

JEDEC STANDARD

QUALITY SYSTEM ASSESSMENT

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JEDEC SOLID STATE TECHNOLOGY ASSOCIATION



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Foreword

This document is based on the quality management system requirements of the international standard ISO 9001:2008 (also documented as the US national standard ANSI / ISO / ASQ Q9001-2008). It contains an audit checklist that is expected to be beneficial for organizations looking for a guideline to help with self-assessments and an understanding of their compliance to the requirements of ISO 9001:2008. This checklist is intended to support the evaluation of quality management systems, but is not sufficient by itself to guarantee full compliance to the requirements of ISO9001:2008.

Introduction

This standard contains a set of questions that can be used to evaluate a quality management system to the requirements of ISO 9001:2008. Each of the questions in this checklist is referenced to the applicable clause in the ISO document. In addition, the section headings in the evaluation matrix match the clause titles in the ISO 9001:2008 standard.

This standard should be used with some amount of common sense. Utilizing checklists for the purpose of auditing can result in too much focus on the checklist at the expense of overlooking important items. It is expected that users of this document will add their own experience and knowledge to the audit process, which may lead to questions or areas of inquiry that diverge from the checklist in this standard.

QUALITY SYSTEM ASSESSMENT

(From JEDEC Board Ballot JCB-13-31, formulated under the cognizance of the JC-14.4 Subcommittee on Quality Processes and Methods.)

1 Scope

This checklist is intended as a tool to allow users to assess the level of compliance of a quality management system to the requirements ISO 9001:2008. The questions in this checklist are of a generic nature and intended to be applicable to all organizations, not just those involved in the electronics industry. It can be useful while performing self-assessments of the organization or other internal audit procedures. It is not intended for use by a contracted third party registrar during a formal audit to the requirements of ISO 9001:2008.

2 Normative Reference

ISO 9001:2008, *Quality Management Systems – Requirements*

ISO 9000:2005, *Quality Management Systems – Fundamentals and Vocabulary*

ANSI/ISO/ASQ Q9001-2008, *Quality Management Systems – Requirements*

3 Terms and Definitions

Organization: A group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Management System: A set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives.

Quality Management System: A management system to direct and control an organization with regard to quality.

Process: A set of interrelated or interacting activities which transforms inputs into outputs.

4 General Requirements

This checklist is provided in tabular format. A space is provided after each question to record the results of the evaluation and any applicable comments. The method of recording the results is a matter of preference and may be different for different users. The following is an example of how the results may be recorded:

Compliant (C)	Fully meets all requirements.
Observation (O)	Minor discrepancy noted, not expected to result in substandard product or service quality.
Discrepant (D)	Non-compliant to requirements, expected to result in substandard product or service quality.
Not Applicable (NA)	Not a part of the organization's quality management system.
Not Observed (NO)	This item was not observed during the evaluation.

The results of the evaluation may be recorded in any other format that provides meaningful information to the checklist user.

ISO Clause	Question	Result	Comments
4	Quality Management System		
4.1	General Requirements		
	Has a quality management system been established?		
	Is the quality management system been documented, implemented and maintained?		
	Is the effectiveness of the quality management system improved over time?		
	Have the various processes necessary for implementation of the quality management system, including any that may be outsourced to an external organization, been identified?		
	a) Do these processes include those that are associated with management activities, provision of resources, product realization, measurement, analysis and improvement?		
	b) Has the deployment of these processes throughout the organization been determined?		
	c) Is the sequence of these processes and the interaction between them defined?		
	d) Are criteria and methods necessary to ensure effectiveness of both the operation and control of these processes defined?		
	e) Are the resources and information necessary for effective operation and monitoring of these processes available?		
	f) Are these processes monitored, measured and, where applicable, analyzed?		
	g) Are actions necessary to achieve planned results and continual improvement of these processes implemented and monitored?		
	Are outsourced processes that affect conformance of product to requirements identified and controlled?		
	Is the type and extent of control applied to these outsourced processes:		
	a) Defined within the quality management system?		
	b) Influenced by the potential impact of the outsourced process on the capability to provide product that conforms to requirements?		
	c) Influenced by the degree to which the control for the process is shared?		
	d) Influenced by the capability of achieving the necessary control through the application of purchasing processes?		