

Technical Bulletin - Update on Quality Management Systems Requirements within the Nuclear Energy Sector Supply Chain



23 January 2019

This Technical Bulletin is to update certification bodies regarding the development of ISO Standards in preparation for the implementation of ISO 19443: third party certification of QMS when supplying products and services important to nuclear safety.

Relevant ISO documents.

ISO 19443:2018 Quality management systems - Specific requirements for the application of ISO 9001:2015 by organisations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS) - issued May 2018

ISO TR XXXXX QMS - guidelines for the application of ISO 19443:2018 - in preparation by ISO WG 85 Management Systems.

This will be a guidance document to assist users in applying the QMS requirements of ISO 19443 relevant to their scope of supply (position in the supply chain/tier) of products and services important to nuclear safety. It does not add or subtract from the requirements of ISO 19443 nor prescribe mandatory approaches or preferred methods to the implementation of the requirements of ISO 19443. It provides examples of possible solutions and identifies good practices.

ISO IEC/TS 23406 Nuclear Sector requirements for bodies providing audit and certification of QMS for organisations supplying products and services important to nuclear safety -- in development by a joint ISO/CASCO working group within ISO WG 85 Management Systems.

This technical specification complements ISO/IEC 17021-1 (it should be considered in the same way as ISO/IEC 17021-XX and ISO/IEC 27006, ISO 50003 and ISO/TS 27006) and will contain applicable, normative, requirements for ISO/IEC 17021-1 accreditation for ISO 19443 quality management systems certification.

Certification bodies who may be considering extending their ISO/IEC 17021-1 accreditation to include this nuclear sector scheme should review the two **DRAFT** documents, once made available by ISO, along with ISO 19443 to ensure their competence definition is sufficiently detailed and that auditors/audit teams (and other personnel undertaking ISO 19443-related certification activities) have demonstrated the necessary competence to conduct effective audits of their clients, consistent with the scope of supply of products and services ITNS.

The draft documents will provide some detailed indications of the expectations of key stakeholders in the nuclear energy sector regarding the management systems and performance of the supply chain with regard to an effective quality management system and conduct of competent audits.

The guidance document, whilst not containing mandatory requirements or preferred methods, provides a description (examples) of the extent of some of the controls that are appropriate to achieve effective implementation of ISO 19443 requirements as applicable to the supply of ITNS items within the supply chain.

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Certification Body auditors will be expected to challenge a supplier's arrangements as presented, to confirm the arrangements achieve the necessary level of control as appropriate for the complexity of the supply contract they have within the supply chain. Certification Bodies (and their clients) should therefore ensure their appreciation of the guidance accordingly.

The detail in the examples may not be appropriate for those at the lower levels of the supply chain BUT the outputs achieved from a supplier's management system will need to be confirmed by auditors as *effectively implemented* for ISO 19443 compliance relevant to the scope of supply and the contracts obtained.

The guidance document provides a very good insight into what a supplier's understanding of nuclear safety should encapsulate and provide for. A Certification Body will need to consider how the audit team can effectively audit and confirm this.

ISO/IEC TS 23406

Certification Bodies attention is drawn to the specific competence criteria, qualification renewal, audit duration (increased time from IAF MD5 and no reductions allowed), and the **normative annexes** expanding on these elements.

Note A3 (2). Requires auditors to pass a written exam on completion of a 3-day (minimum) training course. This "*course is to be delivered by organisations recognised by the nuclear industry at National or International level*". UKAS is investigating how this arrangement will be enacted.

It is anticipated that the documents identified above will be completed mid-2019 and UKAS therefore envisages the commencement of a development project in Q3 (or possibly Q2 if a voting draft is issued) 2019. The development project will require CBs to have in train clients requiring audit for ISO 19443 certification and the audits will need to be full audits and NOT transition audits from existing ISO 9001 certification.

UKAS will continue to provide updates and will formally issue an expression of interest calling notice and details of the development project in due course.

If you have any queries regarding this technical bulletin, please contact the UKAS Technical Manager: Kevin Belson - kevin.belson@ukas.com.