



Quality Control Criteria

Quality Form

QF 24

Effective: 11/15/16

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Revision: 1

Purpose: The purpose of DrJ quality control 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 criteria addressed in this document will be submitted to DrJ Engineering after the TER application has been accepted. 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.

Quality Control Criteria

1.0 General Documentation

- 1.1 Signature: An authorized representative of the manufacturer has signed and dated the documentation.
- 1.2 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.
- 1.3 Quality Revisions: The quality system documentation will be reviewed annually and a record will be maintained.
- 1.4 Product Identification: The product identity will be recognized and consistent with the section of the listing in the TER.
- 1.5 Traceability: The product identification will provide the ability to trace the product back to the production at the manufacturing location.
- 1.6 Work Flow: The manufacturing process will be described in the documentation.
- 1.7 Product Changes: Product changes must be documented along with notification to involved parties.
- 1.8 Organizational Information: Documentation must include the organizational chart and a description of the key positions in the quality program.
- 1.9 Packaging: If packaging and storage effect the product performance, information on the packaging and storage of the product shall be included in the documentation.
- 1.10 Complaints Procedure: Documentation must be in place for complaints about the product, action taken for complaints and the documentation of the actions taken.
- 1.11 Declaration: Verbiage from DrJ QF26 *Evaluation Report Holders Declaration* (included in new project package email attachments) must be listed explicitly in quality manual.

2.0 Material Documentation

- 2.1 Incoming materials: Documentation must include inspection or tests on incoming materials to prove that the materials meet the specifications.
- 2.2 Required Certificate: Documentation of the certificate provided at the time of delivery for the incoming material is required.

3.0 Quality Control: All in-process quality control procedures, including manufacturing process, are monitored and described in documentation.

4.0 Final Inspection: Final inspections and tests conducted before product is labeled and shipped must be in documentation, to ensure that the finished product complies with specifications.

5.0 Nonconforming Materials: Documentation must include how nonconforming materials are separated from production until the manufacturer makes a decision regarding their outlook.

6.0 Measuring and Test Equipment:

- 6.1 Test Equipment: The measuring and test equipment used to determine if a product meets specifications must be identified.

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6.2 Calibration: Frequency of the equipment calibration and traceability of measurements to national standards must be documented.

7.0 Inspection and Test Records

7.1 Quality Control Forms: Any forms, checklists, reports, etc. used by personnel to document tests, inspections and other quality control procedures need to be identified and documented.

7.2 Document Authorization: Quality control forms must be completed and approved by the responsible personnel.

7.3 Record Maintenance: It must be documented that the manufacturer has committed to retaining the completed forms, checklist, etc. for a minimum of 2 years.

Appendix A
Quality Control Criteria Documentation

Company Name:			
Product/ Material:			
Evaluation Report No.:			
Completed By:		Date:	

QC Section	Item Description	Present in QC Documentation and Page No.	Date	Comments if needed
1.1	Signature			
1.2	Manf. Location			
1.3	Manual Rev.			
1.4	Product ID			
1.5	Traceability			
1.6	Work flow			
1.7	Product changes			
1.8	Org Info			
1.9	Packaging			
1.10	Complaints			



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1.11	<i>Declaration</i>			
2.1	<i>Incoming Mat.</i>			
2.2	<i>Required Cert.</i>			
3.0	<i>Quality Control</i>			
4.0	<i>Final Inspection</i>			
5.0	<i>Nonconforming</i>			
6.1	<i>Test Equip.</i>			
6.2	<i>Calibrations</i>			
7.1	<i>QC Forms</i>			
7.2	<i>Document Auth.</i>			
7.3	<i>Records Retention</i>			