DrJ TER Quality Control Manual Criteria

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The purpose of DrJ quality control manual criteria is to establish and maintain well-documented requirements for a quality control system on all products, systems, and materials being recognized in Technical Evaluation Reports (TERs). The criterion identifies what is critical for the technical review of the product and what will need to be included in the applicant's quality system.

Company:	
Product:	
TER Number:	
Revision # of Manual Reviewed:	
Review Completed By:	
Review Date:	

Item	Definition	Complete	References and Comments
Signature	An authorized representative of the manufacturer has signed and dated the documentation.		
Manufacturing Information	The facility name of the manufacturing location, the street address, and name and phone number of the contact person will be clearly stated on the documentation.		
Quality Manual Revisions	The quality system documentation will be reviewed annually and a record will be maintained.		
Declaration *(Language must be explicitly stated in the QC Manual)*	The DrJ Engineering name, mark or evaluation report number will only be used on product(s) that are in compliance with the published evaluation report and the quality control documentation approved by DrJ Engineering.		
	When apprised of field complaints concerning product performance, Report Holder will promptly investigate and respond to DrJ Engineering.		
	Report Holder agrees to permit DrJ Engineering or the third-party inspection agency to examine at distribution points and the manufacturing plant(s) any product labeled as being in conformance with the evaluation report.		
	Report Holder will notify DrJ Engineering in writing if the product is changed from what was originally recognized.		
	Report Holder will notify DrJ Engineering in writing prior to cancellation of the agreement with the inspection agency.		
	Copies of inspection reports for inspections conducted by the inspection agency that indicate any major quality deficiencies shall be forwarded to DrJ Engineering within 10 days of the noted major deficiency.		
	Report Holder will notify DrJ Engineering in writing if the unannounced follow-up inspections have not been conducted as prescribed in the manual approved by DrJ Engineering.		
Organizational Information	Documentation must include the organizational chart and a description of the key positions in the quality program.		

Item	Definition	Complete	References and Comments
Product Identification	The product identity will be recognized and consistent with the section of the listing in the TER.		
Product Changes	Product changes and the process for making them must be documented along with notification to involved parties.		
Manufacturing Process (Work Flow)	The manufacturing process will be described in the documentation.		
Incoming Materials	Documentation must include inspection or tests on incoming materials to prove that the materials meet the specifications.		
Required Certificate	Documentation of the certificate(s) required/ provided at the time of delivery for the incoming material is required.		
Traceability	The product identification will provide the ability to trace the product back to the production at the manufacturing location.		
Quality Control	All in-process quality control procedures, including manufacturing processes, are monitored and described in documentation.		
Quality Control Forms	Any forms, checklists, reports, etc. used by personnel to document tests, inspections, and other control procedures need to be identified and documented.		
QC Documentation Authorization	Quality control forms must be completed and approved by the responsible personnel.		
Test Equipment	The measuring and test equipment used to determine if a product meets specifications must be identified.		
Calibration	Frequency of the equipment calibration and traceability of measurements to national standards must be documented.		
Final Inspection	Final inspections and tests conducted before product is labeled and shipped must be in documentation to ensure the finished product complies with specifications.		
Packaging	If packaging and storage effect the product performance, information on the packaging and storage of the product shall be included in the documentation.		
Record Maintenance	It must be documented that the manufacturer has committed to retaining the completed forms, checklist, etc. for a minimum of two years.		
Nonconforming Materials	Documentation must include how nonconforming materials are separated from production until the manufacturer makes a decision regarding their outlook.		
Complaints Procedure	Documentation must be in place for complaints about the product, action taken for complaints, and the documentation of the actions taken.		

Additional Comments: