

QUALITY MANAGEMENT SYSTEM DOCUMENTS REVIEW CHECKLIST

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1.0 MANAGEMENT RESPONSIBILITY	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>1.1 Quality Policy - the supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.</p>			
<p>1.2 Organization</p> <p>1.2.1 Responsibility and Authority - Responsibility, authority and the interrelation of all personnel who manage, perform, and verify work affecting quality shall be defined, <i>particularly for personnel who need the organizational freedom to</i></p> <ul style="list-style-type: none"> a) <i>initiate action to prevent the recurrence of product nonconformity;</i> b) <i>identify and record any product quality problems;</i> c) <i>initiate, recommend or provide solutions through designated channels;</i> d) <i>verify the implementation of solutions;</i> e) <i>control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.</i> <p>1.2.2 Verification of Resources and Personnel - supplier shall identify in-house verification requirements, provide adequate resources, and assign trained personnel for verification activities. <i>Verification activities shall include inspection, test, and monitoring of the design, production, installation and servicing processes and/or product;</i> design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.</p> <p>1.2.3 Management Representative - Supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of the International Standard are implemented and maintained.</p>			

COMPANY NAME _____

SPECIFICATION NO./WORK ORDER NO. _____

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2.0 QUALITY SYSTEM	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>2.0 Quality System - the supplier shall maintain a documented quality system as a means of ensuring that product conforms to specified requirements. This shall include</p> <p>a) the preparation of a documented quality system program and instructions in accordance with the requirements of the International Standard;</p> <p>b) the effective implementation of the documented quality system procedures and instructions.</p> <p><i>Note: In meeting specified requirements, timely consideration needs to be given to the following activities:</i></p> <p>a) <i>preparation of quality plans and a quality manual;</i></p> <p>b) <i>identification & acquisitions of any controls, processes, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality;</i></p> <p>c) <i>updating, as necessary, of quality control, inspection, and testing techniques, including development of instrumentation;</i></p> <p>d) <i>identification of any measurement requirement involving capability that exceeds the known state of the art in sufficient time for that capability to be developed;</i></p> <p>e) <i>clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;</i></p> <p>f) <i>compatibility of the design, the production process, installation, inspection and test procedures and applicable documentation;</i></p> <p>g) <i>identification and preparation of quality records</i></p>			
<p>3.0 CONTRACT REVIEW</p> <p>3.0 The supplier shall establish and maintain procedures for contract review and for the coordination of these activities. Each contract shall be reviewed by the supplier to ensure that</p> <p>a) requirements are adequately defined and documented;</p> <p>b) any requirements differing from those in the tender are resolved;</p> <p>c) supplier has the capability to meet contractual requirements.</p> <p>Records of such contract reviews shall be maintained.</p>			

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4.0 DESIGN CONTROL	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>4.1 General - the supplier shall establish and maintain procedures to control and verify the design of the product in order to ensure that the specified requirements are met.</p>			
<p>4.2 Design and Development Planning - the supplier shall draw up plans that identify the responsibility for each design and development activity. The plans shall describe or reference these activities and shall be updated as the design evolves.</p> <p>4.2.1 <u>Activity Assignment</u> - the design and verification shall be planned and assigned to qualified personnel equipped with adequate resources.</p> <p>4.2.2 <u>Organizational & Technical Interfaces</u> - organizational & technical interfaces between different groups shall be identified and the necessary information documented, transmitted and reviewed.</p>			
<p>4.3 Design Input - design input requirements relating to the product shall be identified, documented, and their selection reviewed by the supplier for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved with those responsible for drawing up these requirements.</p>			
<p>4.4 Design Output - design output shall be documented and expressed in terms of requirements, calculations and analyses.</p> <p><i>Design output shall</i></p> <ul style="list-style-type: none"> a) <i>meet design input requirements;</i> b) <i>contain or reference acceptance criteria;</i> c) <i>conform to appropriate regulatory requirements whether or not these have been stated in the input information;</i> d) <i>identify those characteristics in design that are crucial to the safe and proper functioning of the product..</i> 			

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4.0 DESIGN CONTROL (Continued)	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>4.5 Design Verification - the supplier shall plan, establish, document and assign competent personnel functions for verifying the design.</p> <p>Design verification shall establish that design output meets the design input requirements by means of:</p> <ul style="list-style-type: none"> a) holding and recording design reviews; b) undertaking qualification tests and demonstrations; c) carrying out alternative calculations; d) comparing the new design with a similar proven design, if available. 			
<p>4.6 Design Changes - the supplier shall establish and maintain procedures for the identification, documentation and appropriate review and approval of all changes and modifications.</p>			
<p>5.0 DOCUMENT CONTROL</p> <p>5.1 Document Approval & Issue - the supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of the International Standard. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue.</p> <p><i>This control shall assure</i></p> <ul style="list-style-type: none"> a) <i>pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;</i> b) <i>obsolete documents are promptly removed from all points of issue or use.</i> 			
<p>5.2 Document Changes/Modifications - changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval <i>unless specifically designated otherwise. Designated organizations shall have access to pertinent background information upon which to base their review and approval.</i></p> <p><i>Where practicable, the nature of the change shall be identified in the document or the appropriate attachments. A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents. Documents shall be re-issued after a practical number of changes have been made.</i></p>			

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6.0 PURCHASING	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>6.1 The supplier shall ensure that purchased product conforms to specified requirements.</p>			
<p>6.2 Assessment of Subcontractors - The supplier shall select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality requirements. The supplier shall establish and maintain records of acceptable contractors.</p> <p><i>The selection of subcontractors, and the type and extent of control exercised by the supplier, shall be dependent upon the type of product and, where appropriate, on records of the subcontractor's previously demonstrated compatibility and performance.</i></p> <p><i>The supplier shall ensure that quality system controls are effective.</i></p>			
<p>6.3 Purchasing Data - Purchasing documents shall contain data clearly describing the product ordered, including, where applicable,</p> <ul style="list-style-type: none"> a) the type, class, style, grade or other precise identification; b) the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel; c) the title, number and issue of the quality system International Standard to be applied to the product. <p>The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.</p>			
<p>6.4 Verification of Purchased Product - where specified in the contract, the purchaser or his representative shall be afforded the right to verify at the source or upon receipt that purchased product conforms to specified requirements. <i>Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection. When the purchaser or his representative elects to carry out verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractor.</i></p>			

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7.0 PURCHASER SUPPLIED PRODUCT	PROGRAM REF.	RESULTS	REVIEW RESULTS
<p>7.0 The supplier shall establish and maintain procedures for verification, storage and maintenance of purchaser supplied product provided for incorporation into the supplies. <i>Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the purchaser.</i></p>			
<p>8.0 PRODUCT IDENTIFICATION & TRACEABILITY</p> <p>8.0 Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents, during all stages of production, delivery and installation. Where, and to the extent that, traceability is a specified requirement, individual product or batches shall have unique identification. This identification shall be recorded.</p>			
<p>9.0 PROCESS CONTROL</p> <p>9.1 General - the supplier shall identify and plan the production and, where applicable, installation processes which directly affect quality and shall ensure these processes are carried out under controlled conditions.</p> <p><i>Controlled conditions shall include the following:</i></p> <ul style="list-style-type: none"> <i>a) documented work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality, use of suitable production and installation equipment, suitable working environment, compliance with referenced standards/codes and quality plans;</i> <i>b) monitoring and control of suitable process and product characteristics during production and installation;</i> <i>c) the approval of processes and equipment, as appropriate;</i> <i>d) criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.</i> 			
<p>9.2 Special Processes - <i>these are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use.</i> Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with the requirements of 9.1. Records shall be maintained for qualified processes, equipment and personnel, as appropriate.</p>			

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10.0 INSPECTION & TESTING	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>10.1 Receiving Inspection & Testing - the supplier shall ensure that the incoming product is not used or processed (except in circumstances described in 10.1.2) until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.</p> <p><i>Where incoming product is released for urgent production purposes, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformance to specified requirements.</i></p>			
<p>10.2 Inprocess Inspection & Testing - the supplier shall</p> <p>a) inspect, test and identify product as required by the quality plan or documented procedures;</p> <p>b) establish product conformance to specified requirements by use of process monitoring and control methods;</p> <p>c) hold product until the required inspection and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 10.1). Release under positive recall procedures shall not preclude the activities outlined in a) above;</p> <p>d) identify nonconforming product.</p>			
<p>10.3 Final Inspection & Testing - the quality plan or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or inprocess, have been carried out and that data meets specified requirements.</p> <p><i>The supplier shall carry out all final inspection and testing in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to specified requirements.</i></p> <p><i>No product shall be dispatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorized.</i></p>			
<p>10.4 Inspection & Test Records - the supplier shall establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria.</p>			

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11.0 INSPECTION, MEASURING & TEST EQUIP.	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>11.0 The supplier shall control, calibrate and maintain inspection, measuring and test equipment, <i>whether owned by the supplier, on loan, or provided by the purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.</i></p> <p>The supplier shall</p> <ul style="list-style-type: none"> a) identify the measurements to be made, the accuracy required and select the appropriate inspection, measuring and test equipment; b) identify, calibrate and adjust all inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, prior to use, against certified equipment having a known valid relationship to nationally recognized standards - where no such standards exist, the basis used for calibration shall be documented; c) establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and action to be taken when results are unsatisfactory; d) ensure that inspection, measuring and test equipment is capable of the accuracy and precision necessary; e) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show calibration status; f) maintain calibration records for inspection, measuring and test equipment; g) assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration; h) ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out; i) ensure the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained; j) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting. <p>Where test hardware (e.g. jigs, fixtures, templates, patterns) or test software is used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production and installation and shall be rechecked at prescribed intervals. <i>The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control. Measurement design data shall be made available, when required by the purchaser or his</i></p>			

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<i>representative, for verification that it is functionally adequate.</i>			
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12.0 INSPECTION & TEST STATUS	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>12.0 The inspection and test status of product shall be identified by using markings, authorized stamps, tags, labels, routing cards, inspection records, test software, physical location or other suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as necessary, throughout production and installation of the product to ensure that only product that has passed the required inspections and tests are dispatched, used or installed.</p> <p>Records shall identify the inspection authority responsible for release of conforming product.</p>			
<p>13.0 CONTROL OF NONCONFORMING PRODUCT</p> <p>13.0 The supplier shall establish and maintain procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use or installation. Control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product and notification to the functions concerned.</p>			
<p>13.1 Nonconformity Review and Disposition - the responsibility for review and authority for the disposition of nonconformity shall be defined.</p> <p>Nonconforming product shall be reviewed in accordance with documented procedures. <i>It may be</i></p> <ul style="list-style-type: none"> a) reworked to meet specified requirements, or b) accepted with or without repair by concession, or c) re-graded for alternative applications, or d) rejected or scrapped. <p><i>Where required by the contract, the proposed use or repair of product which does not conform to specified requirements shall be reported for concession to the purchaser or his representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition.</i></p> <p>Repaired and reworked product shall be re-inspected in accordance with documented procedures.</p>			

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14.0 CORRECTIVE ACTION	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>14.0 The supplier shall establish, document and maintain procedures for</p> <ul style="list-style-type: none"> a) investigating the cause of nonconforming product and the corrective action needed to prevent recurrence; b) analyzing all processes, work operations, concessions, quality records, services reports and customer complaints to detect and eliminate potential causes of nonconforming product; c) initiating preventive actions to deal with problems to a level corresponding to the risks encountered; d) applying controls to ensure that corrective actions are taken and that they are effective; e) implementing and recording changes in procedures resulting from corrective action. 			
<p>15.0 HANDLING, STORAGE, PACKAGING & DELIVERY</p> <p>15.1 General - the supplier shall establish, document and maintain procedures for handling, storage, packaging and delivery of product.</p> <p>15.2 Handling - the supplier shall provide methods and means of handling that prevent damage and deterioration.</p> <p>15.3 Storage - the supplier shall provide secure storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. <i>Appropriate methods for authorizing receipt and the dispatch to and from such areas shall be stipulated. In order to detect deterioration, the condition of the product in stock shall be assessed at appropriate intervals.</i></p> <p>15.4 Packaging - the supplier shall control packing, preservation and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements and shall identify, preserve and segregate all product from the time of receipt until the supplier's responsibility ceases.</p> <p>Delivery - the supplier shall arrange for the protection of the quality of the product after final inspection and test. <i>Where contractually specified, this protection shall be extended to include delivery to destination</i></p>			

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16.0 QUALITY RECORDS	PROGRAM REF.	RESULTS	REVIEWER COMMENTS
<p>16.0 The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records. <i>Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent subcontractor quality records shall be an element of these data.</i></p> <p>All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss. Retention times of quality records shall be established and recorded. <i>Where agreed contractually, quality records shall be made available for evaluation by the purchaser or his representative for an agreed period.</i></p>			
<p>17.0 INTERNAL QUALITY AUDITS</p> <p>17.0 The supplier shall carry out a comprehensive system of planned and documented internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the system. Audits shall be scheduled on the basis of the status and importance of the activity. The audits and follow-up actions shall be carried out in accordance with documented procedures.</p> <p>The results of the audits shall be documented and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found by the audit.</p>			
<p>18.0 TRAINING</p> <p>18.0 The supplier shall establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience.. Appropriate records of training shall be maintained.</p>			
<p>19.0 SERVICING</p> <p>19.0 <i>Where servicing is specified in the contract</i>, the supplier shall establish and maintain procedures for performing and verifying that servicing meets specified requirements.</p>			
<p>20.0 STATISTICAL TECHNIQUES</p> <p>20.0 <i>Where appropriate</i>, the supplier shall establish procedures for identifying adequate statistical techniques required for verifying acceptability of process capability and product characteristics.</p>			

