Quality Assurance Procedure

MANUFACTURING AND INSPECTION OF EQUIPMENT

Abstract

This document describes the procedures and responsibilities involved in the manufacturing, the assembly and the inspection and test of LHC systems, sub-systems, assemblies, sub-assemblies and parts.

It establishes a policy for the control of all stages of manufacturing and assembly, from raw material procurement until final inspection and test, and it defines responsibilities and procedures to verify that all specified requirements are met.

The policy and guidelines apply to all materials, parts and equipment manufactured and/or assembled by Contractors, collaborating Institutes and CERN Divisions or Groups, that are to be installed in the LHC.

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## History of Changes

<table>
<thead>
<tr>
<th>Rev. No.</th>
<th>Date</th>
<th>Pages</th>
<th>Description of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 Draft</td>
<td>1999-05-20</td>
<td></td>
<td>1st draft</td>
</tr>
<tr>
<td>0.2 Draft</td>
<td>1999-06-03</td>
<td></td>
<td>Update following QAPWG meeting of 1999-05-20</td>
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<tr>
<td>1.0</td>
<td>1999-06-16</td>
<td></td>
<td>Released following QAPWG meeting of 1999-06-09</td>
</tr>
<tr>
<td>Section</td>
<td>Title</td>
<td>Page</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-------</td>
<td>------</td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>PURPOSE</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>SCOPE</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>POLICY</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>RESPONSIBILITIES</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>DEFINITIONS</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>PRODUCTION PROCESS DESCRIPTION</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>6.1</td>
<td>MANUFACTURING CHANGE CONTROL</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>6.1.1</td>
<td>DEVIATION AND WAIVER PROCESSING</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>EQUIPMENT IDENTIFICATION AND TRACEABILITY</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>VERIFICATION OF SUBCONTRACTED EQUIPMENT</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>CONTROL OF EQUIPMENT SUPPLIED BY THE CLIENT ORGANISATION</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>PROCESS CONTROL</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>INSPECTION AND TESTING</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>11.1</td>
<td>IN-PROCESS INSPECTION AND TESTING</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>11.2</td>
<td>FINAL INSPECTION AND TESTING</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>INSPECTION AND TEST RECORDS</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>12.1</td>
<td>GENERALITIES</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>12.2</td>
<td>TRACEABILITY OF MATERIALS, PARTS AND EQUIPMENT</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>12.3</td>
<td>CAPTURE OF INSPECTION AND TEST DATA</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>INSPECTION AND TEST STATUS</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>HANDLING, STORAGE, PACKAGING AND DELIVERY</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15.1</td>
<td>HANDLING</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15.2</td>
<td>STORAGE</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15.3</td>
<td>PACKAGING</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>15.4</td>
<td>PRESERVATION</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>15.5</td>
<td>DELIVERY</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>ANNEXES</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>RELATED DOCUMENTATION</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>
1. PURPOSE

This procedure applies to the manufacturing, the assembly, the inspection and test, and the handling and delivery of LHC systems, sub-systems, assemblies, sub-assemblies and parts.

It establishes a policy for the control of all stages of manufacturing and assembly, from raw material procurement until final inspection and test, and it defines responsibilities and procedures to verify that all specified requirements are met.

It provide guidelines for:

- Materials, parts and assemblies identification and traceability.
- The control of manufacturing and assembly processes.
- Inspection and testing.
- The verification of subcontracted equipment.
- The control of equipment supplied by the Client organisation.
- The management of inspection and test records.
- The control of inspection, measuring and test equipment.
- The handling, storage, packaging and delivery of equipment.

The policy and guidelines described in this document shall be used by LHC Project Engineers to specify their requirements for manufacturing, inspection, tests and delivery when writing Technical Specifications (see LHC-PM-QA-307.00 "Design Process and Control" [1]).

2. SCOPE

The policy and guidelines apply to all materials, parts, sub-assemblies, assemblies, sub-systems and systems to be installed in the LHC and manufactured and/or assembled by:

- Contractors,
- Collaborating Institutes,
- CERN Divisions and Groups.

They apply to all stages of manufacturing and assembly, from raw material procurement until final inspection and test.

For the construction of the LHC a number of collaborations have been organised between CERN and other Institutes. These collaborations are of different types depending on the degree of financial and technical responsibility delegated by CERN to the Institutes. As the ultimate responsibility for the successful completion of the LHC rests with CERN, it follows that the policy and guidelines described in this document are applicable whether the client organisation is CERN or a collaborating Institute.

3. POLICY

All materials, parts and assemblies that are to be installed in the LHC shall be inspected and tested to verify that they conform to specified requirements and that they are of an adequate quality for their intended use.

Materials, parts and assemblies shall be inspected and tested according to a quality assurance plan and/or to documented procedures.

Suppliers shall establish and maintain records that provide evidence that the equipment has been inspected and tested. The records shall show clearly whether the
equipment has passed or failed the inspections and tests. Where the equipment fails to pass any inspection or test, the procedure for control of non-conforming equipment shall apply.

Suppliers shall establish and maintain documented procedures for:

- The identification of all materials, parts and assemblies by appropriate codes and numbers to ensure their traceability. These procedures shall conform to LHC-PM-QA-206.00 "LHC Part Identification"[ 2 ] defined by the Project for the identification of all LHC equipment.
- The production, installation, and servicing of processes required for manufacturing and assembly which directly affect the quality of the finished equipment.
- The verification of subcontracted items to ensure they fulfil the specified requirements, are complete, identified and undamaged, and are accompanied by appropriate documentation.
- The verification, storage and maintenance of equipment supplied by the client organisation and provided for incorporation in the equipment to be delivered by the supplier.
- The inspection and test of equipment during manufacturing and assembly.
- The control, calibration and maintenance of inspection, measuring and test of equipment used to demonstrate the conformance of the manufactured and/or assembled equipment to the specified requirements.
- The handling, storage, packaging and delivery of equipment.

The client organisation shall have the right to be present, or to be represented by an organisation of its choice, to witness any inspection and test carried out at the main supplier’ premises or subcontractors’ premises. In cases where the client organisation is not CERN, the right to be present shall be extended to CERN or a representative of its choice.

4. RESPONSIBILITIES

Project Engineers at CERN and in Collaborating Institutes shall ensure that the requirements for quality assurance, as stipulated in Technical Specifications, are in line with the requirements described in this document.

When reviewing Technical Specifications, the LHC Specification Committee shall verify that the requirements for quality assurance are in line with the requirements described in this document.

Project Engineers at CERN and in Collaborating Institutes shall verify that suppliers:

- Understand the requirements for quality assurance,
- Implement the necessary quality assurance plan and/or written procedures,
- Apply the quality assurance procedures during production.

Suppliers and subcontractor shall plan and implement the necessary quality assurance activities to ensure that the requirements of the Technical Specification and appropriate standards and codes are fully met.

Suppliers shall assign a Contract Engineer to be responsible for the contract and its follow-up including all contacts with the client organisation throughout the duration of the contract.
5. DEFINITIONS

Client organisation The organisation responsible for a contract. It can be CERN or an Institute collaborating to the LHC Project.

Contract An agreement, usually legally binding, entered into by two or more parties for the supply of goods or services.

Contract engineer The engineer designated by the supplier to be responsible for the contract and its follow-up, including all contacts with the client organisation throughout the duration of the contract.

Deviation Written authorisation to depart from the originally specified requirements for a product prior to its production.

Equipment Any material, part, sub-assembly, assembly, sub-system, or system designed or provided for use in the LHC.

Product The result of activities or processes. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

Off-the-shelf product A product which is not made to order but is in stock and ready for use.

Supplier In the context of this document the term supplier is used to designate an organisation manufacturing and/or assembling materials, parts and equipment for the LHC. Such organisation may be:
- A company
- A collaborating Institute
- A CERN Division

Traceability The ability to trace the history, application or location of an entity by means of recorded identifications.

Traveller application The application software developed at CERN for the capture and storage in CERN’s EDMS of an equipment's inspection and test reports.

Traveller dossier The set of printed reports documenting the inspections and tests performed on an equipment. The traveller dossier follows the equipment through its production, inspection, delivery and installation.

Waiver Written authorisation to use or release an equipment which does not conform to all specified requirements.

6. PRODUCTION PROCESS DESCRIPTION

The production process is shown in annex A.1. It starts with the placing of a contract between the client organisation and the supplier and ends with the delivery of the
equipment. The technical requirements are described in the Technical Specification and its annexes.

To ensure the traceability of the equipment, i.e. the origin of the materials and parts and the equipment processing history, a set of technical interfaces between the client organisation and the supplier have to be respected during the manufacture, assembly and inspection of the equipment. These interfaces are essentially related to the following activities:

- The preparation of the design documentation if required
- The identification of the equipment.
- The management of inspection and test records.
- The handling of non-conformities.

Contracts may require the construction of a prototype and/or pre-series units before series production is launched.

The production process of a prototype is shown in annex A.2. Depending on the nature of the equipment the client organisation may contribute, in varying degrees, to the design and manufacture. Requirements for equipment identification, traceability and handling of non-conformities [3] do not apply. The prototype production process normally ends with a critical design review that validates the design prior to launching pre-series or series production. A complete set of the design documentation shall be prepared and delivered to the client organisation at this stage.

The pre-series production process is shown in annex A.3. Its aim is to develop and optimise a reliable process for the series production and to validate the production follow-up procedures. Requirements for equipment identification, traceability and handling of non-conformities[3] must be complied with. Again, depending on the nature of the equipment the client organisation may contribute in varying degrees to the pre-series production process.

6.1 MANUFACTURING CHANGE CONTROL

When schedule requirements or potential cost benefits warrant, waivers and/or deviations may be granted. A deviation or waiver is an acceptable departure from the original requirements of the specification, including drawings, or from a production process procedure.

A deviation is a written authorisation to depart from the original requirements given prior to production. A deviation usually results from preliminary engineering tests and analyses, or pre-series production, showing that not all specified requirements can be met.

A waiver is a written authorisation to use or release an equipment that does not conform to the specified requirements during or after production.

Where a waiver or deviation that has an impact on the LHC baseline configuration has been granted (e.g. one that entails a change in a baseline specification or drawing or parameter), the waiver or deviation concession shall be followed by an Engineering Change Request (ECR). The processing of ECR's is described in "Configuration Management - Change Process and Control", LHC-PM-QA-304.00 [4].

6.1.1 DEVIATION AND WAIVER PROCESSING

Request for deviations made by the supplier shall be submitted to the Project Engineer in charge of the contract follow-up. Critical deviations, i.e. those that may have an effect on the equipment performance, durability, interchangeability, interface to other LHC systems, health or safety shall be forwarded to the LHC Project management for review and approval or rejection.
All other deviations shall be approved or rejected by the Project Engineer. The processing of waivers is described in "Handling of Nonconforming Equipment" LHC-PM-QA-310.00 [3].

7. EQUIPMENT IDENTIFICATION AND TRACEABILITY

The supplier shall establish and maintain documented procedures for identifying the equipment. These procedures shall conform to the document LHC-PM-QA-206.00 "LHC Part Identification" [2] defined by the Project for the identification of all LHC components. The equipment identification method shall cover all stages of manufacturing and assembly. That includes in particular:

- Reception of purchased items, subcontracted items and items supplied by the client organisation.
- Manufacturing and assembly.
- Inspections and tests.
- Delivery.
- Installation at CERN if appropriate.

In case the supplier plans to use his own identification system he shall implement a procedure to establish a relationship between his own identification system and the LHC part identification system.

8. VERIFICATION OF SUBCONTRACTED EQUIPMENT

The supplier is responsible for the quality of subcontracted equipment. He shall verify that subcontracted items fulfil the specified requirements, are complete, identified and undamaged, and are accompanied by appropriate documentation.

The client organisation, or its representative, shall have the right to inspect subcontracted equipment at the subcontractor's site and at the main supplier site.

9. CONTROL OF EQUIPMENT SUPPLIED BY THE CLIENT ORGANISATION

The supplier shall establish and maintain documented procedures for the verification, storage and maintenance of equipment supplied by the client organisation and provided for incorporation in the manufactured and/or assembled equipment to be delivered by the supplier.

Any equipment supplied by the client organisation that is found to be damaged or is otherwise unsuitable for use shall be marked and separated from satisfactory equipment.

Lost or damaged equipment shall be recorded and reported to the client organisation.

10. PROCESS CONTROL

The supplier shall make certain that the processes required for the successful manufacturing and/or assembly of critical equipment are adequately planned, documented and controlled.

Critical processes, where quality cannot be determined by inspection and test only, (e.g. welding, bonding, insulating, etc.) shall be controlled by written procedures. The processes shall be carried out under controlled conditions. That means in particular:
• Use of documented procedure where the absence of such procedure could adversely affect quality
• Use of suitable production, installation, and servicing equipment and working environment.
• Compliance to standards, codes and specifications.
• Monitoring and control of process parameters.
• Approval of processes and equipment by the client organisation as appropriate.
• Establishing criteria for workmanship and ensuring that they are respected.
• Suitable maintenance of production equipment to ensure continuing process capability.

11. INSPECTION AND TESTING

11.1 IN-PROCESS INSPECTION AND TESTING

Suppliers shall establish and maintain documented procedures for inspections and tests of the equipment during manufacturing and assembly.

The procedures shall provide for the verification by inspections or tests, at appropriate points in the manufacturing and assembly process, that the characteristics of the item conform to the requirement specified for that stage of the process. In general the verification should be made as close as possible to the point of realisation of the characteristic.

The in-process verification may include:
• Set-up and first piece inspection.
• Inspection or test by machine operator.
• Automatic inspection or test.
• Fixed inspection stations.

Equipment shall be held until the required inspection and test has been completed. Equipment shall not be released for further use until it has been verified and the results of the verification are satisfactory.

11.2 FINAL INSPECTION AND TESTING

The contractor shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of the conformance of the finished equipment to the specified requirements.

The quality plan and/or documented procedures for all final inspection and testing shall require that all specified inspections and tests, including those specified on receipt of equipment or in-process, have been carried out and that the results meet specified requirements.

Inspections and tests procedures shall define:
• The location where the inspection or test is to be performed (supplier premises or client organisation site or CERN site).
• The parameters to be measured.
• The characteristics or functions that have to be verified.
• The acceptance criteria, including any applicable standards or codes.
• The requirements for special tools, fixtures, gauges, test set-ups and measuring equipment.
• Special instructions relative to handling and storage of the equipment.
• Guidelines for the use of sampling inspection if appropriate.
• The data and records that are required and in which form.
• When and how the inspections and tests results are to be reported to the client organisation.

No equipment shall be dispatched until all activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available.

12. INSPECTION AND TEST RECORDS

12.1 GENERALITIES

The supplier shall establish and maintain records that provide evidence that the equipment has been inspected and tested. The records shall show clearly whether the equipment has passed or failed the inspections and tests. Where the equipment fails to pass any inspection or test, the procedure for control of non-conforming equipment shall apply.

12.2 TRACEABILITY OF MATERIALS, PARTS AND EQUIPMENT

To install, commission, operate and maintain the equipment, access to inspection and test records must be ensured over many years. This shall be achieved by storing and maintaining all the necessary inspection and test records in the Engineering Data Management System (EDMS) used for the LHC project at CERN. This is a computer system providing document management facilities for all kind of electronic documents and data. Use of the CERN EDMS requires that all quality records be in computer readable forms. In cases where the use of a computer form is impractical, paper forms may be used and scanned to produce a computer readable document.

12.3 CAPTURE OF INSPECTION AND TEST DATA

The capture and storage of inspection and test records at the supplier's premises may be carried out in one of two ways:

• Use of the CERN traveller application. This software tool is accessible with a World Wide Web browser such as Netscape. It enables on-line storage of inspection and test records in the CERN EDMS.
• Use of the supplier's own production follow-up system. Use of such a system will require appropriate formatting and structuring of the data and documents prior to their copy from the supplier system to the CERN EDMS.

These two alternative methods are illustrated in figure 1.
Figure 1 - Alternative methods to capture and store inspection and tests records
The method used to capture inspection and test data at the supplier's premises and the form in which the same data is stored in the CERN EDMS are interrelated as summarised in table 1. The terms used in that table have the following meaning:

<table>
<thead>
<tr>
<th><strong>Data capture method</strong></th>
<th>The way the data is collected when carrying out inspections and tests.</th>
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<tbody>
<tr>
<td><strong>Data formatting</strong></td>
<td>The operation required after data capture to structure the data in a form acceptable to CERN's EDMS.</td>
</tr>
<tr>
<td>Document means, for example, an MS Excel(^1) spreadsheet or an MS Access document. Structured file is an ASCII file formatted to CERN's specification</td>
<td></td>
</tr>
<tr>
<td><strong>Transfer method</strong></td>
<td>The method used to deliver the data to CERN's EDMS.</td>
</tr>
<tr>
<td>File transfer means transferring the files off-line via Internet using ftp or other software. CD-ROM means the files are written to a compact disk and delivered to CERN by surface or air transport. World Wide Web means the data is entered on-line in the CERN's EDMS via the WWW.</td>
<td></td>
</tr>
<tr>
<td><strong>Database table values</strong></td>
<td>Individual values of parameters, measurements etc. are stored in tables. They are directly accessible from the EDMS.</td>
</tr>
<tr>
<td><strong>Document</strong></td>
<td>A structured document such as an MS Excel spreadsheet. Access to individual values of parameters, measurements etc is done in 2 steps: first access the document from the EDMS, second access values in the document structure</td>
</tr>
<tr>
<td><strong>Document Image</strong></td>
<td>An image of a document, such a scanned paper page, an Acrobat PDF(^2) copy of a computer document, an image of a computer screen. Access to individual values of parameters, measurements etc. is not possible.</td>
</tr>
</tbody>
</table>

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1 MS Excel, MS Access are registered trademarks of Microsoft Corporation.
2 Acrobat is a registered trademark of Adobe Systems Incorporated.
Table 1 - Summary of inspection and test records capture, transfer and storage in CERN's EDMS

<table>
<thead>
<tr>
<th>Data capture method</th>
<th>Data formatting</th>
<th>Transfer method</th>
<th>Possible data storage Form</th>
<th>Usage</th>
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<tr>
<td>Operator filling a paper form</td>
<td>Scanning</td>
<td>File transfer or CD-ROM</td>
<td>DB table values</td>
<td>YES To be avoided</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Document</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Document image</td>
<td></td>
</tr>
<tr>
<td>Operator filling a paper form</td>
<td>Data copied in computer form</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>YES To be avoided</td>
</tr>
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<td></td>
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<td></td>
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<tr>
<td>Measuring instrument producing paper output</td>
<td>Scanning</td>
<td>File transfer or CD-ROM</td>
<td></td>
<td>YES Acceptable</td>
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<tr>
<td>Data acquisition software (e.g. LabVIEW3)</td>
<td>Document</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>YES Acceptable</td>
</tr>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Structured file</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>Recomended</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator filling a computer form on the supplier production follow-up system</td>
<td>Document</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>YES Acceptable</td>
</tr>
<tr>
<td></td>
<td>Structured file</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>Recomended</td>
</tr>
<tr>
<td>Operator filling a CERN Traveller form on-line</td>
<td>Not required</td>
<td>World Wide Web</td>
<td>YES</td>
<td>YES Recomended</td>
</tr>
<tr>
<td>Operator filling a CERN Traveller form off-line</td>
<td>Not required</td>
<td>File transfer or CD-ROM</td>
<td>YES</td>
<td>YES Recomended</td>
</tr>
</tbody>
</table>

The selection of the method used to capture inspection and test data at the supplier's premises and the selection of the data storage form in the CERN EDMS shall be based upon the requirements of the equipment's Technical Specification.

Where the Technical Specification requires that the CERN traveller application be used, suppliers shall plan and install the hardware and communication equipment necessary to operate the traveller application on their premises.

A printed paper copy of inspection and tests records, called the traveller dossier, shall be attached to and follow the equipment through all phases of production, inspection, delivery and installation on the CERN site.

The supplier is responsible for maintaining the consistency of the printed data and documents in the traveller dossier with the electronic data and documents in the production follow-up system.

The data produced by data acquisition software shall be stored in the EDMS in the form of structured ASCII files. The storage of binary files is prohibited.

13. CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

Suppliers shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate the conformance of manufactured and/or assembled equipment to the specified requirements. Inspection, measuring and test equipment shall be used in a manner

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3 LabVIEW is a registered trademark of National Instruments Corporation
that ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data shall be made available, when required by the client organisation or its representative, for verification that the inspection, measuring and test equipment is functionally adequate.

Measuring and test equipment that is found to be out of calibration shall be marked and removed from service until re-calibrated.

14. INSPECTION AND TEST STATUS

Suppliers shall establish and maintain documented procedures for the identification of the inspection and test status of equipment throughout manufacturing, assembly, installation and servicing. These procedures shall provide documentary proof that the equipment has been:

- Approved through the inspection processes, or
- Not inspected, or
- Inspected and failed.

The procedure shall ensure that only equipment that has been inspected successfully, or released under a "use-as-is" non-conformity concession, is delivered, used or installed.

15. HANDLING, STORAGE, PACKAGING AND DELIVERY

Suppliers shall establish and maintain documented procedures for the handling, storage, packaging and delivery of equipment.

15.1 HANDLING

The supplier shall provide methods of handling raw materials, client supplied equipment, subcontracted equipment, and finished equipment that ensure that equipment is not damaged as it is moved during production, and when moved from production line to the storage area. Careful handling at all times and the use of appropriate handling equipment is essential to prevent damage or deterioration.

15.2 STORAGE

The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of raw materials, client supplied items, subcontracted items and the finished equipment pending use or delivery. Appropriate methods for authorising receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of items in stock shall be assessed at appropriate intervals.

15.3 PACKAGING

The supplier shall control packing, packaging and marking processes (including materials used) to the extent necessary to ensure conformance to the specified requirements.
15.4 PRESERVATION

Appropriate methods of equipment preservation shall be implemented (such as cold or chilled storage) while the equipment is under the supplier's control.

15.5 DELIVERY

The equipment must be protected during transportation and must be delivered in sound condition. Where third-party hauliers are used the same responsibility applies. This applies to the quality of all equipment following final inspection and test procedures.

All deliveries and/or collection by the client organisation shall be documented.

16. ANNEXES

A.1 The main production process flow-chart
A.2 The prototype production flow-chart
A.3 The pre-series production flow-chart

17. RELATED DOCUMENTATION

[ 1 ] LHC-PM-QA-307.00 Design Process and Control
[ 2 ] LHC-PM-QA-206.00 LHC Part Identification
[ 3 ] LHC-PM-QA-310.00 Handling of Nonconforming Equipment
Annex A.1 The main production process flow-chart
Annex A.2 The prototype production flow-chart
Annex A.3  The pre-series production flow-chart