IECQ OPERATIONAL DOCUMENT

IEC Quality Assessment System, IECQ

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

IEC Quality Assessment System, IECQ

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IEC QUALITY ASSESSMENT SYSTEM, IECQ

IECQ Operational Document 19443 –

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

FOREWORD

This publication has been prepared by the IECQ Management Committee (IECQ MC) of the IEC Quality Assessment System for Electronic Components (IECQ).

This publication is directly related to the IECQ System management Basic Rules contained in publications (IEC CA 01 + IECQ 01-S), IEC Harmonised Basic Rules (IEC CA 01) plus the IECQ Supplement (IECQ 01-S)

IECQ Operational Document IECQ OD 19443 has been prepared by IECQ working group WG11, of IECQ Management Committee (IECQ MC) 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.

This edition 2.2 is an administrative amendment to update the IECQ title. Edition 2.1 of IECQ OD 19443 replaces the 2.0 edition and is effective from its publication. This edition constitutes a technical revision.

This edition includes the following technical amendment with respect to the previous edition:

a) Include reference to ISO/TS 23406 within Clause 2,

b) Include reference to ISO/TS 23406 within Clause 5,

c) Add missing references to IECQ Rules and Rules of Procedure to ensure clarity of the intended requirements.

The text of this International Standard is based on the following documents:

<table>
<thead>
<tr>
<th>Document</th>
<th>Report on MC Consultation</th>
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<tr>
<td>IECQ WG11-015-CA</td>
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Full information on the report of IECQ MC approval of this publication can be found in the report indicated in the above table.
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.
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, ISO/TS 23406 and IECQ 03-2,
including adequate evidence of training, qualifications, infield experience, etc., that address the requirements of ISO/TS 23406 Annex A and 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 peer assessment, with the assistance of an IECQ Expert (Peer) Assessor approved by WG11, of the submitted documentation and provide a report with recommendation to the IECQ Executive. Such recommendations may include:

d) recommend that scope extension to the IECQ CB is granted
e) recommend granting scope extension on the basis that the next IECQ peer assessment is conducted within X months/years
f) recommend that a site assessment of the IECQ CB be conducted prior to acceptance
g) 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 according to IECQ 02 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, ISO/IEC 17021-3, ISO/TS 23406 and IECQ 03-2.

Note: further guidance may be given in various national or regional publications such as NQA-1.

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 along with the specific requirements of ISO/TS 23406 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. Determination of audit time for the IEC 19443 elements according to ISO/TS 23406.

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.

Multiple Site provisions of ISO/TS 23406 apply.

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.

Surveillance audits of IECQ IEC 19443 certifications shall be conducted in accordance with ISO/TS 23406.

6 Additional requirements

The IECQ certification Scheme allows for inclusion of requirements additional to those contained in ISO 19443, which may include requirements of a National, Regional nature or even customer specific requirements, e.g., those contained in NQA-1.

Where these additional requirements are included in the IECQ process, the reference to these additional requirements must be clearly stated in both the IECQ SAR 19443 checklist audit report and also listed on the IECQ Certificate.

7 Certificate fees

IECQ certificate fees apply as follows: IECQ approved process company certificates, yearly (annual) fee CHF 110, 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.

8 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:

IECQ Secretariat
info@iecq.org
www.iecq.org