people in the organisation that can affect the planning and development of the management system. The relevant interested parties and their relevant requirements may be captured in a table such as table 1 in this article that identifies both the QMS requirements and 'performance' requirements.

Interested parties		QMS Requirement	Performance requirements					
Customers	#	Clauses	Quality	Deliver	Days	Days	CAR	Complaint
Regulatory Bodies								
Certification Body								
Others								

Table 1 - Interested parties and their requirements

PROCESS APPROACH

The adoption of a *process approach* is now an explicit requirement (clause 4.2.2).

For the QMS the 'process approach' should commence with the determination of the key processes needed for communication with customers (enquiries, quotations, sales-order-processing, etc.), planning (including new product introduction and production scheduling), supplier control, manufacturing, test and inspection through to packaging/labeling and delivery to the customer.

Typical QMS processes could include:

- New customers or major new contracts
- Enquiries, estimates and quotations
- NPI (new product introduction)
- Design and development (i.e. product design and development - if applicable)
- Order processing, contract review and production planning

- Purchasing and SQA (supplier quality assurance)
- Production and/or service provision (i.e. manufacturing and processing)
- Product inspect, test and release certification
- Customer satisfaction measurement and concerns handling
- Engineering change management

A description of the sequence and interaction of these processes should become a formal part of the QMS documentation, for example see fig.1.

Once identified, the organisation must ensure that all of its processes are operated under *controlled conditions*. Controlled conditions require: "ensuring every process is undertaken in exactly the same way, every time and by competent personnel to ensure a consistent result".

As a minimum, controlled conditions include:

- planned activities
  - inputs
  - outputs
  - activities/tasks
  - what (with) - i.e. physical resources
  - who - i.e. human resources
  - how - i.e. procedures, SOPs, work instructions, etc.
- planned results
  - management of process-level KPI to ensure that goals/targets are met
  - identification of opportunities for improvement of the processes

Visual aids such as *SIPOC diagrams* and *Turtle diagrams* can be useful in capturing controlled conditions.

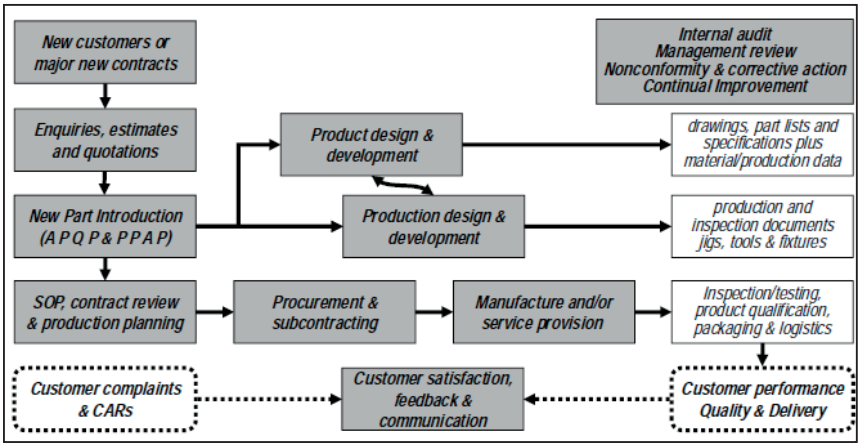

Fig.1 Example of a description of the QMS processes depicting their application throughout the organisation - note that the sequence and interaction of these processes is clearly demonstrated

ISO 9001:2008	ISO 9001:2015
documented procedures (work instructions, SOPs, etc.)	**maintain documented information** *created in order for the organisation to operate - to the extent necessary to support the operation of the QMS and its processes*
Records	**retain documented information** *evidence of results achieved - to the extent necessary to have confidence that the processes are being carried out as planned*

Table 2 New ISO 9001:2015 terminology replacing documented procedures and records

NEW TERMINOLOGY

Products and services

To remove the existing bias towards organisations dealing with physical commodities ISO 9001:2008 has adopted the term *products and services* (i.e. products and services intended for, or required by, a customer).

For example, a steel foundry may provide fully machined castings to one customer, and may just offer machining services to another.

Documented information

The existing terms 'document' and 'record' have both been replaced throughout all clauses by *documented information*.

Whereas ISO 9001:2008 referred to *documented procedures* (e.g. to define, control or support a process) this is now expressed as a requirement to *maintain documented information*. ISO 9001:2008 references to *records* is now expressed as a requirement to *retain documented information* (see Table 2).

ISO 9001:2015 still contains over 30 mandatory requirements for *documented information*, which can refer to traditional 'documents' and 'quality records'. In addition, the organisation must provide suitable documented information to assure the continuing effectiveness of its QMS which can, of course, be in any format and media. The modern trend is towards user-friendly visual documentation rather than lengthy (seldom read) narrative procedures!

The fundamental requirements for creating, updating and controlling documented information are explicitly addressed. Necessary information must be available and suitable for use and adequately protected. Its storage and preservation, distribution, access, retrieval and use must be controlled, with special attention to revision (version) control and the disposition (i.e. removal) of out-of-date information to prevent its unintended use.

The need to retain appropriate documented information as evidence of the results achieved (e.g. inspection/test results, process-level KPIs, customer satisfaction, internal audits, management review, supplier performance, etc.) is also retained. Retention times, access/retrieval and disposition must be defined and information must be protected from 'unintended alterations'. Consideration should also be given to documented information that is managed electronically (e.g. defined back-up processes; protection from corruption; etc.)

The results from monitoring and measurement activities must be analysed and evaluated to determine the need for actions and improvements.

Externally provided processes, products and services

The phrase 'control of externally provided processes, products and services' replaces 'purchasing' to underline the fact that ISO 9001:2015 is applicable to all types of suppliers and subcontractors and not just those who provide physical products. For example it could be applied to conventional purchasing from an (approved) supplier, through an arrangement with an associate company, through the outsourcing of particular processes and functions that the organisation is offering to customers, or by any other means. It also applies to external sources defined by a customer. All of the current requirements are retained plus the adoption of risk-based approach to determine the type and extent of controls appropriate to each external provider and all external provision of products and services.

QMS DOCUMENTATION REQUIREMENTS

It is important to emphasise that organisations are not required to follow an identical clause-by-clause sequence when defining their quality management system, and they are encouraged to use the *process approach* when describing and documenting their unique systems.

The requirements for specific *documented procedures* and a *quality manual* have been removed which should decrease the emphasis on unhelpful and unnecessary documentation. The new focus will be on delivering value to the organisation and their customers rather than creating unnecessary narrative procedures. The result will be that organisations can now decide on the nature and extent of their QMS documentation and documented information. Hopefully in future the QMS documentation will use more 'user-friendly' formats (e.g. flowcharts, turtle diagrams, SIPOC diagrams, etc.).

ISO 9001:2015 still contains over 30 mandatory requirements for *documented information,* which can refer to traditional 'documents' and 'quality records'

It is likely that some sectors (e.g. aerospace/defence) will still require some form of *quality manual.* In which case their sector-specific standards will define the minimum contents needed.

Organisations are, of course, free to use their own preferred style, format and media for such documentation.

The scope of the QMS

The scope of *the QMS* may include the whole of the organisation, specific and identified functions of the organisation, specific and identified sections of the organisation, or one or more functions across a group of organisations. Note that the scope of the QMS will be explicitly included in the third-party certification and must be explicitly stated by the organisation.

Determining the scope of any organisation's QMS involves defining the key activities performed and the types of product and services offered to customers. The scope of the QMS must encompass all daily operations of the organisation, particularly those activities required to:

- provide products and services that consistently meet customer and applicable statutory and regulatory requirements (i.e. the processes of the QMS)
- enhance customer satisfaction
- secure revenue (of course!) and growth of the business

The scope of a QMS may cover many different departments and areas, depending on the size and complexity of the organisation. For example, many 'corporations' own several businesses and companies, meaning the corporation's business scope is quite large and potentially covers multiple products and markets. Smaller organisations have a smaller QMS scope as they are focused primarily on providing families of products and services for their customers.

There is no 'permissible exclusions clause' as such, but the 'scope requirement' (clause 4.3) mandates that when a requirement cannot be applied this fact must be identified and stated in the form of documented information. Where any requirement cannot be applied, this cannot affect the organisation's ability or responsibility to ensure conformity of products and services - in other words all exclusions must be justified!

Summarising, the *QMS scope* must be available and be maintained as documented information stating the:

- products and services covered by the QMS
- justification for any instance where a requirement of ISO 9001:2015 cannot be applied

Risk-based thinking

The requirement for *preventive action* has been replaced by *risk-based thinking*. This concept is addressed in the ISO 9001:2015 requirements for planning, review and improvement of quality management system processes. Applying risk-based thinking can assist in deciding the type and extent of documented information that is necessary.

There is no requirement for formal methods for risk management or a documented risk management process. Consequently organisations can decide whether or not to adopt more extensive risk management approaches, for example the use of:

- S-W-O-T during the analysis of external and internal issues that are relevant to its operations and business
- P-diagrams, DFMEA and FTA in product design
- Process-flowcharts and PFMEA during new product introduction focused on production methods
- Risk register (based on PEST or PESTEL) for supplier selection and evaluation

Organisational knowledge

Knowledge has become key to successful operations, new product introduction and business development in general. ISO 9001:2015 considers knowledge like any other resource and it must be acquired and managed.

An organisation must identify the *knowledge* necessary to carry out its operational and business activities in compliance with the QMS and to achieve the defined objectives.

Such knowledge can be based on internal sources (methoding, simulations, work instructions, technique cards, results of corrective actions, customer feedback, and so on) and external sources (universities, professional bodies, technical standards, conferences, consulting organisations, and so on). Once acquired, it must be maintained, protected and made available where necessary.

The organisation must anticipate changes in knowledge needs and manage the risk of failing to acquire knowledge in due time.

Whatever the source, organisational knowledge is useful and useable information specific to an organisation - it is gained by experience and the proactive search for solution to operational and business challenges. It is information that is used and shared to achieve the organisation's objectives.

Leadership and the quality manager

Leadership now replaces *management responsibility* in line with the EFQM model. An organisation's top management must now demonstrate that they are actively involved in the operation of the quality management system. The removal of all references to the role of *management representative* serves to reinforce the need to see the quality management system embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.

Although there is no specific requirement for a *management representative* it is likely that organisations will elect to have a specific member of management oversee the operation of the QMS and have unrestricted access to top management.

It is inevitable that 'traditional' *quality assurance activities* such as calibration control, inspection/test, control of nonconforming product, internal auditing, etc. will remain the province of a quality manager and his/her team.

It is very likely that the specific need for a 'quality manager' will remain in the aerospace sector to meet regulatory requirements.

Control of nonconforming outputs

The clause 'control of nonconforming outputs' replaces 'control of nonconforming product' and includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

It is likely that an organisation will still define their arrangements for:

- defining the responsibility and authority for reviewing and dealing with nonconforming outputs and the process for approving persons making these decisions
- taking actions necessary to contain the effect of the nonconformity on other processes, products or services
- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts

In addition, the contractual arrangements for the acceptance of nonconforming products by means of concessions and the disposition of scrapped products must also be addressed.

EXPECTED BENEFITS OF ISO 9001:2015

ISO 9001:2015 will help organisations ensure their customers consistently receive high quality products and services, which in turn will bring about many benefits, including satisfied customers, management, and employees - and profits!

ISO 9001:2015 specifies the requirements for an *effective* quality management system and not just blind conformity to requirements! Organisations will discover that using the new standard will help them:

- Organise their processes in a logical manner that reflects their operational and business practice
- Improve the efficiency of processes through the application of risk-based thinking and the P-D-C-A cycle
- Continually improve performance and effectiveness through the use of quality objectives and process-level KPIs again using P-D-C-A
- Rationalise and drastically reduce the volume

of their QMS documentation through the adoption of a process-based approach and the use of modern visual aids
- Create satisfied customers, management, and employees and encourage a business environment where collaboration is the name of the game!

TIMESCALES FOR ISO 9001:2015

Organisations will now be granted a three-year transition period to migrate their quality management system to the new edition of the standard. Nevertheless it is never too soon to plan for the change so the benefits can be realised and exploited.

NEXT ACTIONS

Organisations still using masses of narrative procedures should be investigating a process-based approach to QMS design embodying modern visual approaches.

Many existing ISO 9001 systems are failing to set quantitative quality objectives - which is now a must! Also, these objectives must align with customer satisfaction expectations. To support these 'customer satisfaction metrics' it is mandatory to actively manage process-level KPIs (key performance indicators).

All in all, the publication of ISO 9001:2015 provides an opportunity to re-think and re-design quality management systems with an equal focus on conformity to requirements, performance, effectiveness and improvement.

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Automotive OEMs and suppliers learn about latest drive to tackle porosity in cast metal components

Automotive OEMs and suppliers heard about the latest innovation to solve the problem of porosity when they attended the Engine Expo North America 2015 in Novi, Michigan.

Ultraseal America explained how its new R-FL-Duplex Plus machine is set to transform casting impregnation with its small factory footprint, increased throughput and revolutionary two-stage process.

Fully automated with robotics, the machine is ideally suited to single part processing of automotive components such as engine blocks and is readily integrated into a modern just-in-time production line.

Its modular design is already gathering interest as it can easily be scaled up to achieve a throughput of up to 45 units per hour by adding extra modules to suit requirements.

One of the perennial problems facing powertrain manufacturers is that components manufactured out of cast metals are prone to porosity - microscopic holes within a casting that can cause a part to leak under pressure.

This is of course a major flaw for many cast automotive parts and Ultraseal America has a long history of finding reliable and permanent solutions to the problem of porosity, the latest innovation being the R-FL-Duplex Plus.

With its full automation, the new machine eliminates manual handling of parts and requires minimal downtime for maintenance, thus reducing running costs. All of the water from the process is automatically recycled.

The machine works with Ultraseal's global benchmark recycling sealant Rexeal 100™, giving customers all of the benefits of the company's recycling technology with the added advantage of increased throughput.

Automotive parts that are routinely impregnated include cylinder heads, cam carriers, cam covers, fuel pumps, fuel rails, heads, inlet and fuel system components, oil pans, oil sumps, thermostat housing, timing chain covers, torque converter case/bell housings, transmission cases, pump castings and valve body castings, turbo chargers and water pumps.