

ISO 9001:2015 Quality Management System Audit Checklist

4.3 Determining the scope of our quality management system

Sl. #	Audit Question	Audit Result	Describe the Gap
1	Has our organization determined the boundaries and applicability of our quality management system to establish its scope? (Scope Statement available?)		
2	When determining this scope, did our organization consider: a) the external and internal issues referred to in 4.1? b) the requirements of relevant interested parties referred to in 4.2? c) the products and services of our organization.		
3	Did our organization apply all the requirements of the ISO 9001:2015 standard if they were applicable within the determined scope of our QMS?		
4	Is the scope of our organization's quality management system visually available and maintained as documented information somewhere ?		
5	Does the scope state the types of our products and services covered, and provide justification for any requirement of the ISO 9001:2015 standard that our organization determines as not applicable to the scope of our quality management system?		
6	Are we aware that conformity to the ISO 9001:2015 standard may only be claimed if the requirements determined as not applicable do not affect our organization's ability or responsibility to ensure the conformity of our products and services and the enhancement of customer satisfaction?		

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Yi-Tong Ma



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