

DATASHEET NO 25 QUALITY SYSTEM CRITERIA FOR MANUFACTURERS

(17-06-25 lss 10)

The BBA requires that all products or systems considered for certification or product approval should be manufactured or installed in an environment which delivers products to a pre-defined standard and at a consistent level.

This document defines a set of criteria, which the BBA believes are essential for assuring manufacturing quality.

They form the basis of the BBA Quality Plan (see Datasheet 32).

Competence and training

The manufacturer should maintain a register of persons competent to undertake defined tasks, and the basis on which competency is judged. Staff should be given sufficient training to ensure a consistent and defined standard.



Complaints

The company should record all customer complaints (commercial, technical, those received in writing and verbal statements of dissatisfaction from customers and enquirers), and take appropriate corrective and preventative actions to address them.

Purchasing

The selection and use of suppliers and the purchase of raw materials and components should be controlled against documented specifications.

Manufacturing controls

The manufacturer should formulate and issue suitable instructions to staff to ensure that products meet a consistent and defined standard. Documentation shall also detail the levels of process control, including acceptance criteria required to demonstrate compliance with those standards.

Identification and traceability

The company should identify the product (by name, specification and/or unique number) throughout all stages of production and despatch. Products that are awaiting test, or have been tested and failed, shall be clearly identifiable (by location or otherwise) to prevent release to customers.

The finished product should be traceable to the date, or batch, of production, and where required (by law, by the BBA or by the company) the product should be traceable back to the component raw materials.

Testing and inspection

The manufacturer should define and undertake sufficient regular testing to demonstrate that production meets the required specification and should produce and maintain records of such testing.

Calibration

Equipment used to verify compliance with the product specification, should be of sufficient accuracy. This equipment should be clearly identified, calibrated and traceable to national standards.

Internal auditing

Periodically internal audits are required to assess the appropriateness of the procedures to ensure that they are being followed and achieving their objectives.

Records

The company should hold auditable records of all of the above.

Management review

Top management should carry out a regular critical review of the processes and procedures of the company, including analysis of customer complaints, internal audits and nonconformities, and take the necessary corrective and preventative action.

Some additional Considerations

Many companies achieve great value by extending their management system to achieve compliance with ISO 9001; we recommend that the company consider this as part of the systems.

The BBA is accredited for management systems certification for ISO 9001 (Quality), ISO 14001 (Environment) and ISO 45001 (Occupational Health and Safety). Should the company wish to save money by combining the production surveillance with management systems certification, please contact our Client Services team at: <u>clientservices@bbacerts.co.uk</u>, T: 01023 665200

T: 01923 665300.

At the BBA, we believe it is more important than ever to maintain and improve standards in all organisations.

Quality Control via the principles described in this document is an integral part of that commitment to continuous improvement within our industry.

See also:

Datasheet 10: Assessment and Surveillance of Production. Datasheet 32: Completion of a Quality Plan.

Note: This document may be revised from time to time, for example to take account of improvements and amendments to test and assessment methods and material innovations. Readers are advised to contact the British Board of Agrément to check the latest edition via the following contact methods: Tel: 01923 665300 e-mail: <u>clientservices@bbacerts.co.uk</u>