TITLE: SQR-001
Supplier Quality Requirements

Contents

REVISION HISTORY

Issue No	Description of Change	Author	Date
1.0	First issue	Neil Geering	Dec '18

Table 1 - Revision History

REFERENCED QUALITY DOCUMENTS

Doc Ref No	Quality Document Title

Table 2 - Referenced Quality Documents

DOCUMENT DETAILS

Location of Master: P:\Departments\QUALITY DEPARTMENT\Quality Manual & Procedures

Intended User: Suppliers

Owner: Quality Department

1. PURPOSE OF DOCUMENT

1.1. The purpose of this document is to define the general Quality conditions applicable to all Nu Instruments purchase orders for products and/or services, which will be incorporated into deliverable product.

1.2. By acceptance of an Nu Instruments Purchase Order referencing this document, a Supplier agrees to comply with the Quality Conditions stipulated. Deviations from these requirements are only acceptable by prior written agreement with the Nu Instruments Quality Manager.

1.3. It is the responsibility of the supplier to ensure the current issue of this document is held by reference to the latest purchase order received from Nu Instruments.

2. DOCUMENT PRECEDENCE

2.1. If conflict arises the order of precedence is as follows:

- Contract.
- Nu Instruments Purchase Order.
- Nu Instruments Drawing (where appropriate)
- This Document.

3. ACCEPTANCE OF SUPPLIERS QUALITY SYSTEM

3.1. Each supplier or subcontractor shall hold a current EN ISO9001 Quality Systems Approval or Nu Instruments Quality Systems Approval.

3.2. Second Party (Customer) Approvals are also acceptable, where invoked on the Purchase Order.

3.3. The Nu Instruments acceptance of a supplier will define a scope of approval and all material, work or services supplied to Nu Instruments must be within this scope.

3.4. Any changes to a suppliers' Second or Third Party approval scope or status must be advised in writing to the Nu Instruments Quality Manager as soon as they become known along with changes in Company ownership, management or location.

3.5. Acceptance by Nu Instruments of a suppliers Quality System is based not only on successful demonstration of compliance to the requirements of this document but also on continued delivery of acceptable products/services to Nu Instruments and its customers.

4. SUPPLIERS QUALITY SYSTEM REQUIREMENTS

4.1. Nu Instruments Supplier Quality System requirements are based on the requirements of EN ISO 9001, which are supplemented by additional Nu Instruments specific requirements as per Table 3.

4.2. Approval to EN ISO9001 will constitute suitable demonstration of compliance to this document provided that incorporation of the Nu Instruments specific requirements into the

suppliers Quality System is accomplished. Nu Instruments reserves the right to verify compliance to these requirements by a suitable means such as questionnaire, audit, etc.

ISO 9001 :2015 Section		Additional Nu Instruments Requirements defined in Section(s) of this document
4 - CONTEXT OF THE ORGANISATION		
4.1	Understanding the organisation and its context	
4.2	Understanding the needs and expectations of interested parties	
4.3	Determining the scope of the quality management system	
4.4	Quality management system and its processes	
5 - LEADERSHIP		
5.1	Leadership and commitment	Section 5
5.2	Policy	
5.3	Organisational roles, responsibilities and authorities	
6 - PLANNING		
6.1	Actions to address risk and opportunities	
6.2	Quality objectives and planning to achieve them	
6.3	Planning of changes	
7 - SUPPORT		
7.1	Resources	Section 6
7.2	Competence	Section 7
7.3	Awareness	
7.4	Communication	
7.5	Documented information	Section 8
8 - OPERATION		
8.1	Operational planning and control	Section 9
8.2	Requirements for products and services	
8.3	Design and development of products and services	
8.4	Control of externally provided process, products and services	Section 10 & Section 11
8.5	Production and service provision	Section 12 & Section 13
8.6	Release of products and services	Section 14 & Section 15
8.7	Control of nonconforming outputs	Section 16 & Section 17
9 - PERFORMANCE EVALUATION		
9.1	Monitoring, measurement, analysis and evaluation	Section 18
9.2	Internal audit	
9.3	Management review	
10 - IMPROVEMENT		
10.1	General	
10.2	Nonconformity and corrective action	Section 19

Table 3

5. RIGHT OF ACCESS

5.1. Unrestricted access (with reasonable notice) to the supplier's premises for the purposes of audit or investigation shall be afforded to Nu Instruments, Nu Instruments Customers and Regulatory Authorities as required.

6. CONTROL OF MEASURING EQUIPMENT

6.1. Suppliers are expected to provide the necessary inspection tools and gauging appropriate for the verification of the work they perform for Nu Instruments. Suppliers must take responsibility for maintenance of the equipment calibration by entering it into their own calibration control system and ensuring that only calibrated measuring equipment is used to verify the conformity of parts manufactured for Nu Instruments.

7. CONTROL OF AUTHORISATION

7.1. Where rubber stamps are issued to individuals authorised to perform inspection or manufacturing operations to signify their acceptance then these stamps will be suitably controlled. This control will include records of stamp holders, authorisation of issue, security of use and control of un-issued stamps.

7.2. Lost stamps must never be re-issued, withdrawn stamps must be quarantined for a minimum of 6 months.

7.3. Where electronic signatures are used then the supplier must implement a robust system to control the security and traceability to the individual applying the signature.

8. CONTROL OF RECORDS

8.1. Records must be retained in either hardcopy or electronic formats. If electronic retention is adopted for all or part of the Quality records, then the system and controls shall be described/demonstrated to and approved by the Nu Instruments Quality Manager.

8.2. Prior to the disposal of records pertaining to the manufacture of parts for Nu Instruments, the Supplier shall contact the Nu Instruments Quality Manager requesting permission for the disposal. Nu Instruments also reserves the right to request that these records be transferred to Nu Instruments for retention.

8.3. Records used to show conformity of both the Quality System and the delivered product must be retained for a minimum of 13 years, unless otherwise agreed in writing by the Nu Instruments Quality Manager.

9. PROCESSES

9.1. The processes and process routes used to manufacture parts for Nu Instruments must be planned and documented.

10. PURCHASE OF RAW MATERIAL

10.1. Where a supplier procures material on behalf of Nu Instruments then that material must be from a reputable source holding a suitable quality system approval.

10.2. Upon receipt of material the supplier is responsible for checking to ensure that the correct material has been delivered.

10.3. The use of a Nu Instruments approved source does not relieve the supplier of the obligation to verify conformance of the material nor of the liability for non-conformance should it be identified

11. PROCUREMENT OF SPECIAL PROCESSES

11.1. Where a supplier procures special processes on behalf of Nu Instruments then that service must be provided by a reputable source holding a suitable quality system approval.

11.2. Upon receipt of processed component, the supplier is responsible for checking to ensure that the correct process has been performed and the specification(s) identified on the received documentation tie up with the drawing requirement.

11.3. The use of a Nu Instruments approved source does not relieve the supplier of the obligation to verify conformance of the material nor of the liability for non-conformance should it be identified.

12. FREE ISSUE MATERIAL

12.1. When material or part finished components are free issued by Nu Instruments, the supplier shall maintain adequate control of this to ensure its correct identification, preservation and segregation.

13. PRESERVATION OF PRODUCT

13.1. Throughout processing, suppliers are required to ensure that products are adequately handled, packed, stored and protected in order to keep them free from damage and corrosion.

13.2. Prior to despatch to Nu Instruments parts will be cleaned to a level that will, unless required for protection, remove any residual oils, chemicals, deposits etc. and ensure they are free from any burrs or loose materials.

13.3. Parts will be packed for delivery in a manner that ensures adequate segregation of components, freedom from part to part contact, damage or corrosion during transportation to Nu Instruments.

14. RELEASE REQUIREMENTS

14.1. All materials, goods or services must be released by the supplier in accordance with the Purchase Order requirements.

15. SOURCE INSPECTION

15.1. Nu Instruments reserves the right to conduct source inspection at the supplier’s premises prior to the shipment of parts.

15.2. The requirement to conduct source inspection will be identified on the relevant purchase order and the supplier will advise the Nu Instruments Quality Manager at least 14 working days before the foreseen date of delivery.

16. CONCESSION / PRODUCTION PERMIT APPLICATIONS

16.1. Nonconforming items will only be accepted by Nu Instruments in exceptional circumstances and must not be delivered unless Nu Instruments Quality Department has formally agreed a Concession.

16.2. Concession applications will be made via a Smartsheet web form which is available from the Nu Instruments Quality Manager.

16.3. The suppliers release documentation must clearly indicate the agreed Concession reference number relevant to the applicable part / batch and the part adequately identified and segregated within the batch being delivered.

17. NONCONFORMANCE IDENTIFIED AT SUPPLIER

17.1. Where a supplier identifies a nonconformance that affects previously delivered product, then the supplier will inform the Nu Instruments Quality Manager of this occurrence within 24 hours of discovery stating the following:

- The nature of the nonconformance.
- The quantity of parts affected.
- The date of delivery of the affected parts.

18. INSPECTION

18.1. The supplier is responsible for ensuring that the parts delivered to Nu Instruments comply in all respects to the relevant drawing and/or specification. Evidence of this review will be maintained as part of the manufacturing records (see Section 8).

18.2. If sample inspection is used, then it must be in accordance with BS6001. Use of alternative sampling plans is not acceptable unless agreed in writing by the Nu Instruments Quality Manager.

19. SUPPLIER NONCONFORMANCE IDENTIFIED AT NU INSTRUMENTS

19.1. Nonconforming materials or parts identified at Nu Instruments will be rejected to the supplier on a Returns Note, a copy of which will accompany the returned goods.

19.2. At the discretion of the Nu Instruments Quality Manager, the supplier will be requested to complete details of the cause of the nonconformance and the action take to prevent recurrence. This Supplier Corrective Action Report must be completed and returned to the Nu Instruments Quality Manager within 20 working days of receipt.

19.3. When returning previously rejected goods, the supplier shall make reference to the Returns Note number on their delivery documentation.