IECQ OPERATIONAL DOCUMENT

IEC Quality Assessment System for Electronic Components (IECQ System)

Application of IEC 61340-5-1 for issuing IECQ ESD Approved Process Certification
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IEC Quality Assessment System for Electronic Components (IECQ Scheme)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECQ Operational Document 61340-5-1 –

Application of IEC 61340-5-1 for issuing IECQ ESD Approved Process Certification

FOREWORD


With on-going technical developments the issue of Electrostatic Discharge (ESD) continues to gain prominence in the supply chain management of equipment manufacturers. Such concerns include the verification of compliance of ESD control systems with expected industry practise, with Standards such as IEC 61340-5-1 serving as a minimum criteria.

Following discussions and requests from various industry experts, including those from IEC TC 101, the IECQ Management Committee, during its 2009 meeting agreed to include IEC 61340-5-1 as a specification falling under the IECQ “Approved Process Scheme” and provide for the issuing of IECQ ESD Approved Process Certificates.

To assist in ensuring a common approach by IECQ Certification Bodies (CBs), when processing applications for IECQ ESD Certification, this Operational Document was prepared with Edition 1.0 issued during 2009 along with a Standard IECQ Site Assessment Report Form (SAR 61340-5-1) to provide a consistent method and format for recording assessments to IEC 61340-5-1.

This new Edition 1.1 of OD 61340-5-1 has been prepared following feedback and discussions during the 2010 IECQ series of meetings held in Stevenson, WA, USA and replaces Edition 1.0 upon publication.

Document History

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| February 2009
April 2010  | Original issue Edition 1.1 – Arising from feedback and discussions from the 2010 IECQ meetings, with changes such as:
• updating to align with ISO 9001:2008
• clarification over ESD auditor training requirements
• clarification over requirements for existing IECQ CBs and new CBs joining IECQ for the first time
• other changes to ensure a consistent approach by all IECQ CBs |

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INTRODUCTION

This Operational Document (OD) details the application and use of the following IEC Standard as part of the IECQ Approved Process Scheme:

IEC 61340-5-1, Electrostatics – Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirements

This Operational Document covers the following:

- assessment and qualification of IECQ Certification Bodies (IECQ CBs) to issue IECQ ESD Certificates to organizations successfully being assessed to IEC 61340-5-1, according to the IECQ Approved Process Scheme requirements;
- the method and system of assessment including allocated assessment days;
- other information to ensure the consistent application of IEC 61340-5-1 by IECQ CBs.

IECQ CBs conducting assessments to IEC 61340-5-1 shall record findings using the standard IECQ Site Assessment Report (SAR 61340-5-1) 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 ESD Approved Process Scheme or any other aspect of the IECQ System, may be obtained at www.iecq.org.
Application of IEC 61340-5-1 for issuing
IECQ ESD Approved Process Certification

1 Overview and background

As semiconductor devices continue to become more sensitive to Electrostatic Discharge (ESD) it is important that companies handling these devices develop, implement and maintain effective ESD control programs in their facilities. IEC 61340-5-1 is the most recent and up to date International Standard on the market today for developing ESD control programs.

The electronics industry has requested that organizations, such as the IECQ, develop programs to certify facilities that handle unprotected ESD sensitive devices. IEC 61340-5-1 was written with compliance in mind. The IECQ ESD Approved Process Certification Scheme is also designed to work with a company’s existing quality management system.

While companies with electrostatic discharge requirements as part of their quality management system, may instil confidence in some areas, experience has shown that a specific and dedicated approach to the management and control of ESD is necessary. It is this necessity that led world experts to come together in IEC TC 101 to prepare and issue a dedicated International Standard IEC 61340-5-1.

With devices becoming more and more sensitive to ESD it is imperative that companies implement ESD programs that minimize the risk of ESD damage.

ESD facility assessments under the IECQ ESD Approved Process Scheme ensure a focus on the key technical and administrative elements that can be found in any “good” ESD control program including training, compliance verification and ESD control element selection and function. The IECQ ESD Approved Process Certification assessment also covers purchasing, calibration, non-conforming product, and documentation control as they relate specifically to ESD systems.

In addition, the audit requires that the company demonstrate to the auditor, through “on-site” sample measurements, that the ESD control elements used by the company meet the documented specifications.

2 IECQ CB Acceptance for IECQ ESD Approved Process Certification

For new Certification Bodies, not already participating in an IECQ Scheme, they are required to complete and submit form IECQ/MC/129A/Q to the IECQ Secretariat and undergo the usual assessment required of all IECQ CBs according to IECQ 02.

For Certification Bodies (CBs), already participating in any of the IECQ Schemes that seek to extend their scope to issue IECQ ESD Certification, they shall apply to the IECQ Secretariat using the IECQ Certification Body Scope Extension Application Form (IECQ/MC/130A/Q) and provide sufficient documentation to demonstrate the following:

- IECQ CB procedures include the implementation of the requirements for the IECQ Approved Process Scheme and requirements within this Operational Document;
- IECQ CB procedures shall ensure the use of the IECQ Site Assessment Report (SAR 61340-5-1) for all assessments to IEC 61340-5-1;
- 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 ESD assessment work, including adequate evidence of training, qualifications, infield experience, etc;

IECQ CB shall ensure the use of qualified ESD IECQ Auditors for all IECQ ESD assessments and how this is controlled;

IECQ CBs SSA/NSSA shall be updated to include the extension of scope to IECQ ESD under the IECQ Approved Process Scheme.

3 IECQ CB Assessors

IECQ ESD Approved Process audits to IEC 61340-5-1 shall be conducted by IECQ CB audit teams lead by auditors with ESD training and competence, working in accordance with the IECQ procedures of the approved IECQ Certification Bodies. There are three qualification scenarios for IECQ CBs to be approved to issue IECQ ESD Certification according to IEC 61340-5-1.

a) For existing IECQ Certification Bodies that have lead auditors certified by the ESD Association to the ANSI/ESD S20.20-2007 standard or able to demonstrate an equivalent level of training and competence. These auditors are required to demonstrate their knowledge and understanding of conducting ESD assessment and certification according to the IECQ System, including this OD and SAR 61340-5-1.

b) For existing IECQ Certification Bodies not meeting the requirements of item a) above each auditor would be required to undertake IECQ endorsed on-line training session.

c) New IECQ Certification Bodies, joining the IECQ initially for the purposes of IECQ ESD Certification would first have to meet the requirements for an IECQ CB according to IECQ 02. In addition, the training process as described in items a) and b) above apply.

Internet update training would be provided to “certified” auditors after any technical revisions of IEC 61340-5-1 which result in changes to the certification program.

4 IECQ ESD Approved Certification

For a current list of IECQ CBs approved to conduct and issue IECQ ESD Certification, 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 ESD Certification, along with the following additional requirements.

Companies seeking IECQ ESD Approved Process Certification to IEC 61340-5-1 shall either:

- be certified to ISO 9001:2008, TL 9000 or other approved quality management system, by an ISO 9001 Certification Body that has current accreditation by an accreditation body that is a member of IAF (International Accreditation Forum); or
- have their quality management system assessed by an IECQ CB for compliance with ISO 9001:2008.

Companies and organizations seeking IECQ ESD Certification are required to apply to an IECQ Certification Body to arrange for the certification assessment/audit. The duration of the certification audit is based on the number of employees at a given location. Typically, audits take up to two days but the following guide can be used to assess the optimum on-site audit time.
• ½ day auditor preparation (procedure review, process documentation and audit setup)
• On-site audit days
• Less than 100 people – ½ day to 1 day
• 100 to 2 000 people – 1 day to 1½ days
• Greater than 2 000 people – 1½ to 2 days
• ½ day report

A full certification audit is performed annually for each site that is to be covered by an IECQ ESD Approved Process Certificate.

For the purposes of the IECQ ESD Approved Process Certification audit, 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.

However, each building shall be visited by the IECQ CB Assessor.

As part of the IECQ ESD Approved Process site assessment, an assessment report shall be issued for the initial certification assessment and each surveillance assessment. The IECQ Secretariat maintain standard Site Assessment Report (SAR 61340-5-1) forms covering initial assessments, surveillance assessments and re-assessments.

6 Certificate fees

IECQ Certificate fees apply as follows: IECQ AP ESD Company Certificates, yearly (annual) fee CHF 100, paid to the IECQ Central Office arranged by the IECQ CB. Multiple sites additional certificates & certificate surcharges shall apply in accordance with IECQ OD 011 Clause 4 & 5 respectively.

7 IECQ Secretariat information

Further information concerning the IECQ ESD Certification or any of the other IECQ Certification Schemes may be obtained by contacting the IECQ Secretariat as follows:

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