# The Negative Impact of Annex SL on ISO Management Systems Standards

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## PURPOSE OF REPORT

Annex SL was designed to harmonize all ISO management systems, terminology, and formatting, making it easier for organizations to comply with more than one management system standard. This paper describes:

- The flaws in Annex SL;
- The impairment of the effectiveness of the previous quality, environmental and OH&S management systems standards caused by Annex SL;
- The lack of consistency in following Annex SL guidance by the technical committees who created the new management systems standards;
- The lack of transparency during and after the creation of the new management system by the technical committees;
- The problem Annex SL should address to improve the implementation and auditing for organizations holding multi-system standards.

## CREATION OF ANNEX SL

In 2012, the Technical Management Board (TMB) of the International Organization for Standardization commissioned the Joint Technical Coordination Group (JTCG) to develop Annex SL. All management system standards issued after 2012 are required to be structured in conformance to the ten high level clauses:

Clause 1 – Scope
Clause 2 – Normative references
Clause 3 – Terms and definitions
Clause 4 – Context of the organization
Clause 5 – Leadership
Clause 6 – Planning
Clause 7 – Support
Clause 8 – Operation
Clause 9 – Performance evaluation
Clause 10 – Improvement

The ISO technical committees that develop management system standards are required to include the same high level structure, identical core text and common terms and, core definitions. The belief shared by ISO management and ISO certification bodies (CB's) is with Annex SL in place, organizations will experience less duplication and confusion when implementing multiple management system standards- and the third party management system auditors will be more efficient using a common set of requirements across the various standards and industry sectors.

In the six years since initiation of Annex SL, several new management systems standards have been issued under Annex SL requirements, including the quality standard ISO 9001:2015, the environmental standard ISO 14001:2015 and the Occupational Health & Safety (OH&S) standard ISO 45001:2018. Annex SL achieved its overarching goal. The new ISO management systems standards do now have a common high level structure, identical core text

and common terms and core definitions. In my opinion; however, the standards created under Annex SL guidance were poorly conceived, formatted and written by the technical committees chartered to create the standards.

## FLAWS IN ANNEX SL

By forcing commonality on the quality, environmental and OH&S clause requirements, the new standards are not as clearly presented as their predecessor standards. In conforming to Annex SL requirements, the technical committees made changes to ISO 9001:2008, ISO 14001:2004 and BS OHSAS 18001:2007 that weakened the standards without providing value:

- The new terminology "documented information" provides unnecessary confusion;
- Forced alignment of ISO 14001 and ISO 45001 standards with ISO 9001 created non-value added requirements for those standards;
- Commonality of requirements for all standards caused the dilution of several important ISO 9001 quality requirements.

### "Documented Information" Terminology Change

Under Annex SL, a new term "documented information" was created to describe what were formerly referred to as documents and records. As described by Annex SL, if the organization needs to prepare information and instructions for describing what needs to be done, they are *maintaining* "documented information". This information had formerly been described in the ISO terminology as procedures, work instructions, SOPs and forms. According to Annex SL, if the organization needs to provide information validating performance or results, they are *retaining* "documented information", which was formerly defined as records.

The ISO/TMB Joint Technical Coordination Group in their advisory JTCG/TF4/N28, issued 3 December 2013 JTCG – "Frequently asked questions (FAQ)" describes the need for the new term "Documented Information" with the following answer to a FAQ:

> 13. Why is the term "Documented information" used instead of "Documentation" or "Records"?
>
> "The standard has been updated to reflect current technology. Data, documentation and records are now frequently processed electronically. Therefore the new term "documented information" has been created to describe and take account of this situation. The term *subsumes the previous concepts of documentation, documents, documented procedures and records."

The Merriam Webster dictionary defines *subsume: *to include or place within something larger or more comprehensive: encompass as a subordinate or component.* The new management system standards do not require organizations to replace their existing documents and records terminology with "documented information". Annex A.1 "Structure and terminology" of ISO 9001:2015 states:

> "There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system."

I became aware of the problems with the new Annex SL structure when I wrote my first book for ASQ, "The ISO 14001:2015 Implementation Handbook". I decided organizations could avoid disrupting their management system documentation by disregarding the new terminology "documented information". Quality, environmental and safety records have been an important component of manufacturing and servicing companies for three decades. Any effort to obfuscate or diminish the importance of management system records is not helpful in my opinion. Quality records are often a key component in resolving product performance disputes- even lawsuits. Environmental and employee safety records can be instrumental in avoiding financial penalties- and sometimes as evidence for criminal cases.

When the technical committees prepared the new standards, they were consistent in using *retain* "documented information" in place of "records". Unfortunately, the requirements for *maintaining* "documented information" is used rarely in the new standards, particularly, in ISO 9001:2015; so the need to document many of the key quality procedures, such as corrective action, nonconforming material and internal audits is open to interpretation. The vagueness on what needs to be documented is possibly the most damaging artifact of Annex SL. A later section describes this confusion in more detail. The clients I have assisted in responding to the new standards have maintained the traditional terminology for documents and records and have successfully upgraded to the 2015 standards for ISO 9001 and ISO 14001. I also recommended they document procedures based on the prior standards.

In his book, "Understanding the New ISO Management System Requirements" Dr. David Brewer describes the reason for the changing the terminology was for ISO to adapt to modern technology. He and the TMB were concerned that if a company in today's modern age used a web page, the web page could contain both *records* and *procedure*s. ISO decided to use a single item to cover both documents and records. In my opinion, Annex SL changed the universally accepted, 30-year-old terminology of *documents* and *records* to satisfy the very few companies who might use the internet to manage their "documented information".

The overarching principle in documentation should be to formalize what is needed to ensure users of the documentation have a source for information and instructions that is accurate and timely, providing consistency in managing the business. Quality, environmental and safety records provide evidence of conformance to a specification or requirement. Records are the cornerstone to all management systems. *Retaining* "documented information" as an alternate term for records is both valueless and potentially confusing to employees and management.

**Forced alignment of ISO 14001 and ISO 45001 standards with ISO 9001**

The environmental and OH&S management systems have a lot in common. Many organizations maintain an environmental health and safety (EH&S) department. The leader of the EH&S department will often be assigned responsibility to manage the ISO 14001 and ISO 45001 management systems. The two standards contain quite similar clause requirements. The environmental *aspects* and *impacts* are analogous to the *hazards* and *risks* of the OH&S management system. Both standards have requirements for establishing emergency preparedness and understanding the organization's legal or compliance obligations.. The only significant clause difference between the two standards is ISO 45001 includes "Consultation and participation of workers", while ISO 14001 does not. The ISO 9001:2015 standard has many

quality requirements that are completely unrelated to managing an environmental or an OH&S management system. ISO 9001 has requirements for infrastructure; environment for the operation of processes; organizational knowledge; design and development; release of products; control of nonconforming material; and customer satisfaction that have little commonality with EH&S management.

The Technical Management Board of ISO in preparing Annex SL forced commonality for the high level structure of quality management systems with those of environmental and occupational health and safety. This was a fundamental mistake in my opinion. I am now witnessing where the certification bodies who provide the 3rd party auditors are misusing Annex SL clause commonality to cause non-valued audit requirements. At a recent ISO 14001:2015 audit, the auditor required my client to document a description of the organization's processes and their interactions. The CB's stage 1 audit "Readiness Review" instructed the auditor to verify:

> "*Describe how the Organization defines the interaction between the processes of the management system"*. Auditor: Need more clarity on the interaction between the processes of EMS.

The source of this requirement was the auditor's interpretation of ISO 14001:2015 mandatory clause 4.4 "Environmental Management System":

> "To achieve the intended outcomes, including enhancing its environmental performance, the organization shall, establish, implement, maintain and continually improve its environmental management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard."

How can an organization satisfy this requirement? They could include the process interaction chart from their quality management system. The quality processes of sales, design, etc. do not directly interact with the environmental management system processes, so that chart would not help the organization enhance their EMS. The organization could copy and paste Figure 1 Plan-Do-Check-Act from the Introduction of the ISO 14001:2015 standard. (I witnessed many organizations using a similar chart to satisfy the process interaction chart for their quality management system. I would inform the auditee that the PDCA chart represents the processes and interaction of the major clauses of ISO 9001- and are the same whether the organization makes nuts and bolts or rocket ships- no value.)

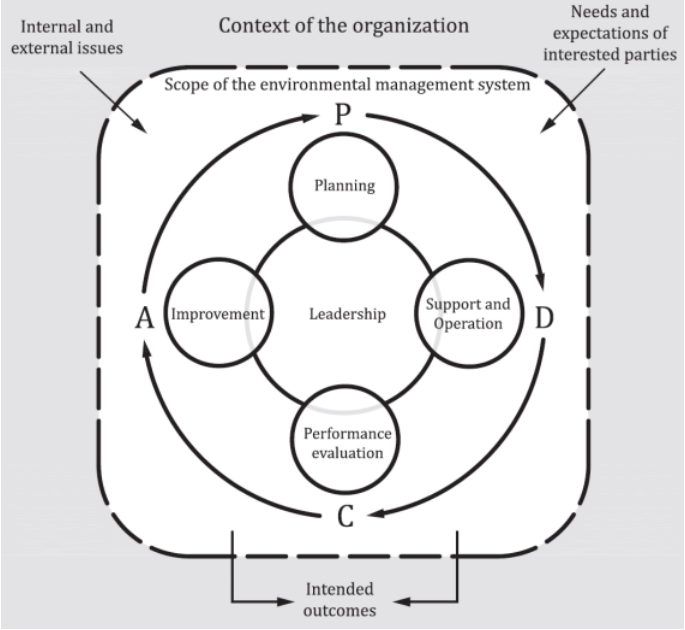
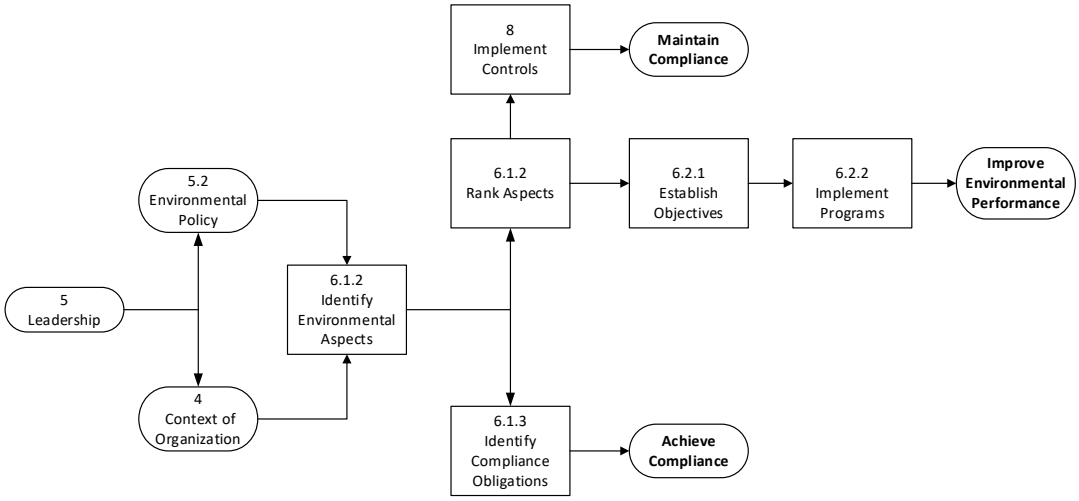



Figure 1—Relationship between PDCA and the Framework of this International Standard
(Source ASQ/ANSI/ISO 14001:2015)

Many organizations have been certified to ISO 14001 since 1996. They have a strong record of environmental stewardship which won't be improved by inclusion of a process- interaction flow chart. Satisfying all the clauses of ISO 14001:2015 will provide evidence that the organization is conforming to clause 4.4. In the case described, rather than argue with the auditor, I provided my client with a flow chart describing the interactions of ISO 14001:2015 that I believe is more definitive than the figure 1 "PDCA" pictogram.




ISO 14001:2015 Process and Interactions

This chart could be used by a company who manufactures chemicals or electronics- it describes the *processes* and *interactions* of ISO 14001. Its value may be in making employees aware of the main clauses of an environmental management system- and possibly satisfying poorly trained

3rd party auditors. It is an example of a non-value added requirement Annex SL caused by the force-fitting of identical core text from ISO 9001 on to ISO 14001 and ISO 45001 management system standards.

The same auditor at my client's ISO 14001:2015 certification audit included "Customer Satisfaction" and "Customer Complaints" as areas to be audited. These are clearly ISO 9001:2015 requirements. When questioned, the auditor responded that with the implementation of Annex SL, the ISO 9001, ISO 14001 and ISO 45001 standards all share the common requirement of customer feedback. He couldn't answer how he would link a requirement in ISO 14001:2015 to describe a nonconformance, should the organization not have a process to monitor customer satisfaction. It is unfortunate that Annex SL is providing poorly trained 3rd party auditors a new opportunity to embarrass the CB's that hire them.

**ISO 9001 alignment weakened ISO 14001 in 2004**

The attempt to harmonize management system standards using ISO 9001 as the "core" standard dates back to 2004. The original issue of ISO 14001 in 1996 included the requirement: "documents are periodically reviewed, revised as necessary and approved for adequacy by authorized personnel." *Periodic* clearly indicated the need for the organization to establish a cycle time for review of environmental documents. The first revision to ISO 14001 in 2004 removed the word *periodic* to align with ISO 9001:2000 document control terminology. In environmental (and OH&S) documentation, organizations should establish a *review* process for documentation commensurate with the risks of deviation from employee instructions. The intent of the review process is to ensure the environmental documentation (work instructions, SOPs) *matches current practices*. Operating personnel often improvise on how they perform a task to either improve their efficiency or save steps. This can't be allowed without management approval. The Internal Audit process may be a suitable method of monitoring *documentation vs. practice,* provided audit notes include evidence that work instructions were validated. In most cases, work instructions should be reviewed by the appropriate authority at a defined frequency. Work Instructions related to the ISO 14001 and ISO 45001 compliance obligations and operational controls of the organization should be formally reviewed at least annually by the process owners.

**Dilution of ISO 9001 Key Requirements**

While many of the harmonization issues were caused by adapting ISO 9001 terminology and clause requirements to ISO 14001 and ISO 45001, the Technical Committee (TC176) that prepared ISO 9001:2015 diluted three important clauses of ISO 9001 and also removed the requirement for a quality manual and *documented procedures* during the 2015 update:

- Function of the quality manual;
- Vagueness on what needs to be documented;
- Validation of processes;
- Monitoring or measuring of processes;
- Verification of purchased product;

Function of the quality manual

ISO 9001:2015 does not require a quality manual. This is another artifact of Annex SL "documented information" terminology that has the potential to provide more harm than good in my opinion. How many of the one million or more organizations currently certified to ISO 9001:2008 will toss out their existing quality manual? Very few I believe. The Annex A1 "Structure and terminology" of ISO 9001:2015 explains why a quality manual may not be necessary or helpful:

> "The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes."

This guidance is frankly, *incoherent*, as is much of the information contained in Annex "A" of ISO 9001:2015 "Clarification of new structure, terminology and concepts". What should have been communicated in Annex "A" was: "organizations with a quality manual that currently includes paraphrasing of each ISO 9001 clause requirement- going back through several ISO 9001 revisions- should limit the quality manual requirements to those described in ISO 9001:2008." Clause 4.2.2 "Quality manual":

> The organization shall establish and maintain a quality manual that includes:
>
> a) The scope of the quality management system, including details of and justification for any exclusions (see 1.2);
> b) The documented procedures established for the quality management system, or reference to them, and
> c) A description of the interaction between the processes of the quality management system.

ISO 9001:2008 had a clear set of requirements for a quality manual that could be recorded in a dozen or so pages. An effective quality manual should be the organization's *policy* statement of how they will manage their quality management system in conforming to ISO 9001:2015. The quality manual is a high level consolidation of the key elements- or *roadmap* of the relevant quality documentation. The recommended contents of a quality manual to include ISO 9001:2015 requirements:

- A description of the organization's business model including the context of the organization and expectations of interested parties;
- The scope (the activities, processes and buildings and locations) of the quality management system;
- The description (and justification)of those ISO 9001:2015 requirements, which are not applicable to the quality management system, as they do not affect the organization's ability or responsibility to ensure the conformity of its products and services (exclusions);
- The documented procedures established for the quality management system, or reference to them;
- A description of the processes and their interaction between the processes of the quality management system, including the process used to manage the interactions of the processes
- The Quality Policy;

- A description of how the organization has defined responsibilities and authorities to manage the quality management system.

ISO 14001:2015 and ISO 45001:2018 do not contain a requirement for an EMS or OH&S manual, but both standards require under clause 7.5 "Documented information":

> 7.5.1 General
> The organization's OH&S (or EMS) management system shall include:
> a) Documented information required by this document
> b) Documented information determined by the organization as being necessary for the effectiveness of the OH&S (or EMS) management system.

An organization's environmental or OH&S management system can also be summarized in several pages of a manual that includes the organization's environmental (or OH&S) policies and overview of how the organization will address the clause requirements, providing linkage to other documentation in the management system. For organizations that are certified to ISO 14001 and ISO 45001, an integrated EH&S (environmental health and safety) manual can be effectively implemented. Combining the quality manual with the EH&S manual can also be done, provided the quality manual contents is as described above and the EH&S policies are not "forced" to conform to quality system's terminology. Many integrated manuals I have audited were "quality centric" with the environmental or OH&S policies incompletely tacked-on. Not a good approach.

<u>Vagueness on what needs to be documented</u>

Possibly the most damaging change of Annex SL, is the vagueness of what needs to be documented in the management systems. The *documented procedures* of ISO 9001:2008 are now referred to as *maintaining documented information* and ISO 9001:2008's *records* are described as *retaining documented information*. In ISO 9001:2008, documented procedures were required for six clauses: Control of documents; Control of records; Internal Audits; Control of nonconforming product; Corrective Actions; Preventive actions. ISO 9001:2015 Annex "A" (informative) "Clarification of new structure, terminology and concepts" describes "documented information":

> A6 Documented information
> "Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information". Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention."

A search of ISO 9001:2015 for "maintain documented information" does not indicate any of the six clauses (preventive actions no longer a requirement) that were required to be documented in ISO 9001:2008 are required to be documented. How many of the million organizations currently certified to ISO 9001:2008 are going to toss their six required document procedures? How many 3rd party auditors will allow an organization to

manage their quality management system without a documented procedure for any of the six base line processes? Very few, I would guess. The TC 176 can point to Claus 4.4 "Quality management system and its processes" that requires:

> 4.4.2 To the extent necessary, the organization shall:
>
> a) Maintain documented information to support the operation of its processes;

So now the organization and auditor face a quandary: how are the processes evaluated to determine which ones need to be documented? Is the design process more necessary (important) than sales or purchasing? The irony here is ISO 9001:2008 limited the documented procedures to the six required, thus preventing overzealous auditors of forcing excessive documentation on auditees. TC 176 has allowed the "maintenance of documented information" requirements to be arbitrary. The ISO 14001:2015 and ISO 45001:2018 standards were also impaired by the documented information terminology, although many of the clauses in those standards contain "The organization shall *maintain* and *retain* documented information…"

Validation of Processes

ISO 9001: 2015 removed a main sub-clause from ISO 9001: 2008, Validation of Processes, clause 7.5.2 and moved the requirement into 8.5.1 Control of production and service provision.

> ISO 9001:2008, 7.5.2 Validation of processes for production and service provision
> "The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered."
> ISO 9001: 2015, 8.5.1-f Control of production and service provision
> "Controlled conditions shall include the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement and the implementation of release, delivery and post-delivery activities."

This change is unfortunate, in my opinion, as validation of processes can be an important component of an organization's quality performance, and has often been overlooked by both auditors and organizations. In ISO 9001: 2008, if an organization did not have reason to validate processes; clause 7.5.2 was excluded with justification as why validation was not required. If an organization can measure their products, either by dimensional, functional or visual standards, then the organization would not have validation requirements. Examples where validation of processes is a key component of an organization's quality controls include:

- soldering (where integrity of the joints can't be verified by measurement);
- welding;
- heat treating or plating

In these cases, the manufacturer could not ensure the product met requirements without damaging the product; thus a process validation is needed to ensure the product meets the specification. By moving the validation requirement into a lower level of the Production and service provision- and removing the important wording: *deficiencies become apparent only after the product is in use or the service has been delivered-* re-enforces the idea that validation is only a

requirement for a production machine. Validation of the quality management system processes has been a requirement since ISO 9001:2000 was issued almost twenty years ago. The change in the 2015 ISO 9001 standard was driven by attempting to make the quality production and service provision match more closely with the operational planning and control clauses of the environmental and OH&S standards in support of Annex SL. I often encounter organizations who respond to the validation requirement by including a comment in their documentation: "We will validate any process where deficiencies become apparent only after the product is delivered"- without defining what the processes are- and how they are validated. If the organization measures or monitors all their products before release to customers they should declare the sub- clause 'f' of 8.5.1 as not being a requirement. The next revision of ISO 9001 should correct this error.

Monitoring or measuring of processes

Another unfortunate change was the elimination of the clause relating to *monitoring and measurement of processes*. This requirement was also initiated with the 2000 revision of ISO 9001 and was a major step in causing certified organizations to view their quality management system as a series of *processes* that should be monitored or measured to set a baseline for improvement.

> ISO 9001: 2008 clause 8.2.3:
> "The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate."

This was generally interpreted by organizations and 3rd party auditors to require the organization to establish metrics (and goals) for their core processes: sales; design; purchasing; production or service. Support processes should be, at a minimum be monitored as part of the organization's internal audit process. If the organization determined a metric was not practical or useful for a core process then those process would also be monitored by the internal audit process. To align with Annex SL guidelines and have all management systems include the same ten high level clauses, the writers moved the monitoring requirement into clause 9 "Performance evaluation".

> 9.1 Monitoring, measurement, analysis and evaluation:
> "The organization shall evaluate the performance and the effectiveness of the quality management system."

ISO 9001:2015 has two additional performance evaluation clauses that indicate the monitoring process requirements are similar to ISO 9001:2008.

> 4.4 Quality management system and its processes:
> 4.4.1c: Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
> 4.4.1g: Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.

During a recent audit, the organization did not have metrics for their sales or design processes. I issued the nonconformance against clause 4.4.1c; however, I could have cited clause 9.1 also. ISO 9001: 2008, clause 8.2.3 was much easier to explain to my client,

as clause 8.2.3 includes the need to take corrections when metrics are not met. There are several other clauses of ISO 9001:2015 where the requirements are intermixed in more than one clause, making auditing more difficult. Clause 6.3 "Planning of Changes" is a new clause; however, many other clauses of ISO 9001:2015 include management of change.

Verification of purchased product

The third clause from ISO 9001:2008 that was made less clear in ISO 9001:2015:

> 7.4.3 Verification of purchased product:
> "The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements."

ISO 9001:2015 included the inspection of purchased parts in clause 8.4 "Control of externally provided processes, products and services":

> Clause 8.4.2 Type and extent of control:
>
> "The organization shall:
> d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements."

I provided an audit for a manufacturing client recently and noted a discrepancy on how the employee tasked with receiving a purchased material had not followed the organization's incoming inspection plan. Under ISO 9001:2008, clause 7.4.3 "Verification of purchased product", the *requirement*, *finding* and *evidence* of the nonconformance would be easy to explain to my client. Under ISO 9001:2015, the client could argue they had: d*etermined the verification, or other activities, necessary to ensure that the externally provided processes, products and services met requirements*. They had decided not to verify or inspect the items! Clause 8.4.2 is open to interpretation. The change in wording from ISO 9001:2008 Clause 7.4.3 provided confusion without any value added.

**THE TECHNICAL COMMITTEE INCONSISTENCIES**

The technical committees did not conform to all the Annex SL requirements when preparing ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018.

- Lack of clarity in some ISO 9001: 2015 clauses;
- The Annex to ISO 9001:2015 allows avoidance of the requirement for "risk- based thinking";
- Inconsistent process to provide users of the standards with "common core definitions";
- Inclusion of prescriptive "Notes" in the standards that are not conforming to Annex SL guidelines.
- Lack of Transparency by TC 176

**Lack of Clarity in ISO 9001: 2015 Clauses:**
Several clauses of the ISO 9001:2015 are not clearly expressed. Clause 6.1, "Actions to address risks and opportunities" contains two formatting errors in defining auditable requirements. It is not helpful when a clause references a previous requirement by clause number without including the actual wording of the referenced clause. A clearly defined set of requirements for a clause should be completely defined within the text of the clause. Dropping down four levels (6.1.2.a.1) does not help the reader identify the requirement.

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;
b) how to:
   1) integrate and implement the actions into its quality management system processes (see 4.4);
   2) evaluate the effectiveness of these actions

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

Consistent with "commonality of text" as required by Annex SL, clause 6.1, "Actions to address risks and opportunities", ISO 14001:2015 and ISO 45001:2018 also include the cross-referencing and over-indexing of clauses. This clause is incoherent by any standard- and the organization need not document their plans as described in the Annex.

**The Annex to ISO 9001:2015 allows avoidance of "risk- based thinking"**
I believe the addition of risk analysis (and deletion of preventive action) is a good addition to ISO 9001:2015- and along with "Organizational Knowledge" is the only significant improvement in ISO 9001:2015. Unfortunately, In the Annex to ISO 9001:2015, TC 176 made the risk analysis *voluntary.*

ISO 9001:2015 clause 6.1 "Actions to address risks and opportunities" defines the following requirement as defined above requires the organization to: "consider the issues referred to in 4.1 (context) and the requirements referred to in 4.2 (interested parties) and determine the risks and opportunities that need to be addressed" Annex "A" to ISO 9001:2015: "Clarification of new structure, terminology", is intended to clarify the requirements of clause 6.1, "Actions to address risks and opportunities". The interpretation provides a path for organizations to essentially ignore the new requirement related to analyzing and addressing risk, as the clarifications indicates risk planning documentation is not required.

A.4 Risk-based thinking:
"Although (6.1) specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards. Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1 the organization is responsible including whether or not to retain documented information as evidence of its determination of risks. "

I asked the US Chair for WG/TG22, the Interpretations Committee for US TAG-176 the following question using TC 176 Form# N691R2:

"Does ISO 9001:2015 Clause 6.1 require an organization to provide documented information as evidence that the organization has determined the risks and opportunities that need to be addressed?" His answer follows:

"No, ISO 9001:2015 does not require an organization to provide documented information as evidence of determining risk or opportunities. Annex A.4 of ISO 9001:2015 states: …the organization is responsible for its application of risk based thinking and the actions it takes to address risk, <u>including whether or not to retain documented information as evidence of its determination of risks. (emphasis added)."</u>

Unfortunately, the CB auditors don't read (or understand) the Annex of ISO 9001:2015 and have written NC's against clause 6.1, requiring my client to retain a "Risk Register" including risk- analysis for all processes. We won appeal, as my client had identified several risks related to maintaining skilled work force- and sole sourced suppliers- with actions defined. I believe most 3rd party ISO 9001 auditors will expect some form of documentation to indicate risk-based thinking is part of the organization's quality management system. A guideline I use in training internal auditors: "If it is not documented, it didn't happen." How an auditor can determine if an organization is applying risk- based thinking, without objective evidence (documentation) is contrary to the concept of auditing. From the genesis of ISO 9000 in 1987, anecdotal or verbal evidence has never been acceptable verification for satisfying a requirement.

Annex A, "Clarification of new structure, terminology" provides confusion, not clarification. TC 176 should modify this "double-speak"- and clarify what is expected of organizations related to risk analysis. The annexes in ISO 14001:2015 and ISO 45001:2018 provide clarity on how an organization may address risks based on the *context on which the organization operates (ISO 45001) or the hazards associated with the activities of the organization (ISO 14001)*. This is useful advice, as it allows the organization latitude in establishing risk analysis consistent with its business model.

**Inconsistent process to provide users of the standards with "common core" definitions**

Annex SL requires the management system standards to use identical definitions for such terms as *organization, interested party, policy, objective, competence and conformity*. ISO 9001:2015; ISO 14001:2015 and ISO 45001:2018 approach inclusions of definitions differently. The quality

management standard, ISO 9001:2015 does not include the definitions key to users of the standard. To obtain the definitions, the user of ISO 9001:2015 is required to purchase, ISO 9000:2015 from ISO, ANSI or ASQ for $176-$209. The ISO 14001:2015 and ISO 45001:2018 standards include the definitions in the standards. An individual seeking to obtain the quality management system standard and related definitions has to spend twice as much as someone seeking the same information for the environmental or OH&S standards. Annex SL allows TC 176 to include definitions in a separate document without explaining *why* definitions- important to assisting understanding of the text of the requirements- are not located directly in the standard.

**Inclusion of prescriptive "notes" in the standards**

ISO 9001:2015 and ISO 45001:2015 describe notes as follows: Information marked as "NOTE" is for guidance in *understanding* or *clarifying* the associated requirement. Dr. David Brewer, author of "Understanding the New ISO Management System Requirements" (and a sponsor of Annex SL) describes "Notes" added to a management system as follows:

> "A note in an ISO management system is intended to assist readers, to understand the requirement. It does not modify the requirement or imply that a particular way of meeting the requirement is itself a requirement. A sure test of one's understanding of the note is that the requirement should not change if the note is ignored."

Three of the standards released after Annex SL was issued provide notes that are a collection of information- some useless and some prescriptive and problematic. As Dr. Brewer explains a "Note" included at the end of an ISO clause should not provide the organization with advice or options on how to satisfy the requirement- or what a 3rd party auditor can accept as conformance to the requirement. Some examples of misapplied notes follow.

ISO 9001:2015 Clause 8.2.3, "Review of the requirements for products and services"

**Note**: *In some situations such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information such as catalogs.*

- This note is prescriptive- but also not helpful. I have audited the catalogs of many organizations; they are often poorly maintained.

ISO 9001:2015 Clause 9.1.3, "Analysis and evaluation"

**Note**: *Methods to analyze data can include statistical techniques.*

- Quite a revelation in 2015! Organizations have been employing statistical techniques for over 50 years to analyze data.

ISO 45001:2015 Clause 5.4, "Consultation and participation of workers"

**Note:** *Obstacles and barriers can include failure to respond to worker inputs or suggestions, language illiteracy, barriers or reprisals or threats of reprisals, and policies or practices that discourage or penalize worker participation.*

- This Note is quite problematic as it suggests a 3rd party auditor should get involved in a possible workers and management dispute relating to company policy. The auditor can be easily set-up by a troubled worker.

ISO 45001:2015 Clause 5.4, "Consultation and participation of workers

*It is recognized that the provision of training at no cost to workers and the provision of training during working hours, where possible, can remove significant barriers to worker participation.*

- A management system standard should not advise an organization on how to spend its money.

ISO 45001 Clause 8.1.2, "Eliminating hazards and reducing OH&S risks"

**Note**: *In many countries, legal requirements and other requirements include the requirement that personal protective equipment, "PPE" is provided at no cost to workers.*

- A third party auditor in the U.S should stay clear of informing the management of the organization that they are violating the law by not providing free safety shoes or safety glasses to employees. I wouldn't make observations regarding a potential legal issue in any country.

ISO 9001:2015 Clause 7.1.4, "Environment for the operation of processes"

**Note**: *A suitable environment can be a combination of human and physical factors, such as:*

*a) Social (e.g. non-discriminatory, calm, non-confrontational);*
*b) Psychological (e.g. stress-reducing, burnout prevention, emotionally protective);*
*c) Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise)*

*These factors can differ substantially depending on the products and services provided.*

- The intent of clause 7.1.4 is to cover work environment issues such as work area temperature and humidity and electrostatic conditions and dirt that can cause nonconforming product. There are many products that need to be produced (and measured) in a controlled temperature/ humidity environment. A 3rd party auditor is not qualified to make judgements on the social, psychological or physical condition of workers related to the quality of product they produce.

ISO 45001 Clause 8.1.4.2, "Contractors" and 8.1.4.3 8.1.4.3 Outsourcing

**Note***: It can be helpful to include the occupational health and safety criteria for the selection of contractors in the contractual documents.*

**Note:** *Coordination with external providers can assist an organization to address any impact; outsourcing has on its OH&S performance.*

- Both notes are providing advice on how to address a requirement.

ISO 45001 Clause 9.1 "Monitoring measurement analysis and performance evaluation."

**Note**: *There can be legal requirements or other requirements that is national and international standards concerning the calibration or verification of monitoring and measuring equipment.*

ISO 45001 Clause 10.2, "Incident, non-conformity and corrective action".

**Note**: *The reporting and investigation of incidents without undue delay can enable hazards to be eliminated and associated OH&S risks to be minimized as soon as possible.*

- Both these notes provide information the organization or 3rd party auditor should discover somewhere other than in a management system standard.

ISO 14001:2015 Clause 6.1.2 "Environmental Aspects"

**Note**: *Significant environmental aspects can result in risks and opportunities associated with either adverse environmental impacts, threats or beneficial environmental impact opportunities.*

ISO 14001:2015 Clause 6.1.3 "Compliance Obligations"

**Note**: *Compliance obligations can result in risks and opportunities to the organization.*

- Both notes provide advice to the organization that assumes the organization doesn't understand that environmental aspects can harm or help the environment, and that violating laws is risky.

ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018 contain additional prescriptive or advice-giving notes related to what to put in an environmental policy, tips on how to train workers, how to evaluate risks and what may be part of the organization's infrastructure. ISO 9001:2008 also contained several prescriptive "Notes". ISO 14001:2004 had none in the clause requirements. BS OHSAS 18001:2007 had several "Notes" that were clarifying in nature, not prescriptive. I suggest the Technical Management Board of ISO, in managing Annex SL review all new management system standards for proper use of "Notes" before allowing release of the standard.

The examples of Notes described in this report are providing much more than "guidance in understanding or clarifying the associated requirement" as defined by the authors of Annex SL. While the US TAGs may argue the Notes aren't part of the requirements- and are not auditable. The obvious question is: if no one *can* or *will* use the "clarifications" -why are the prescriptive notes included in the standards?

**Lack of Transparency by TC 176**

Annex SL requires the technical committees preparing the management systems standards (MSS) be *transparent* during preparation and implementation of the MSS.

> **Annex SL section 8.2.4**
>
> SL.8.2.4 Transparency of the MSS development process
>
> MSS have a broader scope than most other types of standard. They cover a large field of human endeavour and have an impact on a wide range of user interests.
>
> Committees preparing MSS should accordingly adopt a highly transparent approach to the development of the standards, ensuring that possibilities for participation in the process of developing standards are clearly identified, and the development processes being used are understood by all parties.
>
> Committees should provide information on progress throughout the life cycle of the project, including:
>
> - the status of the project to date (including items under discussion),
> - contact points for further information,
> - communiqués and press releases on plenary meetings, and
> - regular listings of frequently asked questions and answers
>
> Maximum use should be made of the resources of the ISO Central Secretariat to facilitate the transparency of the project and the committee should, in addition, consider the establishment of a dedicated open-access website.

SL.8.2.5 Process for interpretation of a standard

The committee should establish a process to handle interpretation questions related to their standards from the users, and should make the resulting interpretations available to others in an expedient manner. Such a mechanism can effectively address possible misconceptions at an early stage and identify issues that may require improved wording of the standard during the next revision cycle.

Of the three standards only the TC 207committee, preparing the environmental standard ISO 14001:2015 followed the Annex SL requirements for transparency as indicated by my research. I had a question on interpreting a clause of ISO 14001:2015. I contacted the Secretary of ISO/TC 207/SC 1 who directed me to the committee's procedure "1n1358 Revised SC1 Interpretation procedure".

http://users.neo.registeredsite.com/9/2/0/18247029/assets/1n1358_Revised_SC1_Interpretation_procedure_TC_207_ems.pdf.

TC 207 also maintains a list of ISO 14001 implementation FAQs received from various sources.

The committee that prepared ISO 45001:2018 was project committee PC 283. BS OHSAS 18001:2007 was not an international standard; it was prepared and administered under the British Standards Institute (BSI). PC 283 was recently approved as a technical committee TC 283. I contacted the Committee Manager for ISO/TC 283 with a question on ISO 45001:2018, who promptly provided an answer. The Committee Manager also indicated TC 283 will be forming a FAQ compilation- good start for a new committee, administering a new standard.

Both TC 207 and TC 283 allow users of their standards to request an answer to implementation questions by emailing in the US to: standards@asq.org- with your name, address, phone, e-mail and organization or business. Members from other countries can contact their technical committee's country representative.

The process to have an implementation question answered related to ISO 9001:2015 via TC 176 is quite different from US TAG 207. I contacted standards@asq.org with an interpretation question on ISO 9001:2015. I was directed to US TAG 176 SOP SC2-TG22-001 rev 1-"US Guidance for handling requests for interpretation of the requirements of ISO 9001". The following link allows access to the SOP:

http://users.neo.registeredsite.com/9/2/0/18247029/assets/WG22_Interpretation_Guidelines_SC2-TG22-001_v012717c.pdf.

The procedure includes a form (not user friendly) to be filled out and forwarded to standards@asq.org. The only acceptable questions are those that can be answered with "yes" or "no". The procedure provides two examples of acceptable questions- and five guaranteed rejections. An example of a reject:

Question: *Can a consultant audit a company they have consulted with? Are they being impartial?*

Unacceptable because: This question actually asks two (2) separate questions, both of which can be answered with a "Yes" or "No". (e.g. is a "yes" answer applicable to the

first question, the second question or both?). Requestor should submit two (2) separate requests, one for each question.

While I appreciated the response from the US Chair for WG/TG22, the Interpretations Committee for US TAG-176 on my question related to clause 6.1, "Risk- Based Thinking", the TC 176 response to user interpretation question is more bureaucratic than transparent. I believe TC 176 is not following Annex SL guidance as described in section SL.8.2.5 "Process for interpretation of a standard."

**THE TECHNICAL MANAGEMENT BOARD SELECTED THE WRONG PROBLEM**:

I suggest the Technical Management Board for ISO set out to solve a problem that wasn't the biggest concern for audited organizations and the certifying bodies who provide the auditors for multiple standard audits. I've assisted many organizations in preparing the documentation and implementation plan for multi-standard management systems. In the case of an organization maintaining ISO 9001 certification, that wanted to add ISO 14001 (or OHSAS 18001), I would utilize the existing appropriate documentation from ISO 9001 (document and records, corrective actions, training, internal audits and management review) and customize the procedures for ISO 14001- and then add the procedures unique to ISO 14001. Annex SL will not change my approach- in fact; the standards constructed under Annex SL are not as easy to interpret and combine as their predecessors ISO 9001:2008 and ISO 14001:2004 and BS OHSAS 18001:2007.

I believe the bigger problem in harmonizing the management systems standards lies in conducting efficient, organization-friendly audits to multi-management standards, not the *structure* of the individual standards. When an organization is certified to more than one standard, there are three options available to the certification bodies and organizations for scheduling the multiple standard audits.

1) Each audit can be conducted independently, at different times by different auditors;

2) The three standards can be audited during the same timeframe as a combined audit with the auditors qualified to audit only one or two of the standards;

3) An integrated audit can be conducted where the audit team is qualified to audit all of the three standards.

The integrated audit of option 3 is the most efficient in terms of cost and interruption of the organization's day to day activities. I have conducted many integrated audits for smaller companies, combining the ISO 9001 and ISO 14001 clauses that had commonality (document and record control, corrective action, training, internal audits and management review). For larger organizations, where several audit days were required to conduct the audits, the integrated audits were not always possible as some members of the team were not qualified to audit one of the standards; so the audits would be a combined audit with only a few clauses audited as an integrated process. The implementation of Annex SL did nothing to assist organizations and certifying bodies in moving towards the more efficient integrated audits.

Another challenge for organizations holding multi-management systems is being audited separately if the organization holds sector specific certifications such as automotive TS

16949; telecommunications TL 9001; medical products ISO 13485 and aerospace AS 9100. The Technical Management Board of ISO would provide valuable assistance to certified organizations with multi- standards and sector specific schemes if they found a way to alleviate the redundancy that results in separate, independent audits. It is not just the 3rd party cost of the audits; it is the interruption of the organization's daily routine and time required to prepare and respond to the auditors.

**SUMMARY/ NEXT STEPS**

Annex SL created an overly restrictive process for the preparers of management system standards with its harmonization guidance. The fundamental mistake in my opinion- as described in this report- was forcing quality terminology and structure on the environmental and OH&S management systems. The current ISO 14001:2004 and BS OHSAS 18001:2007 standards were weakened by the harmonization with the quality management system. The commonality of requirements for all standards caused the dilution of several important ISO 9001 quality requirements. The initiation of the "documented information" terminology has generated confusion without contributing any value to certified organizations. My recommendations:

- Annex SL should be modified or rescinded and the technical committees be allowed to use the former management systems standards guidance;
- ISO 9001:2015; ISO 14001:2015 and ISO 45001:2018 should be revised on a fast track;
- An Advisory note should be issued by TC 176 clarifying risk- based thinking documentation requirements for ISO 9001:2015;
- An Advisory note should be issued by the appropriate International Organization for Standardization function explaining how "Notes" can be used;

I realize I have no standing with the International Organization for Standardization. ISO has a bureaucratic process for review and comments related to management systems standards that I do not wish to utilize. It was never clear to me how the Technical Management Board of ISO received input or feedback from certified organizations, management system experts or experienced 3rd party auditors during the writing of Annex SL. Was there a draft proposal circulated outside the halls of ISO, requesting feedback?

The American National Standards Institute (ANSI) provides oversight to the US TAGs. ISO 9001:2008 and ISO 14001:2004, approved for publishing by ANSI were clearly written, properly formatted and did not contain the prescriptive notes. These management system standards contain the professionalism and clarity I would expect ANSI requires of other standards they approve. ISO 9001:2015; ISO 14001:2015 and ISO 45001:2018 are not professionally drafted as demonstrated in this report.

I plan to release this paper via various social media links, soliciting inputs and feedback before forwarding the paper and questions for ANSI related to ANSI's oversight of the US TAGs and how they were involved in releasing the new standards. If you have a comment or correction/ suggestion to my analysis, I would appreciate an e-mail to at miltdentch@gmail.com.

Of particular interest would be your experiences in contacting the technical committees or technical advisory groups for feedback or implementation questions. I will include the feedback I receive and post the feedback on my website: www.mpd-qe-consulting.com. Please indicate if you wish to have your name included with the comment.
Thank you!

**Milt Dentch ISO BACKGROUND**

- 30 years' experience as ISO 9001, ISO 14001 and OHSAS 18001 as a manager of an audited organization, CB lead auditor, consultant and internal auditor trainer;
- 35 years of direct manufacturing experience as an engineer and plant manager responsible for operations, quality, environmental and safety departments;
- Exemplar Global (RAB) QMS and EMS lead auditor for twenty years, conducting over 500 audits to the ISO 9001, ISO 14001 and OHSAS 18001 standards;
- Conducted audits, including integrated international audits to all three standards;
- Assisted several clients in upgrading to the 2015 version of ISO 9001 and ISO 14001;
- The Quality Press of the American Society for Quality (ASQ) published my books on implementing ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018.