# UNITED STATES ACCREDITATION BOARD

## ISO 9001:2015

The purpose of this Advisory Note is to introduce initial thoughts of United States Accreditation Board (USAB) regarding the impending changes to ISO 9001. It is a preliminary document in view of the fact that further DIS from ISO is expected.

It is not the responsibility of accreditation bodies to direct how standards must be interpreted. It is the view of USAB that the quality profession is much misguided in believing that standards, once written, should then need further guidance, documentation and authoritative comment in order to work with them. In our view, any standard that is not capable of being understood on its own meritsis a poor standard and this view is held particularly with regard to ISO 9001:2015. That is not to say that the document itself is a bad one. It has much of merit and is very well principled in its ethos.
However, as a certification tool it is not deemed a satisfactory document as the quality profession has had to develop a whole raft of other documents and protocols in order to deal with it.
Nonetheless, it is the document we have to work with and so work with it we must.
ISO DIS 9001 has introduced four major changes:

(i) New structure – see Appendix A, contents list for the new standard
(ii) "Risk-based thinking" This is expanded in the extract from the standard in Appendix B.
(iii) More extensive list of definitions.
(iv) Useful annexures

With regard to the new structure; the DIS makes it clear that it is not a requirement that the documented quality management systems must reflect the same structure as the standard. USAB up holds this view. However, certifiers are advised to develop their own check lists against the new standard on a sentence-by-sentence basis. They are advised to encourage registrants to do the same but as a means of reducing audit time only. It is not to be treated as a requirement.

With regard to "Risk based thinking" USAB is dismayed at the approach that TC176 (The standards writing committee) has taken on this. They have defined Risk as "**the effect of uncertainty on an expected result.**" For decades risk has been described as a probability of an event occurring. Now it is described as something else. Only time will tell what the consensus of the quality profession will be as a result of this but our view is that a good deal of time and money will be expended because of it.

It is USAB view that the effect of uncertainty will be an action that has to be applied to something and inthis instance, it will be the quality objectives of the registrant organization. Therefore, one would expect there to be more clarity in defining the quality objectives of the organization as a result of this new revision. Previously quality objectives were always required to be measurable and they were often attributing rather than variables. Now an organization will be expected to discern the uncertainty of a quality objective being achieved and to determine the responsive actions necessary to restore certainty in the quality objective being met. One could observe that this is what Preventive Action addressed and therefore all that has happened is that one term has been replaced by another?

Please note that the DIS has definitions of Quality Objectives and also for Objectives. In addressing Risk Based Thinking the DIS refers only to objectives which have a far wider interpretation and scope than quality objectives. Because of this it is essential that the certifier defines its own approach. One may wish to consider that a list of possible risks be compiled that demonstrates the registrants.

conscientious approach to the standard's requirements? However, when the process approach was introduced in year 2000 very few organizations bothered to compile a list of processes for their quality system to address and Accreditation bodies and certification bodies have been very weak on this since.Therefore, it is difficult to determine what the typical quality profession response will be.

With regard to a more extensive list of definitions, USAB is concerned that this will provoke more semantics, pedantry and debate over interpretations of clauses and registrant compliance with a standard. The ethos of simplicity is not being met by this standard and it will require all participants to invest more time in the study and understanding of Terms & Definitions.

With regard to Useful Annexures there are three:

(i) A - Clarification of new structure, terminology and concepts
(ii) B - Quality management principles
(iii) C - The ISO 10000 portfolio of quality management standards

With regard to the requirement for Records and procedures is less clear with all documents being termed "documented information" and 'retained documented information' now meaning records and'maintain documented information' now meaning procedure. However, within the text of the standard there is no string of words "maintain documented information" (except when describing scope of the organization and a generalized 'catch-all' statement), or retain documented information From this may be inferred that the numbers of procedures may be reduced but the number of records may need to increase.

With regard to the number of principles has reduced and these appear more rationale. However Quality Profession practice gave scant regard to principles in the past and so it is unlikely that these would have much prominence. Nonetheless USAB rate these principles highly for certifiers wishing to assess the ethos of an organization and its ISO 9001 compliance and would therefore support certifiers in their endeavors to bring them to the fore in auditing practice.

One must be mindful that all ISO 100000 series of documents are guidelines and not requirements. The inclusion of these documents by reference in ISO 9001 brings them closer to becoming quasi- requirements. Awareness of these standards is therefore essential but compliance is not.

**USAB advice.**

The requirements of ISO 17021 take precedence over all those certifiers do. It is for the certifier to defineits own scheme for the assessment and registration of registrants. However, it is unwise to be as novel and dissimilar from the rest of the quality profession as to invite condemnation or ridicule.

Therefore, USAB will expect, as a minimum, to see the following:

- **Training records** showing study and evaluation of the new standard at all levels in the organization.
- **Changes in audit report structure** or required content to reflect the new emphasizes of the standard.
- **Plans** for the introduction of assessment and registration of clients to the new standard.
- **NOTE:** An interregnum of three years is generally recognized in which registrations to the ISO 9001:2015 will be valid but USAB encourage a two-year target.
- Consider the compilation of "**Potential Risk lists"** as an aide memoire for registrants to demonstrate compliance with this aspect of the new standard.
- Require registrants to have **undergone study** or further training of the new standard.
- **Really study the annexures.**
- **USAB** will acknowledge certifications to ISO 9001:2015 from the day following date of publication by ISO. Certifiers should be able to demonstrate via written statement how registrants have been able to achieve certification in such a short time.

**END**


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