IEC Quality Assessment System for Electronic Components (IECQ System)

Application of ISO 19443 for issuing IECQ products and services ITNS approved process certification
IECQ
OPERATIONAL DOCUMENT

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECQ operational document OD 19443 –

Application of ISO 19443 for issuing
IECQ products and services ITNS approved process certification

FOREWORD

This OD is the result of the April 2019 series of IECQ Singapore meetings and sets out the process for:

1) qualification of IECQ certification bodies (CBs) that wish to include ISO 19443 within their IECQ approved process (AP) scheme scope, and

2) procedures for processing applications and issuing certificates that include ISO 19443 within the scope of certification.

Document history

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INTRODUCTION

IECQ operational document OD 19443 details the application and use of the following international standard as part of the IECQ approved process (AP) scheme:

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

This OD covers the following:

- assessment and qualification of IECQ certification bodies (CBs) to issue IECQ certificates covering “certification of organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)” to organizations that have been successfully assessed to ISO 19443, according to the IECQ AP scheme requirements
- requirements of IECQ CB staff to conduct assessments and audits to ISO 19443
- the method and system of assessment including allocated assessment days
- other information to ensure the consistent application of ISO 19443 by IECQ CBs

IECQ CBs conducting assessments to ISO 19443 shall record findings using the standard IECQ site assessment report (e.g. SAR 19443) as listed for use by IECQ CBs located on the IECQ website, under “Standard Forms”.

Further information concerning these procedures or any other aspect of the IECQ ITNS approved process scheme or any other aspect of the IECQ System, may be obtained at [www.iecq.org](http://www.iecq.org).
1 Overview and background

The need for organizations to maintain specifications accepted by their customers when supplying component parts and services that are important to nuclear safety (ITNS) is evident. International Standard ISO 19443 sets out the management system framework as a tool to be used to monitor and control the supply chain.

The generic IECQ approved process (AP) scheme provides for the independent assessment and issuing of an international IECQ certificate of conformity for organizations that have demonstrated compliance with declared standards and/or specifications, for example IEC 61340-5-1 for the management of electrostatic discharge (ESD).

With the growing need for organizations to provide independent proof of compliance with ISO 19443 as organizations supplying products and services ITNS to the nuclear energy sector, member countries of the IECQ System have agreed to integrate ISO 19443 into their internationally standardized process certification scheme, noting the long established and successful IECQ schemes.

With the global nature of the nuclear industry supply chain, all stakeholders benefit from a single global approach to the assessment and certification of organizations to the International Standard ISO 19443.

Therefore the IECQ Management Committee has integrated ISO 19443 into its IECQ AP scheme.

IECQ independent third party products and services ITNS facility assessments, under the IECQ AP scheme ensures a focus on the key technical and administrative elements that provide confidence that the requirements of ISO 19443 have been met.

2 IECQ CB acceptance for IECQ product and services ITNS approved process certification

New certification bodies (CBs), not already participating in an IECQ scheme, are required to complete and submit form IECQ/MC/129G/Q to the IECQ secretariat and undergo the usual qualification and peer assessment required for all IECQ CBs according to IECQ 02.

IECQ CBs, already participating in any of the IECQ schemes that seek to extend their scope to issue IECQ products and services ITNS certification, shall apply to the IECQ secretariat using the IECQ CB scope extension application form IECQ/MC/130G/Q and provide sufficient documentation to demonstrate the following:

- IECQ CB procedures include the implementation of the requirements for the IECQ AP scheme and requirements within this OD
- IECQ CB procedures shall ensure the use of the IECQ site assessment report SAR 19443 for all assessments to ISO 19443
- IECQ CB procedures include the technical review of assessments and the issuing of IECQ certificates of conformity
• IECQ CB shall have clearly recorded their IECQ lead auditors qualified for product and services ITNS assessment work according to ISO 19443, including adequate evidence of training, qualifications, infield experience, etc, that address the requirements of ISO/IEC 17021-1 Annex A

• IECQ CB shall ensure the use of qualified IECQ ITNS auditors for all IECQ product and services ITNS assessments and how this is controlled

• IECQ CB statement of surveillance arrangements (SSA/NSSA) shall be updated to include the extension of scope to IECQ product and services ITNS according to ISO 19443 under the IECQ AP scheme

The IECQ Secretary shall carry out or arrange to have conducted a review of the submitted documentation and provide a report with recommendation to the IECQ Executive. Such recommendations may include:

a) recommend that scope extension to the IECQ CB is granted
b) recommend to grant scope extension on the basis that the next IECQ peer assessment is conducted within X months/years
c) recommend that a site assessment of the IECQ CB be conducted prior to acceptance
d) recommend that scope extension not be granted and that the scope extension application is placed on hold or withdrawn

The IECQ Secretary shall provide a cost estimate for this review and the IECQ CB shall indicate its acceptance of this cost estimate prior to commencement of the review of submitted documentation.

Where the IECQ Executive grant the scope extension this shall be endorsed at the next CABC meeting.

3 IECQ CB auditors

IECQ approved process audits that include ISO 19443 shall be conducted by IECQ CB audit teams led by auditors which have been qualified by their IECQ CB as successfully completing the necessary training and competence criteria set by the IECQ CB, in line with ISO/IEC 17021-1 and ISO/IEC 17021-3.

4 IECQ approved certification

For a current list of IECQ CBs approved to conduct and issue IECQ certification that include ISO 19443, please visit the IECQ website: www.iecq.org.

5 The assessment and certification process

The general requirements for the assessment and certification of IECQ approved process, detailed in IECQ 03-2 apply concerning IECQ certification that include products and services ITNS to ISO 19443, along with the following additional requirements:

a) that the IECQ CB audit and certification procedures are followed
b) while the IECQ CB may utilize external resources for part of the process, e.g. use of contract auditors, the IECQ CB to whom application is made shall maintain control and be responsible for the overall certification process including the final certification decision and on-going certification maintenance
Companies and organizations seeking IECQ certification that covers products and services ITNS are required to apply to an IECQ CB to arrange for the certification assessment/audit. The duration of the certification audit is based on the type, nature and number of products or services provided along with the number of employees at a given location. Typically, audits take up to two days but the following guide can be used as a basis to assess the optimum on-site audit time:

- 1-day auditor preparation (procedure review, process documentation and audit setup)
- On-site audit days
- Less than 50 people – ½ day to 1 day
- 51 to 200 people – 1 day to 2 days
- 201 to 2 000 people – 2 days to 3 days
- Greater than 2 000 people – to be determined as part of audit planning

At all times, it is the IECQ CB that is conducting the assessment/audit that determines the scope of the assessment/audit and required auditor days in consultation with the client.

A full certification audit is performed annually for each site that is to be covered by an IECQ approved process certificate that includes products and services ITNS.

For the purposes of the IECQ approved process certification audit that includes ISO 19443, a “site” can include multiple buildings located in close proximity to each other that are:

- part of the same line of business
- have a common management and management system

As part of the IECQ approved process site assessment that includes ISO 19443, an assessment report shall be issued for the initial certification assessment and each surveillance assessment. The IECQ secretariat maintains standard site assessment report (e.g. SAR 19443) forms covering initial assessments, surveillance assessments and re-assessments.

6 Certificate fees

IECQ certificate fees apply as follows: IECQ approved process company certificates, yearly (annual) fee CHF 100, paid to the IEC Central Office arranged by the IECQ CB. Multiple sites additional certificates and certificate surcharges shall apply in accordance with IECQ OD 011 Clause 4 and 5 respectively.

7 IECQ secretariat information

Further information concerning the IECQ products and services ITNS certification or any of the other IECQ certification schemes may be obtained by contacting the IECQ secretariat as follows:

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