QUALITY MANAGEMENT SYSTEM CHECKLIST - ISO 9001:2008

(STATUS A = Acceptable; N = Not Acceptable; N/A = Not Applicable)

Item No.	ISO Ref	Standard Requirements	Status A,N,N/A	Comments
	4	**Quality Management System (QMS)**		
1.	4.2.1 & 5.1 & 5.3 & 5.4	Does the QMS documentation include: - documented statements of quality policy and objectives promulgated by management that are consistent and measurable and provide commitment to continual improvement - a quality manual. - required documented procedures (refer below) - documents, including records, to ensure planning, operation and control of processes and the sequence and interaction of these processes - required records.		
2.	4.2.2	Does the **Quality Manual** include: - the scope of the QMS and exclusions - the documented procedures or references to them - a description of the interaction between the processes.		
3.	4.2.3	Is there a procedure for the **Control of Documents** that defines: - the approval, review and update of documents - the identification of the revision status and format of changes to documents - the identification and use of obsolete documents - the identification and control of necessary external documents - how the latest version of the documents are available on site (if applicable).		
4.	4.2.4	Is there a procedure for the **Control of Records** that covers the identification, storage, protection, retrieval, retention time and disposition. Are records readily identifiable and retrievable.		
	5	**Management Responsibility**		
5.	5.5	**Responsibility, authority and communication** Has management ensured that Responsibility and Authority are defined and communicated within the organisation. Has a member of the organisation's management been appointed with the responsibility and authority to manage the QMS. Are appropriate communication processes established within the organisation.		
6.	5.6	**Management Review** Has management planned the review of the QMS including assessing opportunities for improvement using all available inputs. Are records of the reviews maintained/actioned?		
	6	**Resource management**		
7.	6.1	**Provision of Resources** Are resources provided to implement, maintain and improve the QMS and to meet customer requirements.		
8.	6.2	**Human Resources** Are personnel with the necessary competence performing work affecting the conformity of the product. Is training provided to meet required competencies Are personnel aware of the relevance and importance of their activities and their contribution to the quality objectives. Are appropriate records maintained.		
9.	6.4	**Work Environment** Does the organisation manage the conditions under which work is performed that are needed to achieve conformity to product requirements.		

	7	Product realization		
10.	7.1	**Planning & product realization** Is a quality plan prepared for a specific project/contract detailing the processes and documents, including as appropriate, the verification, validation, monitoring, measurement, inspection and test activities and the criteria for product acceptance. Are appropriate records maintained.		
11.	7.2	**Customer-related Processes** Does the organisation determine and review requirements related to the product (including maintenance) prior to tendering. Are records and actions from the review maintained. Are documents amended and relevant personnel notified when changes are made to the product. Are there affective arrangements for dealing with customer complaints.		
12.	7.3 7.3.1	**Design and Development** Does the organisation plan and control the development of a product by determining: - the stages - the appropriate review, verification and validation - the responsibilities and authorities.		
13.	7.3.2	Are design and development inputs determined and records maintained for: - the functional and performance requirements - applicable statutory and regulatory requirements.		
14.	7.3.3	Are design and development outputs approved and do they: - meet the input requirements - contain or reference acceptance criteria		
15.	7.3.4	Are systematic review of design and development performed at suitable stages to: - evaluate the ability of the results to meet requirements - identify any problems and propose necessary actions.		
16.	7.3.5 7.3.6	Are planned verification and/or validation requirements performed and are outcomes and necessary actions recorded.		
17.	7.3.7	Are design and development changes identified, reviewed verified, validated as appropriate and approved. Are records maintained of the changes, review of the changes and necessary actions.		
18.	7.4 7.4.1	**Purchasing** Does the organisation ensure that a purchased product confirms to specified requirements. Is the type and extent of control of the supplier dependant on the effect of the purchased product on the final product. Does the organisation evaluate and select suppliers on their ability to meet the organisation's selection criteria. Are results and actions of evaluations recorded.		
19.	7.4.2	Does the purchase information define the specified requirements		
20.	7.4.3	Does the organisation establish and implement the inspection of other activities to ensure product verification.		

21.	7.5 7.5.1	**Production and Service Provision** Has the organisation controlled processes for planning and production that include, as applicable: - the specifications of the product - the availability of work instructions, as necessary - the use of suitable equipment - the availability and use of monitoring and measuring devices - the implementation of monitoring and measuring and - the release of hold points.		
22.	7.5.2	Are processes validated where the resulting output cannot be verified by subsequent monitoring or measurement.		
23.	7.5.3	Is the product identified where appropriate. Is the product status identifiable with respect to monitoring and measuring requirements.		
24.	7.6	**Control of Monitoring and Measuring Equipment** Where necessary, is measurement equipment identifiable and calibrated to appropriate standards and at nominated intervals and are calibration records maintained.		
	8	**Measurement, analysis and improvement**		
25.	8.1	**General** Does the organisation plan and implement the monitoring, measurement , analysis and improvement processes needed to: - demonstrate conformity of product - ensure conformity of the QMS - continually improve the effectiveness of the QMS.		
	8.2	**Monitoring and measurement**		
26.	8.2.1	**Customer Satisfaction** Are methods determined for the monitoring of Contractor Performance Reports.		
27.	8.2.2	**Internal Audits** Is there a planned audit program covering and including processes relative to their status and importance.		
28.	8.2.2 (cont.)	Is there a documented procedure defining the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records.		
29.	8.2.2 (cont.)	Are the actions to eliminate detected nonconformities followed up and verified.		
30.	8.2.4	Is there evidence of specification criteria in ITPs and the authorisation for release of the product (including Hold Points if appropriate)		
31.	8.3	**Control of nonconforming product** Is there a documented procedure defining the controls and related responsibilities and authorities for dealing with a nonconforming product.		
32.	8.3	Are there records of nonconformities, actions taken, including concessions obtained.		
33.	8.4	**Analysis of data** Are records available from processes to verify conformity to product requirements.		
34.	8.5 8.5.1	**Improvement** Does the organisation continually improve the effectiveness of the QMS through the use of quality policy, quality objectives, audit results, corrective and preventative actions and management reviews.		
35.	8.5.2 8.5.3	Is there a procedure to manage nonconformities and potential nonconformities.		
36.	**NOTE:**	Any ambiguity in this checklist shall be referred to the International standard for resolution.		