IATF 16949:2016

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-016

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Instructions:

This manual is used as a template in developing your IATF 16949:2016 Automotive Quality Management System.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QM-016 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

Table of Contents – (this page)

1.0 Purpose/Scope

1.1 This procedure describes the quality management system (QMS) processes for ensuring control of the initial release and changes to the documented information essential for the production or services provided by Your Company.

1.2 The procedure applies to all documented information essential to the product or service and to the procedures defined as essential to the operation of the QMS.

2.0 Responsibilities and Authorities

2.1 The Quality manager / Quality team leader / Management representative has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality manager, the Quality team / ISO steering committee is responsible to ensure that personnel have access to and are aware of relevant QMS documentation and changes.

2.3 Additional responsibilities for the document owner, the document control coordinator, department managers, engineers, employees, and the Management rep are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References.

3.1.1 This document addresses clause 7.5 of the IATF 16949:2016 standard covering, Documented information.

3.1.2 QM-016 Quality Manual.

3.2 The documented information collectively describes the QMS where a typical pyramid-shape documentation structure provides for:

- Tier I - Manual
- Tier II - Procedures (P-xxx)
- Tier III - Work Instructions (WI)
- Tier IV - Quality Records

3.3 Definitions: Definitions related to this procedure are provided in the document numbering instruction WI-750-001.

4.0 Resources

4.1 None, (unless an electronic document control system is used).

5.0 Instructions

5.1 The QMS includes the documented information required by the IATF 16949:2016 international standard and the documented information determined to be necessary for an effective QMS.

1.0 Purpose/Scope

1.1 The purpose of this procedure is to describe the system that provides controlled conditions under which the production processes are performed at Your Company.

1.2 The procedure applies to the release of products and services.

2.0 Responsibilities and Authorities

2.1 The Quality manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality manager, the Quality team / ISO steering committee is responsible to ensure that processes are performed under controlled conditions.

2.3 Additional responsibilities for the Quality manager / quality team are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References: This document relates to clause 8.6 of the IATF 16949:2016 standard, covering release of products and services.

3.2 Definition: Production processes: Processes that contribute or result in the product or service being produced or the product or service being provided.

4.0 Resources

4.1 As listed in the applicable production documentation.

5.0 Instructions

5.1 In support of the procedure P-851 for control of production and service provision, this procedure addresses the control of changes and the post-delivery activities.

5.1.1 The Quality team / ISO steering committee ensures that systems are implemented under controlled conditions.

- The documented information for production and service provision are included in the QMS-Process identification worksheet, F-440-001.

5.2 A suitable infrastructure and process environment include manufacturing equipment where production processes are controlled and managed to achieve product conformance and continual improvement.

5.3 Release of products and services is performed after the verification activities at the appropriate stages ensure that product and service requirements are met. An example of a typical inspection report, form F-910-004 can document results.

5.3.1 Product release criteria and product release authority are documented on

5.1.3 Executive Management may require that the performance of certain processes be monitored using statistical techniques to ensure the required level of performance.

5.1.4 Statistical Techniques may be applied, as necessary, to the following:

- Control of process performance.
- Corrective and preventive action analysis and effectiveness.
- Customer complaints.
- Customer perception survey feedback.
- Establishment of sampling plans for inspection and testing.
- Evaluation of non-conformance defect categories.
- Evaluation of the measurement system.
- Set up of process equipment.
- Testing and validation of processes.
- Testing and validation of produce / service designs.
- Any other company wide situations that require statistical monitoring.

5.2 Statistical Sampling.

5.2.1 When specified, statistical sampling is used for new product or service design, verification of those designs, incoming inspection, in-process inspection, and final inspection.

5.2.2 The sampling plan to be used for an inspection is documented in the inspection instruction. Where a sampling plan has not been defined, the sampling defaults to C = 0 Sampling Plans.

5.2.3 For attribute data sampling, the acceptable level is zero defects.

5.3 Review of Sampling Methods.

5.3.1 The Management Representative regularly evaluates the suitability and effectiveness of the sampling methods that have been utilized. The evaluation is performed by analyzing trends in product nonconformances, audit findings, customer survey perception feedback, customer complaints and other various feedback information.

5.3.2 If the sampling plans are not effective, they are modified to improve their effectiveness. Regular evaluations may also determine that the statistical techniques in use are no longer of any value and the recommendation to discontinue or modify, would be made.

5.4 Analysis and use of data.

5.4.1 Quality and operational performance trends are compared with progress toward objectives and results in actions to support:

- Development of priorities for prompt resolution of customer-related problems.
- Determination of key customer-related trends and correlation to aid in status review, decision making and longer term planning.
- An information system for timely reporting of product information resulting from actual use.

5.4.2 A method of analysis is provided with procedure P-913 for root cause analysis.

6.0 Forms and Documented Information

6.1 F-911-001 Frequency Distribution Report

6.2 P-720 Competence and awareness

6.3 P-910 Monitoring, measuring, analysis, and evaluation

6.4 P-913 Root cause analysis

6.5 List the forms that you have referred to above. These forms, charts and summaries may be system generated and are typically standard and are controlled.

- Assign form control numbers such as F-911-001 for the Frequency Distribution Report.
- List records that must be maintained and add them to the Quality Records Table.
- Reference input and output requirements for management review meetings.

7.0 Opportunities and Risks

7.1 The planning procedure P-600 for Planning for the Quality management system addresses opportunities and risks (risk-based thinking).

7.2 As applicable to your company, make use of your organizational knowledge, lessons learned and experience with the activities associated with **Statistical techniques** to determine the opportunities and risk that need to be addressed and that can:

- Give assurance that the procedure can achieve its intended result(s).
- Enhance desirable effects, and prevent or reduce undesired effects.
- Achieve improvement.

8.0 Revision History

Revision	Date	Section	Paragraph	Summary of change	Authorized by
A				**Initial issue**	

INSERT YOUR COMPANY LOGO/NAME HERE

F-740-001
Comment and Suggestion Report

Instructions

- You are encouraged to make comments and/or suggestions for the improvement to the QMS known to your supervisor.
- Use the form below to communicate your suggestions and/or comments to ensure are noticed so that prompt reporting and subsequent timely improvement actions can be initiated.
- Your inputs can be reported by filling out this simple form available at the ISO bulletin boards.
- Your inputs can be reported verbally, in which case, your supervisor fills out the form below.
- Thank you; we appreciated your help and efforts in improving our quality performance.

QMS Comment and Suggestion Form	
Name: _____	Date: _____
Location:	
Equipment:	
Description of your observation / comment:	
Suggested improvement action:	
Supervisor remarks:	
Action taken:	

INSERT YOUR COMPANY LOGO/NAME HERE

F-750-006
Document Revision Checklist

Document Name:		**Document Number:**
Changes	Revision approved by supervisor and plant quality control	
	Accept previous changes	
	Update header to current date	
	Date all attachments (new or changes only)	
	Update page numbering	
	Make new changes using revision tool	
	Run spell check	
	Reprint original (white paper), including all attachments	
	Password protect document	
Master List	Update document information in the master list including date, records, attachments, related documents and references.	
	If form, attachment or reference changes, search master lists for other affected documents and issue a document change request form. New references require number identification.	
	If there are related documents, check to see if review or changes are indicated.	
Training	a) Determine level of training required with supervisor (NN, RQ, EM)	
	b) Update training summary date of revision and level of training required for the revision	
	c) Check training summary for list of individuals trained on the document	
	d) For required training send change memo to supervisor listing individuals to be trained	
	e) For employee training send memo to manager or supervisor in charge of employee training	
Approval	Give new original and attachments to supervisor and quality control to sign	
Distribution	a) Check distribution summary for listing of controlled copies	
	b) Copy onto controlled paper.	
	c) Remove obsolete master copy and stamp it “Obsolete”. Attach change request and file in the “Obsolete” binders.	
	d) File new original in master binder	
	e) Distribute controlled copies as indicated by controlled copy list.	
	f) Remove & discard obsolete controlled copies.	

NN=None Needed RQ=Required EM=Employee Meeting O=Original, no revision yet

INSERT YOUR COMPANY LOGO/NAME HERE

EQUIPMENT PROBLEM REPORT

EQUIPMENT DESCRIPTION: _____

LAST TASK PERFORMED: _____

JOB NUMBER: _____

DATE: _____ TIME: _____

OPERATOR: _____

REPORTED BY: _____

DESCRIPTION OF PROBLEM:

ACTION TAKEN

PROBLEM INVESTIGATED BY: _____

PROBLEM RESOLUTION DATE: _____

INSERT COMPANY NAME/LOGO HERE Easily Customizable using your company name and logo.

IATF 16949:2016 Automotive Quality Management Systems - The Basic Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating a Quality Management System (QMS) against the requirements of the new Automotive standard. The IATF 16949:2016 standard includes the requirements of ISO 9001:2015 and specifies additional automotive industry requirements.

In the checklist, each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. Because the automotive standard refers to ISO 9001:2015 for many of the requirements, you will need to have copies of the IATF 16949:2016 and ISO 9001:2015 standards to use along with this checklist so that, if required, you can refer to the requirements.

The intent of the main clauses of the new standard is summarized in blue font, and additional information is provided for the IATF 16949:2016 to supplement the intent of ISO 9001:2015.

Blue font summarizes the new standard

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed.

In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also, note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to comply with the IATF 16949:2016 standard.

---	QUALITY MANAGEMENT SYSTEM	Currently in Place	Compliant Yes / No	If No - % Completed	Items Needed
4	**CONTEXT OF THE ORGANIZATION**				

For ISO 9001:2015, this clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.

For IATF 16949:2016, sections are introduced to supplement requirements for the scope of the QMS, customer specific requirements, conformance of products and processes, and product safety.

	them? • Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results? • Opportunities for improvement of the processes and the QMS?				
4.4.1.1	**Conformance of products and processes**				
	How does your company ensure conformance to all customer, statutory & regulatory requirements for all products and processes, including service parts and those that are outsourced?				
4.4.1.2	**Product safety**				
	What processes are documented for the management of product safety related products and manufacturing processes?				
	Do the processes include, as applicable: • Your identification of the statutory and regulatory product safety requirements? • Customer notification of above product safety requirements? • Special approvals, typically by the customer, for design FMEA? • Identification of product safety related characteristics? • Identification and controls of safety related characteristics of product and at the point of				

	Is the quality policy appropriate to the purpose and context of the organization and supports the strategic direction? Does the quality policy provide for a framework for setting and reviewing quality objectives? Does the policy include a commitment to satisfy applicable requirements? Does it include a commitment to continual improvement of the QMS?				
5.2.2	**Communicating the quality policy**				
	How do you ensure that your quality policy is: • Communicated, understood, and applied within your company? • Available as documented information? • Available to relevant interested parties?				
5.3	**Organizational roles, responsibilities, and authorities**				
	Has top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company? Has the top management assigned the responsibility and authority for: • Ensuring that the QMS conforms to the requirements of ISO 9001:2015 standard? • Ensuring that the processes are delivering their intended outputs?				

Requirements of IATF 16949:2016

Trainer's Guide

Overview

This course is designed to train employees on the requirements of IATF 16949:2016. The course covers the structure, emphasis and requirements of the standard.

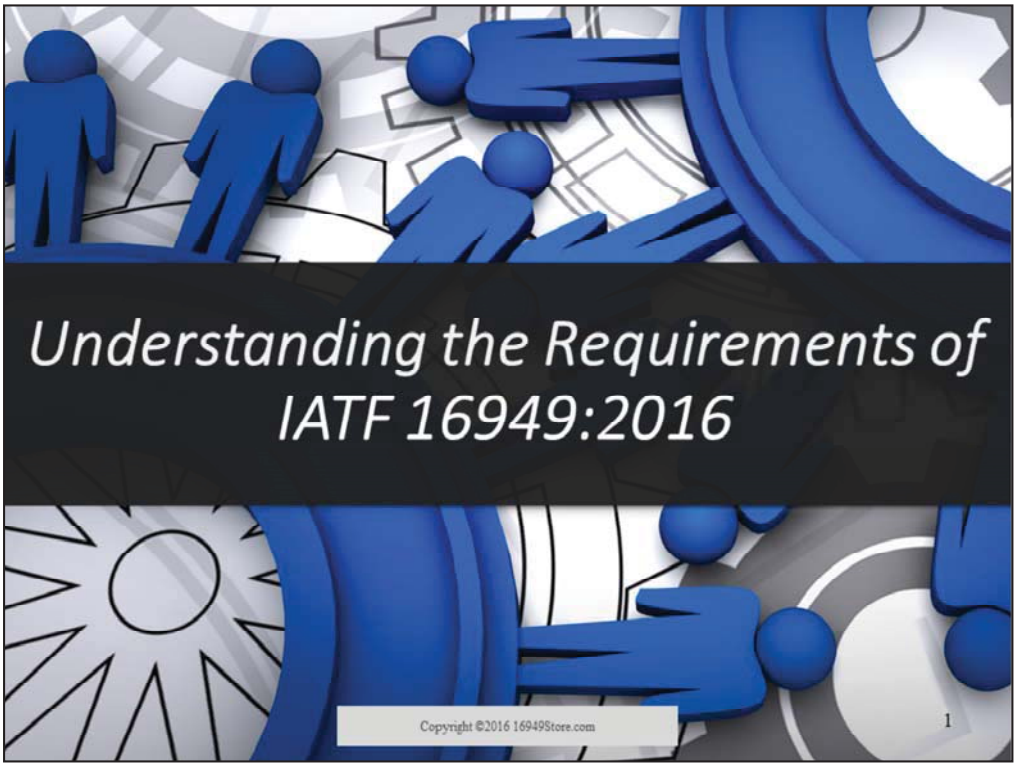
The course is approximately two hours long; the length may be changed by covering less detail, or by adding the suggested group exercises.
To begin preparing for the training session:

• Print the Notes pages of the PowerPoint presentation. (Open the PowerPoint presentation, select “Print”, and select “Notes Pages”).

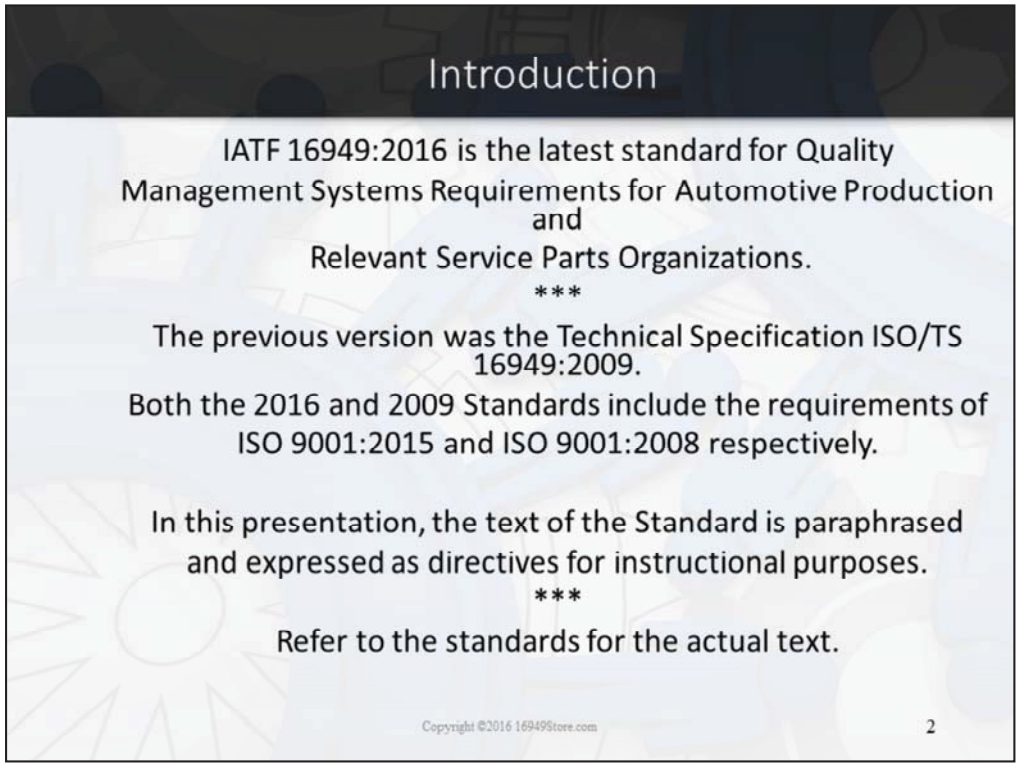
• Print a copy of the Student Manual. You will then be able to prepare for the presentation using this guide and reviewing the speaker notes and student manual.

The content of the student manual matches the information in the PowerPoint slides. Let students know this at the beginning of the presentation to make it easier for them to take notes. The speaker notes provide additional detail.

You will need one copy of the standard for the trainer, and you may want copies for each student to refer to for details. Standards are available electronically from:
http://16949store.com/buy-standards/



Understanding the Requirements of IATF 16949:2016

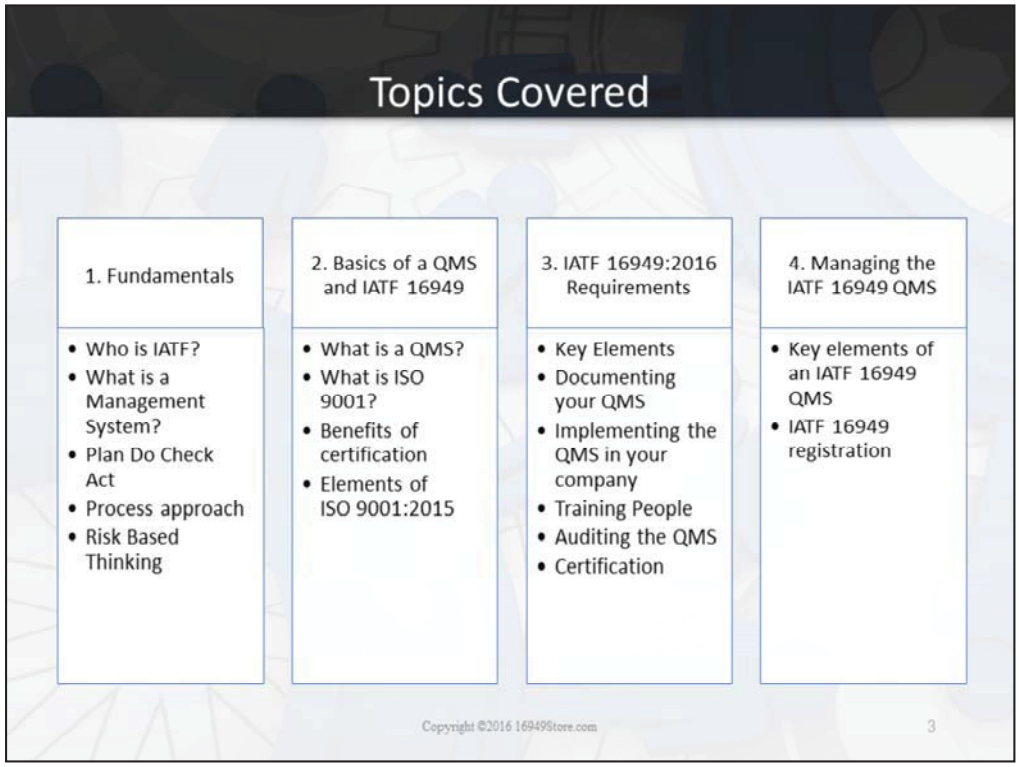


The IATF 16949:2016 standard has proven to be a most popular and effective way for companies to manage their Quality Management System (QMS)

The International Automotive Standard IATF 16949:2016 is restructured and contains 10 sections or clauses numbered 1 through 10.

It is important to note that the standard is revised to incorporate the new clause structure and content of ISO 9001:2015.

Also, new automotive industry requirements, definitions, and notes are included.



Today we will cover the following topics so that you will better understand your company's Quality Management System.

I will begin by providing some basic information regarding management systems and the IATF standard.
I will then explain:
What is a QMS and What is IATF 16949
Why is it important to your company to achieve IATF 16949 registration
What are the benefits of achieving registration
What are the elements necessary to establish and manage and IATF 16949 QMS, and
How can you support your company's QMS.
For the rest of the training, we will use the term QMS which means the Quality Management System.

INSERT COMPANY NAME/LOGO HERE

IATF 16949:2016 Automotive Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the Oct 1, 2016 1st edition of the IATF 16949:2016 international automotive standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to keep in mind that the standard does not require mandatory procedures for the various QMS processes; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement, be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and tittles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During the assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

---	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS	STATUS
4	**CONTEXT OF THE ORGANIZATION**		
4.1	**Understanding the organization and its context**		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)? How do you monitor and review the information related to the external and internal issues?		

	Additional Questions		
4.2	**Understanding the organization and its context**		
	With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, have you determined: • The interested parties relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? How do you monitor and review the information about the interested parties and their relevant requirements?		
	Additional Questions		
4.3	**Determining the scope of the quality management system**		
	To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)?		

	• Products and services covered by the QMS?		
	When a requirement of ISO 9001:2015 can be applied, has your company applied it (see also clause 4.3.1 below)? When requirements cannot be applied, and to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected? Has your company provided justification for any instance where a requirement of the standard cannot be applied? Is the scope of the QMS available and maintained as documented information?		
	Additional Questions		
4.3.1	**Determining the scope of the quality management system - supplemental**		
	When determining the scope of the QMS, are the supporting on-site or off-site functions, such as design centers, corporate headquarters, and distribution centers, included in the QMS scope?		
	• In determining the scope of the QMS, have you considered product design and development (per clause 8.3) as the only permitted exclusion? • If applicable, is this exclusion justified and maintained as documented information? • Do you recognize that permitted exclusions do not include manufacturing process design?		

