NovaSignal™

# Supplier Quality Requirements

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## 1. PURPOSE

To define the requirements by which Supplier production and service activities will be established, controlled, and maintained for the manufacturing or distribution of NovaSignal products.

## 2. SCOPE AND APPLICATION

The requirements specified herein will be included on the Purchase Order, Contract, or other formal agreement (hereafter, referred to as the Contract) between NovaSignal and the Supplier.

Unless expressly excluded by the Contract, General Requirements (Section 4) applies to all Contracts. Supplemental Quality Requirements (Section 5), apply only when the specific requirement is included on the Contract.

Any Supplier exceptions shall be documented and approved by NovaSignal.

## 3. DEFINITIONS AND ACRONYMS

### 3.1 Definitions

**Complaint**: Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

**Specification:** Technical specifications for each Product (BOMs, test and manufacturing instructions, dimensions, drawings, performance characteristics, etc.) that is provided to and accepted by Supplier.

**Off-The Shelf Product:** Products delivered to a supplier design specification or an industry standard. Products that are not designed or delivered specific to NovaSignal design specifications.

**Custom Product:** Product manufactured and delivered in accordance with NovaSignal drawing or design specification.

**Supplier:** Organization providing a service or product in accordance with a NovaSignal Contract

**Contract / Purchase Order:** Legal agreement between NovaSignal and the Supplier to provide products or services.

### 3.2 Acronyms

| | |
|---|---|
| **CFR** | Code of Federal Regulations |
| **COC** | Certificate of Conformance |
| **DWF** | Detailed Work Form |
| **DWI** | Detailed Work Instructions |
| **FAI** | First Article Inspection |
| **FDA** | Food and Drug Administration |
| **ISO** | International Organization for Standardization |
| **KPI** | Key Performance Indicators |
| **OTS** | Off-the-Shelf |
| **QAP** | Quality Assurance Procedure |
| **RoHS** | Restriction on the use of Hazardous Substances |
| **SCAR** | Supplier Corrective Action Request |

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# 4. GENERAL QUALITY REQUIREMENTS

## 4.1 Quality Management System

4.1.1 When required by Contract, the Supplier's Quality Management System shall be compliant with the applicable requirements of ISO 9001, ISO 13485 and/or 21 CFR Part 820 Regulation. NovaSignal may identify such requirements during the Supplier approval process and/or may reference as appropriate on the Contract.

4.1.2 A copy of the Supplier's certificate of registration to Quality System standards must be provided to NovaSignal. Subsequent updates to registration certificates must also be provided to NovaSignal.

4.1.3 Changes to the Supplier's Quality System registration status must be communicated immediately to NovaSignal in writing.

4.1.4 The Supplier shall flow-down the requirements of this document as applicable to sub-tiers.

4.1.5 All products/items manufactured and distributed by the Supplier shall comply with NovaSignal specifications as defined on the Contract.

## 4.2 Control of Records

4.2.1 Production records shall be made available to NovaSignal and to the appropriate regulatory authorities (e.g., Notified Body, FDA, etc.) upon request by NovaSignal.

4.2.2 Records pertaining to product quality and manufacturing history shall be kept on file for at least 7 years after the related device is no longer sold.

4.2.3 The Supplier shall ensure during Contract review that all necessary documents referenced on the Contract are obtained and a process is implemented to ensure the current revision of documents on file.

## 4.3 Training and Qualification of Personnel

4.3.1 The Supplier shall implement a process to qualify and ensure appropriate personnel are performing product and process activities necessary to fulfill the Contract.

4.3.2 Training shall conducted be in accordance with the requirements of ISO 9001 and/or ISO 13485, where applicable.

## 4.4 Supplier Performance

4.4.1 Supplier performance will be evaluated using the Key Performance Indicators (KPI) defined in the NovaSignal Supplier Scorecard Form, DWF-00008-013.

4.4.2 Failure to meet a KPI may trigger a Supplier Corrective Action Request (SCAR), an audit request and/or the request for the Supplier to submit an improvement plan.

## 4.5 Engineering Changes

4.5.1 Any Supplier initiated changes impacting NovaSignal products and/or Contract requirements may not be implemented until written approval from NovaSignal has been received by the Supplier.

4.5.2 This includes deviations from NovaSignal drawings/specifications, or the Supplier production process that could potentially affect the form, fit, or function of NovaSignal products.

## 4.6 Work Transfer

4.6.1 NovaSignal must approve of any transfer of work from one Supplier (or sub-tier) facility to another in writing.

4.6.2 If the Supplier is transferring work from one Supplier (or sub-tier) facility to another, the Supplier shall notify NovaSignal at least 90 days before beginning the transfer.

4.6.3 A work transfer plan shall be developed and communicated with the following info:

- High Level Schedule
- Affected Part Numbers and Purchase Orders
- Product and Process Qualification Plan

## 4.7 Certificate of Compliance (COC)

4.7.1 For each delivery of products on the Contract, the supplier shall include in the shipment documentation a statement called a Certificate of Compliance which shall include the following:

- Part Number, Revision, Description of Parts Ordered
- Delivered Quantity
- Date and Authorized Signature
- Serial Numbers or lot numbers/date codes where applicable
- Contract or Purchase Order Reference
- Statement that certifies that all items were produced in accordance with requirements defined on the Contract

## 4.8 Restriction of Hazardous Substances (RoHS)

4.8.1 All materials used in delivered product to NovaSignal shall be RoHS compliant.

4.8.2 A certification statement or test results providing evidence of RoHS compliance shall be submitted by the Supplier in the initial shipment/FAI documentation and/or upon request.

## 4.9 Complaint Handling Process

4.9.1 The Supplier shall have a documented process for receiving and processing customer complaints. Any complaints received from NovaSignal shall be investigated, corrected, and preventive action implemented. Records of complaint handling shall be retained by the Supplier.

4.9.2 Complaints related to Safety, Medical Device Reportable (MDR), or Advisory events shall be handled in the most urgent manners.

4.9.3 The Supplier's complaint handling process shall also include provisions for the receipt and investigation of returned products. Any product returns from NovaSignal shall be documented, investigated, and resolved. Records of returned product analysis shall be retained by the Supplier and provided upon request.

## 4.10 Supplier Corrective Action Request (SCAR)

4.10.1 NovaSignal may issue a written SCAR to the Supplier because of a specific incident or trends in Supplier performance.

4.10.2 SCAR responses shall be completed using a format and timeline approved by NovaSignal. The Supplier is responsible for responding to the corrective action within the established due date or requesting an extension prior to the corrective action becoming past due.

## 4.11 Auditing

4.11.1 NovaSignal shall have the right to perform quality audits and/or inspections at the Supplier and sub-tiers facilities at its discretion. Audit personnel shall be escorted and confined to designated areas, specific to NovaSignal products. NovaSignal will notify the Supplier and communicate the audit scope prior to performing any audits.

4.11.2 Competent authorities shall have the right to perform appropriate checks on the conformity characteristics and performance of devices. These checks include both announced and, if necessary, unannounced inspections of the Supplier.

## 4.12 Notification of Escape

4.12.1 When the Supplier has determined a non-compliance to Contract requirements for products delivered to NovaSignal, the Supplier shall notify NovaSignal within one business day if there is a potential safety issue or within three business days for non-safety related escapes. The notification should contain a description of the non-compliance and appropriate information to effectively identify and contain the product.

4.12.2 After the initial notification, a detailed corrective action plan shall be provided with a timeline approved by NovaSignal. Dependent on the severity of the escape, NovaSignal may issue a formal SCAR.

## 4.13 Inspection Planning and Sampling

4.13.1 When sampling inspection is used to verify product, an inspection plan shall be defined with appropriate risk and documented by the Supplier. The Inspection Plan shall be provided to NovaSignal upon request.

4.13.2 The Inspection Plan shall contain:

- Sample size and frequency
- List of Monitored Characteristics
- Tools and procedure used to validate results.
- Requirement for Zero Defects

4.13.3 The sampling plan should be in accordance with industry standards (i.e. ANSI Z1.4 or Z1.9).

4.13.4 When Critical Dimensions are specified on the NovaSignal drawing, the inspection plan shall ensure these dimensions are identified in inspection planning and verified as part of the ongoing inspection process.

## 4.14 Calibration

4.14.1 Measuring equipment used to verify product (including automated test equipment) shall be calibrated using standards traceable to NIST standards with evidence of calibration maintained on file.

4.14.2 A documented process shall be in place to identify and periodically monitor calibration status of appropriate measuring equipment.

## 4.15 First Article Inspection (FAI)

4.15.1 For Suppliers delivering a Custom Product in accordance with a NovaSignal Drawing, a First Article Inspection shall be performed on at least one part from a representative lot when the following events occur:

- First production run of a new part
- New Drawing Revision due to an engineering change.
- Major change in production site (e.g. work transfer)
- Change in manufacturing process (i.e. using new technology, new equipment, or mold)

Note – a sample quantity larger than one may be requested for FAI verification and will be noted on the Contract.

4.15.2 A FAI report shall contain the following:

- A full dimensional inspection report
- Certificates of Analysis and/or Material Certification for applicable material and process requirements
- Component Traceability list providing evidence of compliance to BOM requirements (for assemblies only)
- RoHS Certification of Compliance or Test Results

4.15.3 The First Article Report shall be submitted with the shipment documentation for the first delivery of product.

## 5. SUPPLEMENTAL QUALITY REQUIREMENTS

Quality Requirements in this section apply only when directly referenced on the Contract.

### 5.1 QR-001 – Inspection Plan Approval - Critical Dimensions

For Critical Dimensions specified on the drawing, the Supplier shall perform inspection in accordance with a NovaSignal approved inspection and sampling plan. Inspection results shall be kept on file and provided to NovaSignal upon request.

### 5.2 QR-002 - Inspection Plan Submittal - Critical Dimensions

For Critical Dimensions specified on the drawing, the Supplier shall perform inspection in accordance with a NovaSignal approved inspection and sampling plan. With each delivery of product, the Supplier shall provide an inspection report detailing actuals results versus requirements.

### 5.3 QR-003 – 100% Inspection - Critical Dimensions

For Critical Dimensions specified on the drawing, the Supplier shall perform 100% inspection in accordance with a NovaSignal approved inspection plan. With each delivery of product, the Supplier shall provide an inspection report detailing actuals versus requirements.

### 5.4 QR-004 – Material Certification / Certificate of Analysis

With each delivery of product, the Supplier shall provide a Certificate of Analysis for raw material which includes mechanical and chemical test values showing compliance to applicable standards.

### 5.5 QR-005 – Functional Test Data

With each delivery of product, the Supplier shall provide a functional test data sheet which shows the actual results obtained during functional testing on each unit or lot versus requirements specified in the applicable specification.

### 5.6 QR-006 – Variation Control Plan

The Supplier shall establish a variation control plan which defines the statistical methods and parameters used to control manufacturing processes for Critical Dimensions or Characteristics specified by NovaSignal. The plan shall be submitted to NovaSignal for approval.

The plan should contain minimum sample lot quantity necessary and statistical measures required to verify and achieve process capability and control (ex: Control charts, Cpk > 1.33).

## 6. REVISION HISTORY

| Revision # | Supersedes Date | Author | Revision Summary |
|---|---|---|---|
| A | -- | Sean Parrish | ECO-003314<br>• Initial release<br>• Replaces DWF-00008-003 Supplier Agreement Form. |
| B | 17 Sept 2020 | Sean Parrish | DCO-000005<br>• Revised document formatting.<br>• In Section 4.10, removed reference to SCAR DWI-00008-004. |