

QS-9000 Update Third Edition

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Agenda- QS-9000 Changes

- Overview of the major changes to QS-900 as released in the 1998 Third Edition
- Section by section analysis

Overview

- The Third Edition released April 15, 1998; suppliers mandated to implement by Jan 1, 1999
- Requirement section has expanded from 56 to 59 pages
- The standard has been reduced from three sections to two sections

Areas Where Major Changes Have Occurred Which Need Emphasis

- 4.2 Quality Systems - added all of old Section II here
- 4.9.2 & 3 Process Control re-defined capability requirements
- 4.10.6 - added laboratory requirements
- 4.11.2.b.1 - added qualifications for calibration services

Vocabulary/Abbreviations

- ISO Guide 25 - (G25) This symbol will be used when the requirement has been taken from this laboratory standard
- IASG - When a sanctioned interpretations has been incorporated into the new standard. (IASG) will be placed in the text .
- New additions - (98) will be placed in the text when the requirement is new

What Happened To Section II Of The Old Standard?

- PPAP has been added to 4.2, Quality Systems (4.2.4)
- Continuous improvement has been added to 4.2.5
- Manufacturing capabilities has been added to 4.2.3.6, 4.2.6 & 4.7.1

Introduction

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- Re-defined **should** as a flexible **shall**
- Defined the words **typical** and **examples**
- Noted supplements to QS (i.e. TE)
- Added new diagram on document relationships;
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4.1 Management Responsibility

- 4.1.2 Organization - added note f), requiring customer to be represented internally (98)
- 4.1.3 Management Review - must include review of all sections of standard (IASG)
- 4.1.4 Development of goals and plans based on a defined method (98)
- 4.1.4 Business plan is a controlled document (IASG)

4.1 Management Responsibility

- 4.1.6 - Notification of registration body when supplier on a quality status by Big Three. (98)

4.2 Quality Systems

- 4.2.3.2 Defined addition of special characteristic (98)
- 4.2.3.4 Added product safety (98)
- 4.2.3.6 Mistake-proofing (from old Section II)
- 4.2.4 PPAP (from old Section II)
- 4.2.5 Continuous Improvement (from old Sect II)
- 4.2.6 Facility and Tooling Management (from old Section II)

4.3 Contract Review

- Added two notes; very minor change

4.4 Design Control

- Added note at top of page to define responsible organization
- 4.4.1.1 added statement about deploying knowledge from previous projects (98)
- 4.4.8.1 added statement on coordinating validation with customer (98)
- 4.4.9.2 Shall consider impact of design change (98)
- 4.4.11 Insure confidentiality of new design info (98)

4.5 Document and Data Control

- 4.5.2.1 added note to check impact of a new spec; possible PPAP impact;, very minor change to this section (98)

4.6 Purchasing

- 4.6.1.1 & 2 Expanded note on customer approved supplier
- 4.6.1.2 government safety and environment changed statement slightly from second edition (98)
- 4.6.2.1 Clarified/added a little to subcontractor development (98)

4.7 Customer Supplied Product

- 4.7.1 Added customer owned tooling must be permanently marked (former old section II 3.4)

4.8 Product Identification and Traceability

- Added note saying “where appropriate in the ISO portion is not applicable.” (98). The section for QS now reads “the supplier shall have documented procedures”

4.9 Process Capability

- 4.9.b.1 Added requirement on cleanliness of premises (98) (note the working environment portion of internal auditing was deleted)
- 4.9.b.2 Added requirement on contingency plan in case of major production interruption by supplier (98)
- 4.9.d.1 Added further definition of special characteristic and control
- 4.9.g.1 Added two more requirements to preventive maintenance; packaging tooling and improvement goals(98)

4.9 Process Control (continued)

- 4.9.1 Added note on job instructions available at the work station (IASG)
- 4.9.2 MAJOR CHANGE on how process capability and SPC is handled (98)
- 4.9.3 Control requirements different from those in 4.9.2 shall be documented on the control plan (98)
- 4.9.4 slight change of wording on job setups (98)

4.10 Inspection and Test

- 4.10.2 Incoming product quality - redefined to 4 methods (98)
- 4.10.4.2 Added requirement of a packaged final product audit (98)
- Deleted use of certification as a method of incoming inspection (98)
- 4.10.6 MAJOR CHANGE added a section on supplier laboratory (G25)
- 4.10.7 Added statement on accredited laboratories (IASG)

4.11 Inspection Measuring and Test Equipment

- 4.11.1 Added note on the use of ISO 1012-1:1992
- 4.11.2b **Added note about including the tooling department in the scope (IASG)**
- 4.11.2.b.1 Added section on qualified calibration services (G25)
- 4.11.2d Added note clarifying ISO 9001 calibration status indicators, the records of calibration meet this requirement

4.12 Inspection and Test Status

- Added note clarifying that **location of product** is **not** an **acceptable** indicator of inspection status (IASG)

4.13 Control of Nonconforming Product

- 4.13.1.2 Added statement requiring a visual identification requirement

4.14 Corrective and Preventive Actions

- 4.14.1.2 Added use of mistake-proofing methodology as appropriate (98)
- 4.14.2.2 If corrective action is taken on one product, the impact must be reviewed on similar processes (98)

4.15 Handling, Storage, Packaging, Preservation and Delivery

- 4.15.6.2 Production scheduling; a note was added on **use of forecasts** (IASG)
- 4.15.6.3 Electronic communications - supplier must be able to receive customer schedules electronically (98)

4.16 Control of Quality Records

- 4.16.1 Added note specifying which records must be included for maintenance on the life of the part (98)
- 4.16.1 Re-stated the “minimum” retention period
- Deleted statement about superseded records which are to be included in PPAP when changes occur (98)

4.17 Internal Quality Audits

- 4.17 Added note - no specified checklists required (98)
- 4.17.1 Added statement about schedule and increasing frequency when a customer complaint occurs (98)
- Deleted statement about including working environment (98)

4.18 Training

- 4.18.1 Added note to clarify what training effectiveness could be (98)
- Deleted statement requiring training to be considered a strategic element

4.19 Servicing

- Added two notes to clarify servicing

4.20 Statistical Techniques

- Re-numbered sections but the content is unchanged

II:Customer Specific - Chrysler

- Require all suppliers to be third-party registered
- Added product creation process and PAP
- Changed language of significant characteristics, annual layout & added appearance masters
- Added Process Signoff Process (PSO) and tied it to PPAP
- Added statement on control plans, also “forever requirement -extended enterprise
- Added electronic communication requirement
- Deleted sampling table and product

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II. Customer Specific - Ford

- Added annual layout requirement
- Deleted SDS initiative, and on-going process monitoring
- Deleted qualification and acceptance criteria
- Added APQP status reports and run-at-rate
- Deleted lab qualification requirements, as not applicable to Ford, Sections 4.10 & 4.11

II. Customer Specific - GM

- Added two requirements for Australian suppliers to Holdens
- Added requirement that **PPAP must be used with sub-contractors**
- Added **year 2000 requirement**, along with electronic communication and shipment notification statement

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Changes to Appendix A through J

- Major changes and additions to most of the appendices.
- Appendix I adds most of the other IASG interpretations that were not added in the text

Recommendations for Action

- Three situations which will require different action plans:
- 1) Already registered to QS-9000
- 2) Will become registered in the first half of 1998
- 3) Will become registered late in 1998 or early 1999

Action Plan For Registered Suppliers

- Update Level I Quality Manual and assign responsibility for procedural changes
- If your company has **major** laboratory facilities immediately start to develop a laboratory manual or procedures as required by section 4.10. You can use ISO Guide 25
- Consult with your registrar as to how/when you should upgrade-either later this year or early next year

Registration Plan

First Half of 1998

- Finish developing your system to the Second Edition; register system; then update to the new Third Edition
- If you have extensive laboratory facilities, start working on your new laboratory procedures now; Use 4.10 of the Standard and ISO Guide 25 for assistance

Action Plan To Register Last Half of 1998 Or Early 1999

- Consider revising your Level I quality manual and procedures now, before registration; changes in the Standard are small and at the stage of the process you are in this should not delay registration; this is if you have 6 to 8 months to your registration date.

Summary

- Third Edition can be implemented with some work; but in most cases changes are adjustments rather than something brand new
- The additional laboratory requirements can be added by the use of ISO Guide 25 as a reference manual