



TECHNICAL REPORT

EIA-681™

Issued	1996-07
Reaffirmed	2001-05
Stabilized	2015-08

Assessment Guide for Process Certification

NOTICE

This document has been taken directly from the original TechAmerica document and contains only minor editorial and format changes required to bring it into conformance with the publishing requirements of SAE Technical Standards. The release of this document is intended to replace the original with the SAE International document. Any numbers established by the original document remain unchanged.

The original document was adopted as an SAE publication under the provisions of the SAE Technical Standards Board (TSB) Rules and Regulations (TSB 001) pertaining to accelerated adoption of specifications and standards. TSB rules provide for (a) the publication of portions of unrevised specifications and standards without consensus voting at the SAE committee level, and (b) the use of the existing specification or standard format.

SAE Technical Standards Board Rules provide that: "This report is published by SAE to advance the state of technical and engineering sciences. The use of this report is entirely voluntary, and its applicability and suitability for any particular use, including any patent infringement arising therefrom, is the sole responsibility of the user."

SAE reviews each technical report at least every five years at which time it may be revised, reaffirmed, stabilized, or cancelled. SAE invites your written comments and suggestions.

Copyright © 2015 SAE International

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of SAE.

TO PLACE A DOCUMENT ORDER: Tel: 877-606-7323 (inside USA and Canada)
Tel: +1 724-776-4970 (outside USA)
Fax: 724-776-0790
Email: CustomerService@sae.org
<http://www.sae.org>

SAE WEB ADDRESS:

Full document details: SAE EIA681

SAE values your input. To provide feedback on this Technical Report, please visit <http://www.sae.org/technical/standards/EIA681>

Documents

Document Sharing Hub

EIA STANDARD

Assessment Guide for Process Certification

EIA-681

JULY 1996

(Reaffirmed May 2001)

ELECTRONIC INDUSTRIES ALLIANCE

**GOVERNMENT ELECTRONICS AND
INFORMATION TECHNOLOGY ASSOCIATION**



A SECTOR OF



NOTICE

EIA Engineering Standards and Publications are designed to serve the public interest through eliminating misunderstandings between manufacturers and purchasers, facilitating interchangeability and improvement of products, and assisting the purchaser in selecting and obtaining with minimum delay the proper product for his particular need. Existence of such Standards and Publications shall not in any respect preclude any member or nonmember of EIA from manufacturing or selling products not conforming to such Standards and Publications, nor shall the existence of such Standards and Publications preclude their voluntary use by those other than EIA members, whether the standard is to be used either domestically or internationally.

Standards and Publications are adopted by EIA in accordance with the American National Standards Institute (ANSI) patent policy. By such action, EIA does not assume any liability to any patent owner, nor does it assume any obligation whatever to parties adopting the Standard or Publication.

This EIA Standard is considered to have International Standardization implication, but the International Electrotechnical Commission activity has not progressed to the point where a valid comparison between the EIA Standard and the IEC document can be made.

This Standard does not purport to address all safety problems associated with its use or all applicable regulatory requirements. It is the responsibility of the user of this Standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations before its use.

(From Project Number 4967, formulated under the cognizance of the Quality and Reliability Engineering Standards (QRE) Committee.)

(This document was reaffirmed by the EIA in May 2001)

Published by

©ELECTRONIC INDUSTRIES ALLIANCE 1996
Technology Strategy & Standards Department
2500 Wilson Boulevard
Arlington, VA 22201

PRICE: Please refer to the current
Catalog of EIA Electronic Industries Alliance Standards and Engineering Publications
or call Global Engineering Documents, USA and Canada (1-800-854-7179)
International (303-397-7956)

All rights reserved
Printed in U.S.A.

PLEASE!

**DON'T VIOLATE
THE
LAW!**

This document is copyrighted by the EIA and may not be reproduced without permission.

Organizations may obtain permission to reproduce a limited number of copies through entering into a license agreement. For information, contact:

Global Engineering Documents
15 Inverness Way East
Englewood, CO 80112-5704 or call
U.S.A. and Canada 1-800-854-7179, International (303) 397-7956

Assessment Guide for Process Certification

Table of Contents

1. FOREWORD	1
2. INTRODUCTION	2
3. PURPOSE	2
4. SCOPE	2
5. REFERENCE DOCUMENTS	3
6. DEFINITIONS	3
7. ASSESSMENT OBJECTIVES	5
8. ASSESSMENT SCHEMES	6
8.1. First Party Assessment	6
8.1.1. Pre-Assessment Review	7
8.1.2. Performing an Assessment	7
8.1.3. Process Validation	7
8.1.4. Qualification	8
8.1.5. Approval	8
8.2. Second Party Assessment	8
8.3. Third Party Assessment	8
8.3.1. Independent Registrar	8
8.3.2. Manufacturing Line Approval	10
8.3.3. Technology Approval	11
9. AUDITING	12
9.1. Roles and Responsibilities	12
9.1.1. Auditors	12
9.2. Audit Procedure	14
9.2.1. Initiating the Audit	14
9.2.2. Preparing the Audit	16
9.2.3. Executing the Audit	17
9.2.4. Corrective Action follow-up	19

10. QUALITY SYSTEM MATURITY ASSESSMENT	19
11. VALIDATION	20
11.1. Process Certification	20
11.2. Administration	21
11.3. Design	21
11.4. Manufacturing	21
12. QUALIFICATION OF PRODUCTS	22
13. CERTIFICATION	23
14. MAINTENANCE	23
14.1. Change Notification	23
14.2. Decertification	24

Assessment Guide for Process Certification

1. Foreword

The widespread use of the ISO 9000 series of standards demonstrates that the industry has recognized the need for a comprehensive set of requirements that provides a model for evaluating a producer's Quality System. Many companies around the world have used these standards as a means for evaluating their own quality systems development and have made improvements by correcting deficiencies found during their own assessment process. At the same time, many companies' supplier management programs have incorporated the requirement for ISO 9000 compliance by suppliers in lieu of using their own set of quality systems requirements.

A major driving force in the rapid growth in the use of the standards has been the acceptance, by OEMs, of ISO 9000 registration by an independent accredited registrar instead of conducting their own audits. Some companies consider registration of their suppliers a requirement for doing business. Producers gain a third-party certification and subsequent registration by making an arrangement to be audited by an independent registrar. The registrar grants certification and lists the company in its register of companies with certified quality systems when their quality systems documentation and implementation meet the requirements of the applicable ISO 9000 standard.

Although widespread use of third party certifications of the quality systems has been achieved, many companies have supplemented them with a second-party (purchaser) assessment that has requirements that go beyond the requirements of the ISO 9000 series of standards. Certain market-segment certification schemes, such as in the automotive industry, have added requirements which are considered necessary to satisfy their particular quality verification needs. These ISO-9000 "plus" systems generally focus on adding continuous improvement and customer satisfaction with the supplied product or service.

Recently, the concept of allowing a "certified" company to qualify an entire process rather than individual parts has been introduced and has achieved growing success. Based on this concept, the Electronics Industries Association (EIA) in the United States produced a generic standard on Process Certification that combined the ISO9000 "plus" principles with a process validation requirement for product qualification. The National Electronic Process Certification Standard, EIA-599, was produced in August 1992 and has been recognized as a comprehensive and non-prescriptive set of requirements that, when achieved, results in a producer that consistently provides a product or service that meets or exceeds the purchaser's requirements.

The principles of EIA-599 have been introduced into international assessment schemes for Manufacturing Line Approval under the IEC and Technology Approval under CECC and IECQ. EIA-599, like ISO 9000, provides only the model for process certification and other alternative schemes may be used to achieve it.

It has long been recognized that most companies go through a maturity process of continuous improvement. Many companies start out with a basic means of process control and produce good products. Because of market pressures, a competitive company must introduce ways of reducing cost, and reliability risk to their customers. Previous qualification systems have failed to take into account this natural maturity progression. As outlined in this guide, a producer adhering to the principles of Process Certification (EIA-599) should receive less external auditing and rely more and more on internal audits and controls as the company follows their maturity progression. The trade offs between maturity level and audit frequency will be discussed in more detail in Section 10 and in Annex A.

2. Introduction

The focus of process certification is on the collection of processes that combine to produce products and services to the customer's satisfaction. This guide has been developed for use in a variety of assessment schemes to evaluate a producer's compliance to the requirements of Process Certification. A common thread used in all of these schemes is the emphasis on the use of the EIA-599 requirements for validation and qualification to confirm and demonstrate that the total system produces the expected results. The goal of this assessment guide is to provide a consistent method for first, second, and third party assessments of a producer's facility.

The approach used throughout this guide is that the producer's own systems be used to demonstrate, with objective evidence, that the intent and purpose of the particular requirement under evaluation has been satisfied. Variation in implementation and technique from producer to producer is acceptable. The elements of this guideline are based on the use of a non-prescriptive approach.

In addition to providing a method for assessing compliance, an option is presented for judging the level of maturity in quality systems development. This is aided by the use of a Quality System Maturity Matrix described in Annex A. Annex B provides flowcharts of the various assessment schemes that are used. A generic checklist for use by either internal or external auditors is provided in Annex C. Annex D provides an example of a checklist for combining an ISO 9001 audit with Process Certification in a specific technology.

Since compliance to the ISO 9000 series standards is required in EIA-599, it is intended that this Assessment Guide be consistent with the applicable ISO Standards.

3. Purpose

It is the purpose of this document to provide guidance for companies and registrars to achieve a consistent assessment of a producers compliance to the requirements of Process Certification (EIA-599). In addition, a technique is provided as an option for the assessment of a producer's level of quality system maturity.

4. Scope

This Assessment Guide is applicable to any assessment technique that wishes to embrace the principles and concepts presented in the EIA-599 National Electronic Process Certification Standard.

5. Reference Documents

ANSI/EIA-599 National Electronic Process Certification Standard

ISO-9001 Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation and Servicing

ISO-9002 Quality Systems- Model for Quality Assurance in Production and Installation

ISO-9004 Quality Management and Quality System Elements-Guidelines

ISO 10011-1 Guidelines for Auditing Quality Systems - Part 1: Auditing

ISO 10011-2 Guidelines for Auditing Quality Systems- Part 2: Qualification criteria for quality systems auditors

ISO 10011-3 Guidelines for Auditing Quality Systems- Part 3: Management of audit programs

ISO-8402 Quality Management and Quality Assurance- Vocabulary

IECQ Rules of Procedure QC 001 002-3 Clause 2 (Organization Approval) and Clause 6 (Technology Approval)

JESD39-A Quality System Assessment

NIST Malcolm Baldrige National Quality Award Criteria

IEC 1739 Integrated Circuits -Procedures for Manufacturing Line Approval and Quality Management

6. Definitions

Assessment

A systematic examination of the extent to which an entity is capable of fulfilling specified requirements

Audit

A systematic and independent assessment to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Auditee

An organization being audited.

Auditor

A person qualified to perform quality audits.

Audit Observation

A statement of fact made during quality audit and substantiated by objective evidence.

Certified Process

A process that, through demonstration and validation, has been determined to produce product capable of consistently achieving or exceeding customer requirements.

Client

A person or organization requesting the audit

Customer

The recipient of a product provided by the supplier.

Objective Evidence

Information which can be proved true, based on facts obtained through observation, measurement, test or other means.

Procedure

A specified way to perform an activity

Producer

The organization that provides a product to the customer

Product

The result of activities or processes

Process

A set of interrelated resources and activities which transform inputs into outputs.

Process Characterization

The determining of relationships between process parameters and process outputs or product characteristics.

Qualification Process

The process of demonstrating whether an entity is capable of fulfilling specified requirements.

Quality Evaluation

A systematic examination of the extent to which an entity is capable of fulfilling specified requirements.

Quality Management

All activities of the overall management function that determine the Quality Policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement, within the quality system.

Quality System

The organizational structure, responsibilities, procedures, processes, and resources needed to implement quality management.

Service

The results generated by activities at the interface between the supplier and the customer and by supplier internal activities, to meet the customer needs.

Total Quality Management

A management approach of an organization, centered on quality, based on the participation of all its members and aiming at long term success through customer satisfaction, and benefits to the members of the organization and to society.

TQM Plan

A description of the quality management system.

Note: Documentation of this description may take different forms and may be called the Quality Manual or imbedded in the producer's operations procedures. It is not the intent of this document to dictate specific terminology. However, the terminology of referenced standards will be followed to the extent possible.

TRB or equivalent organization

The Technical (Technology) Review Board is the management structure responsible for the process under review. A TRB shall consist of representatives of all functions described in the TQM Plan, such as marketing, sales, design, technology development, fabrication, testing and quality assurance as applicable.

Validation

Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Validator

A person certified to perform process validations

Verification

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

7. Assessment Objectives

The assessment objectives for process certification should be established in the beginning of the assessment process. An assessment is generally designed for one or more of the following purposes:

- to determine the compliance of the system elements with the specified requirements
- to determine the effectiveness of the implemented system in meeting the specified requirements.
- to provide the assessed producer with the opportunity to improve their quality system.
- to permit the listing of the assessed producer's facility and/or assessed process in a register.
- to verify that the system continues to meet specified requirements and is being effectively implemented.

8. Assessment Schemes

Several international, national, and domestic assessment methodologies have been developed recently that are based on the common principles and concepts of process certification. While any particular system would be certifiable under any of these schemes, the rules and procedures for a formal assessment will vary from one scheme to another. These schemes are outlined in this Section and flow charted in Annex B of this document. The generic procedures for accomplishing Process Certification for First, Second, and Third party assessments are provided as they relate to their use of the principles and concepts of Process Certification.

8.1. First Party Assessment

A producer's journey through the quality progression starts with an internal objective evaluation of the company's compliance with the Quality Standard being used. A maturity level evaluation may also be done at the same time. It is best practice that the manufacturer set up a system that works in the company culture. Externally forced quality systems seldom are accepted by employees and usually result in decreased productivity.

A first party (self) assessment may be conducted using the same tools and techniques as the second and third party assessors use when conducting a process certification. However in this case, it is up to the producer to provide the audit team.

It is recommended that the overall management of the certification process and on-going maintenance be carried out by a designated Technology Review Board (TRB) or some equivalent organization. (EIA-599, section 5.1).

It is recommended that the process certification use cross-functional teams to carry out the audit and have the overall management of the process be done by the designated TRB or equivalent organization.

It is recommended that the audit team follow the same guidelines that the customer would follow when certifying the process.

The assessment team would then conduct a process audit following the applicable audit procedures of Section 9. The checklist of Annex C can be used as a tool to guide the auditors.

After successful completion of the audit, the audit team then performs the validation procedure of Section 11 and reviews the results of qualification, Section 12.

The assessment team should present a statement of compliance to the TRB or equivalent organization. It is recommended that the ongoing internal qualification of product and process change management be conducted under the requirements of process certification and managed by the TRB or equivalent organization to ensure processes that consistently provide a product that meets or exceeds the customer's requirements.

8.1.1. Pre-Assessment Review

Pre-Assessment Review is the first critical phase of the audit. It gives the initial information necessary to decide whether to commit time and resources in an audit of the specific producer.

In the pre-assessment review, one or more of the following types of information may be used:

- a description of the producer's quality management system (e.g. Quality Manual) and supporting documentation.
- a description of the process flow (e.g. flow chart) that may include design, development, manufacture, test, and shipment (i.e. the entire process flow).
- a description of key process control points and controls (e.g. process control plan) validation plan (Section 11.) qualification plan (Section 14.)

After a successful review and coordination, an on site audit and validation may be scheduled.

8.1.2. Performing an Assessment

Audits are conducted to give an independent assessment of the producer's capability to meet the needs of the customer. If the customer has unique requirements, then it is usually necessary to validate that the producer has control over those specific processes that are related to the needs of the customer. If the producer has been audited by a third party, then only those additional requirements need be addressed.

The quality management system, facility, and processes are evaluated during the audit. Generally the audit team uses a checklist to ensure that producer is in compliance with the requirements. A typical audit checklist for process certification is provided in Annex C. If the producer already has ISO 9000 certification, it may not be necessary to repeat the ISO 9000 part of the audit. It is recommended that Section 9 of this guide be followed as applicable to assure a consistent audit process.

8.1.3. Process Validation

A Process Validation is the confirmation that the selected process requirements have been satisfied and that the total system works effectively. A second and important feature of the validation is that it can provide structured communications channels so that the customer's needs and the capability of the process are matched more closely.

It is recommended that the guidelines of Section 11 be followed by the assessment team and producer when conducting the validation.

8.1.4. Qualification

Qualification of the process requires data that demonstrates that the total system (management, tools, and technology) is capable of delivering high quality products from that process. Qualification is the formal procedure used to generate the data that demonstrates that the process is capable of fulfilling specified customer requirements. The qualification procedures should be developed from the producer's intimate knowledge of the process and clearly show that the product meets the customers expectations. It is recommended that the guidelines of Section 12 be followed during the qualification procedure.

8.1.5. Approval

Upon successful completion of the audit, validation, and qualification, the assessment body (TRB in the First Party scheme) should then make a judgment, based upon the data presented, about the producer's compliance with the process certification requirements and make the appropriate approvals for shipment of product from the certified process. The formal recognition is usually in the form of a certified source certificate issued by the assessment team.

8.2. Second Party Assessment

A second party (customer) assessment is used, by the customer, to determine if a supplier's quality system and processes are in compliance with the requirements of process certification. Annex B shows a typical certification flow chart for a second party assessment. The certification methodology is the same as described in Section 8.1 with the exception that the customer, rather than the TRB, provides the assessment team and the final certification approvals.

8.3. Third Party Assessment

This section presents several third party assessment schemes to accomplish process certification but does not preclude the use of others that may be developed if the principles of EIA-599 are followed.

8.3.1. Independent Registrar

The use of an independent registrar may be selected in lieu of the assessment schemes presented in earlier sections of this guide. In this case, it is recommended that the client select a registrar that has implemented rules of procedure and codes of practice that are complementary to the international schemes to further standardization and customer acceptance of process certification. A generic procedure and list of practices for registrars conducting process certifications are presented in the following paragraphs of this section.

8.3.1.1. Procedure

The client arranges for the certification by submitting an application to the selected registrar. An agreement on the scope and objectives is made and documented.

A documentation review prior to the on-site audit is conducted to determine whether the requirements of process certification can be achieved. As a minimum, the review should include the following documents:

- a) Description of the process to be certified (including control plan for critical process parameters).
- b) Summary statement of TQM policy
- c) Organization chart which includes the organization responsible for managing the certified process (Technology Review Board or equivalent)
- d) Description of the quality management system (e.g. Quality Manual)
- e) Certificate from an accredited registrar that attests to the compliance with the appropriate ISO 9000 standard or a statement of compliance (self declaration)
- f) Qualification plan for approval

After a successful documentation review, an on-site audit is conducted to audit the process and review the process capability demonstration. See Section 9 and 11 of this document for the general audit procedures and the validation procedure.

Following the successful execution of the Qualification plan by the auditee, the test report is sent to the registrar for review and approval (Section 12).

A certificate of approval is issued by the registrar upon successful completion of on-site audit and acceptance of the qualification tests. Issuing of the certificate implies that the process has been certified and may be listed along with any associated techniques or products in the register.

8.3.1.2. Recommendations

Since compliance to the requirements of the appropriate ISO 9000 standard is a requirement of process certification, it is recommended that the registrar be accredited by an ISO recognized accrediting body.

The audits should be carried out by experts experienced in the applicable audit procedures and having technical expertise in the technology undergoing the process certification.

The audits should be conducted in compliance with the ISO 10011 standards on quality system audits.

The auditing body should have means for protecting the confidential and proprietary information of both the client and the producer.

8.3.2. Manufacturing Line Approval

The following is the proposed Manufacturing Line Approval assessment scheme for semiconductors under the IECQ system. The requirements are provided in IEC STD 1739. The assessment scheme provides for the initial approval, ongoing maintenance of the approval, reassessment as necessary, and registration in a Qualified Manufacturer List (QML). A flow chart of the Manufacturing Line Approval Procedure is provided in Annex B.

To achieve and maintain Manufacturing Line Approval, the following must be satisfied:

- a) a certification according to ISO 9000, or equivalent, as appropriate to the activities of the organization.
- b) approval of the manufacturing line
 - validation
 - qualification
- c) release of qualified products
- d) continuation and retention of approval

A Technology Review Board (TRB) or equivalent organization is the primary organization for the control of a technology within a qualified manufacturing line or task. The TRB is responsible for development of a TQM plan, review and maintenance of all qualified processes, process change control, reliability data analysis, failure analysis, corrective actions, recall procedures, rework or reprocessing rules and qualification status of the technology. Each of the

Manufacturing Line Approval elements shall be operated under the producer's quality management system.

A documentation audit by the National Supervising Inspectorate is performed to verify the TRB structure, the TQM plan and the process capability of the manufacturer.

The manufacturing line is audited by the NSI to assess compliance with the requirements of the manufacturer's internal documentation and the systems and plans declared for Manufacturing Line Approval.

A certificate of approval is issued upon successful completion of all qualification tests and acceptance of the qualification documentation by the NSI. Generally, issuing of the certificate of approval leads to:

- listing on the QML register, listing of the approved manufacturing lines with associated techniques.
- a list of corresponding qualified products to be maintained by the manufacturer and made available to the NSI.

8.3.3. Technology Approval

Technology Approval is a method of approving a complete technological process (design , process realization, product manufacture, test and shipment) covering the qualification aspects common to all products as determined by the technology under consideration.

The procedures for Technology Approval of Electronic Component Manufacturers are prescribed in detail in the International (IECQ) system Rules of Procedure . A flow chart of the system is provided in Annex B.

Before a manufacturer is permitted to release products under Technology Approval, it is necessary that all relevant aspects of the manufacturing facility meet the requirements of the system (e.g., ISO 9000 registration). In particular, the manufacturer shall prepare a Technology Approval Declaration Document (TADD) covering his technology. The TADD shall relate to the entire scope of the proposed Technology Approval and be fully maintained during the life of the approval.

The manufacturer applies in writing to the body designated in the rules stating the scope of the proposed Technology Approval , as defined in the appropriate Technology Approval Schedule (TAS) , and clearly defines the activities and technologies for which approval is sought. The manufacturer also provides a statement of his corporate management's commitment to continuous quality improvement and customer satisfaction.

In addition to the Quality Manual, the manufacturer provides definition of the operational infrastructure (if not already contained in the quality manual) which includes a declared management structure for managing the Technology Approval and ensuring the conduct of periodic system reviews.

After submission of the TADD and implementation program to the National Supervising Inspectorate , a statement of readiness in respect to the requirements of Technology Approval is submitted when the manufacturer is satisfied that these requirements have been met and can be demonstrated , as indicated by his own internal audit. The manufacturer accepts the right of the Inspectorate to audit and verify any claims made in the statement of readiness.

The Inspectorate audits the manufacturer's implementation of the TADD and, following a satisfactory assessment, the manufacturer proposes a list of products he intends to release under Technology Approval. The Inspectorate then proposes to the authority designated in the System's rules that a Technology Approval Certificate be issued. Technology Approval is granted when all of the requirements have been met and a certificate is issued to the manufacturer by the responsible national authority.

9. Auditing

9.1. Roles and Responsibilities

The roles and responsibilities of the auditors and the auditee involved in the assessment are outlined in ISO 10011-1, Guidelines for auditing quality systems-Part 1. In this section, the guidelines are repeated and augmented (shown in *italics*) as needed for a process certification assessment.

9.1.1. Auditors

9.1.1.1. Audit team

Whether an audit is carried out by a team or an individual, a lead auditor should be placed in overall charge.

It is strongly recommended that the team include experts with specialized background in the technology and processes included in the scope of the audit.

Auditor trainees and observers may be included on the audit team with agreement by the client, auditee, and the lead auditor.