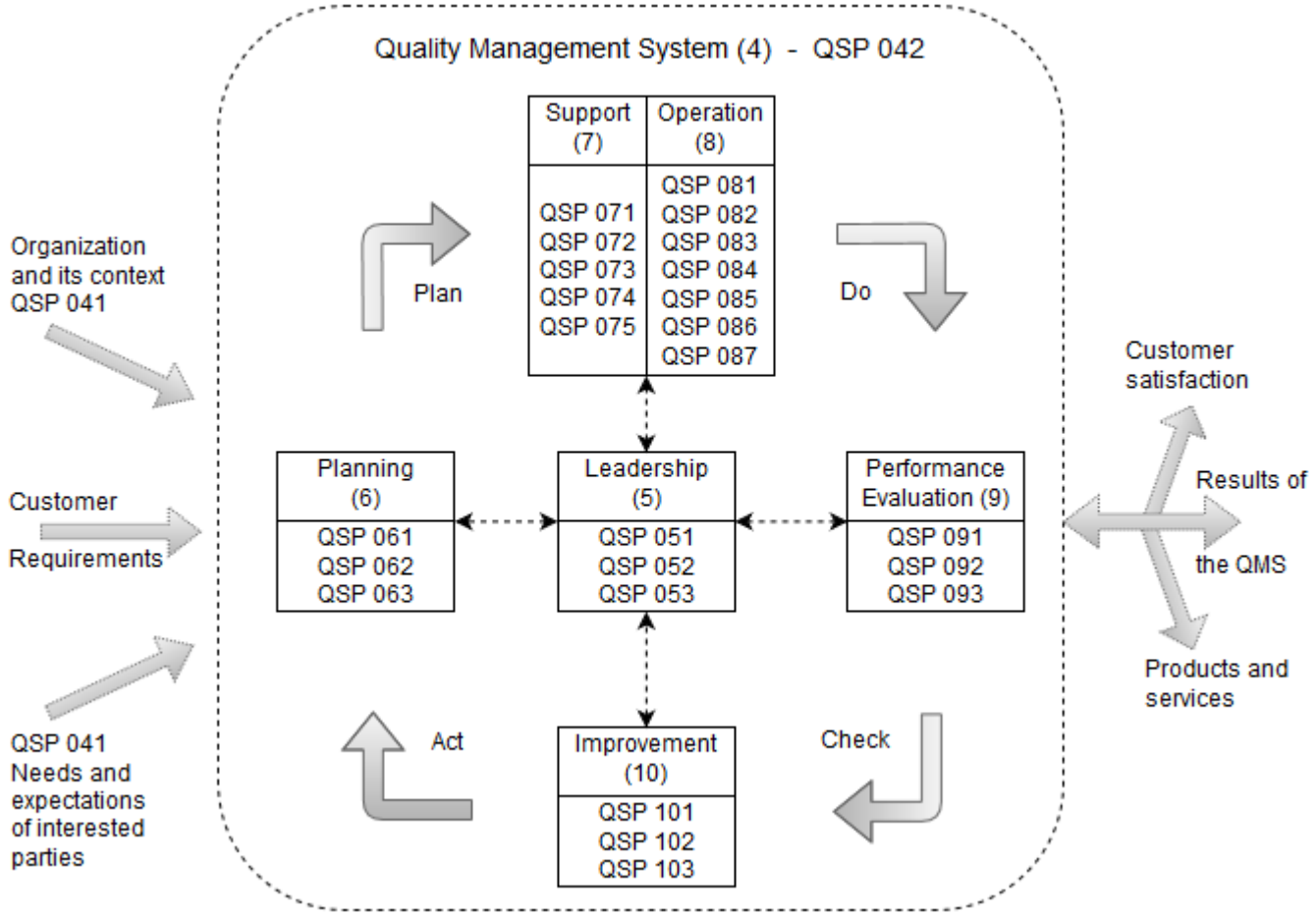
AAA Inc	ISO 9001:2015 INTERNAL AUDIT CHECKLIST			
	Issued by: **Quality Assurance**	Date: **00-00-00**	Revision: **A**	**QF-092-1**

Refs	Requirements	What to look for and how	Comply	Auditor notes and evidence

This is also an ISO 9001:2015 compliance checklist. The requirements for each process are paraphrased from ISO 9001 and there is a reference to the corresponding clause of the standard (first column). The checklist is carefully designed to completely cover all requirements of the ISO 9001 standard. If, when customizing the Process Map, you delete or add processes, make sure that you re-associate the corresponding clauses in ISO 9001 and don't leave any out (e.g., maintain completeness of the checklist in regard to compliance with ISO 9001).

You should customize this checklist on three levels: 1) align it with any changes in the Process Map, 2) further develop the "Requirements" column to add other relevant requirements (if any), and 3) edit the "What to look for and how" column to make it appropriate to the products, operations, practices and issues that are relevant in your company. The third item in particular will require the most customizing.



Refs	Requirements	What to look for and how	Comply	Auditor notes and evidence
QSP 041 Context and interested parties				
4.1	Determine external and internal issues that are relevant to the purpose and strategic direction of the company	*Are the issues determined? Who determined the issues? How are the issues documented? Are there both internal and external issues? How are the issues communicated (Quality Manual, training, etc.) Are the issues reviewed from time to time to ensure their continual relevance?. Are there any records demonstrating that external issues were reviewed? Were there any issues added or removed after the initial set of issues were determined?*	*Note "Yes" for compliance and "No" for noncompliance.*	
4.2	Determine interested parties relevant to the QMS and their requirements.	*Are interested parties determined? Who determined the interested parties? How is it documented who the interested parties are? Are the requirements of the interested parties determined? Are the interested parties reviewed from time to time to ensure their continual relevance?. Are there any records demonstrating that interested parties were reviewed? Were there any interested parties added or removed after the initial determination?*		
QSP 042 Quality management system processes				
4.3	Determine the • Scope of the QMS • ISO 9001 requirements that don't apply to the company	*Are the boundaries and applicability of the QMS established and documented? How is the scope documented? (Quality Manual).* *When determining the scope, are external and internal issues considered? Are requirements of interested parties considered?* *Are there any ISO 9001 requirements that are claimed not to apply to the company? Are these claims substantiated? Are these claims reasonable and justified? Are any ISO 9001 requirements related to enhancing customer satisfaction excluded?*		
4.4	Define the processes of the QMS	*Are processes needed for the quality*		

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		management system identified and established (process map)? Is the sequence and interaction between these processes determined (process map)? Are criteria and methods for the operation and control of quality system processes established (operational procedures)? Are required resources available? Are quality system processes monitored and measured (internal audit, customer satisfaction, manufacturing process performance, etc.)? Is the quality system being continually improved? *NOTE: most of these questions can only be fully answered after completing the entire audit.*		
QSP 051 Leadership and Commitment				
5.1	Top management shall • support, promote and be accountable for the effectiveness of the QMS • communicate the importance of conforming to the QMS requirements • provide resources for the QMS • establish the quality policy and quality objectives • promote improvement	*Do employees understand the consequences of failing to meet requirements? Is there a quality policy? Are quality objectives defined? Are management reviews being conducted regularly? 'Are adequate resources necessary for the quality system provided? Are there specific examples how management promotes improvement?*		
5.1.2	Top management shall demonstrate leadership and commitment with respect to customer focus.	*What measures are implemented to ensure that customer requirements are determined and met (processes, procedures, training, monitoring, auditing, etc.)?* *Are there any risks related to customer satisfaction determined?*		

In the DEMO version of the software, the checklist includes only the first three processes. The full version includes all 26 processes listed below.

Refs	Requirements	What to look for and how	Comply	Auditor notes and evidence

QSP 041: Context and interested parties
QSP 042: Quality management system processes
QSP 051: Leadership and commitment
QSP 052: Quality policy
QSP 053: Roles, responsibilities and authorities
QSP 061: Risks and opportunities
QSP 062: Quality objectives
QSP 063: Planning of changes
QSP 071: Resources
QSP 072: Competence
QSP 073: Awareness
QSP 074: Communication
QSP 075: Documented information

QSP 081 : Production/service provision and quality planning
QSP 082: Sales, contracting and customer communication
QSP 083: Design and development of products and services
QSP 084: Purchasing and subcontractor control
QSP 085: Production and service provision
QSP 086: Release of products and services
QSP 087: Control of nonconforming outputs
QSP 091: Monitoring, measurement, analysis and evaluation
QSP 092: Internal audit
QSP 093: Management review
QSP 101: Opportunities for improvement
QSP 102: Corrective and preventive actions (CAPA)
QSP 103: Continual improvement