1.0 Purpose/Scope

1.1 To outline the requirements for control of measuring and monitoring equipment at Your Company.

1.2 The procedure applies to equipment where monitoring or measuring is used for evidence of conformity of products and services

2.0 Responsibilities and Authorities

2.1 The Quality assurance manager / Management representative has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality assurance manager and where monitoring or measuring is used for evidence of conformity of products and services, the Quality team / AS steering committee is responsible for determining the resources needed to ensure valid and reliable monitoring and measuring results.

2.3 The Quality team / AS steering committee is responsible to designate the Equipment coordinator, and to assign responsibility for calibration and maintenance of the equipment.

3.0 References and Definitions

3.1 Reference:This document addresses clause 7.1.5 of the AS 9120 B standard, covering monitoring and measuring resources.

3.2 No definitions

4.0 Resources

4.1 None, (unless an electronic equipment calibration tracking system is used).

5.0 Instructions

5.1 The Quality team / AS steering committee determines and provides the resources needed to ensure valid and reliable results when monitoring and measuring is used to verify conformity to requirements.

5.1.1 With procedures P-810 for Operational planning and control, P-851 for Control of production and service provision, and P-910 for Monitoring, measurement, analysis and evaluation, consideration is given to monitoring and measuring resources to ensure that they are:

- Suitable for the specific type of monitoring and measuring activities undertaken,
- Maintained to ensure their continuing fitness for their purpose and documented information maintained as evidence of fitness for purpose.
- Calibrated or verified in suitable environmental conditions.

5.2 The Quality team / AS steering committee ensures that measuring instruments are calibrated when measurement traceability is considered to be an essential part of providing confidence in valid measurement results, or is a statutory or regulatory requirement, or is customer or interested party expectations.

'clean' (unmarked) version.

- The Document control coordinator inserts the approver's initials into the electronic copies when making the approved documents available.
- The Document control coordinator maintains a list of documented information in Section D of the Quality manual and enters the information in the List of documented information, form F-750-001.
- The Document control coordinator maintains a list of the QMS records in Section R of the Quality manual and enters the information in the Records documentation matrix, form F-750-002.

5.4 Document Identification and Distribution

5.4.1 All documents contain the following information:

- Company name
- Title
- Document Number
- Current Revision and Date

5.4.2 The system for the numbering of documents is outlined in the document numbering instruction WI-750-001.

5.4.3 Document owners obtain the document number from the Document control coordinator.

5.4.4 Document owners or other responsible persons obtain customer or regulatory agency approvals as required by contract or regulatory requirements.

5.4.5 Approved documents are submitted to the Document control coordinator and entered on the Master Documentation Lists, form F-750-003, as outlined in the Master Document List work instruction. Approved documents containing original signatures are the "Master" copies and are kept in the Master Document file.

5.4.6 Quality records are maintained as listed in the Quality records table. The table, form F-750-004 contains information relative to document number, record Identification, responsibility, record index, file/archive location, retention, and disposition.

5.4.7 The Document control coordinator retrieves and makes new and revised documents accessible and available as required and distributes copies to points of use according to the Master Documentation Lists.

5.4.8 Hard copies are controlled by listing the distribution of the document on the master list and printing the documents on blue paper to indicate they are controlled. Forms may be printed on white paper.

5.4.9 The document templates for the manual, procedures and work instructions include an auto print date. Electronic copies of the Manual, the Procedures, and Work Instructions that are printed for use are controlled by this print date. Printed copies are only valid for 24 hours

from the print date unless stamped “controlled copy” in red ink. Copies of these controlled documents are not authorized.

5.4.10 For documented information electronically managed, the data is protected. It is saved on an external drive on a daily basis and stored off-site for protection from loss, unauthorized changes, unintended alteration, corruption, and physical damage.

Blue text throughout the manual highlight areas for customization

5.4.11 Examples of retained documented information include items such as:

- Manufacturer, distributor, and repair station test & inspection reports
- Purchase orders/contracts
- Certificates of conformity, copies of authorized release certificates
- Nonconformance, concession, and corrective actions
- Lot or batch traceability
- Storage, preservation, or shelf life condition, such as time, temperature, humidity.

5.5 Document revisions

5.5.1 Documents are reviewed during regular use and during internal audits and are updated as found necessary during these reviews.

5.5.2 All employees are responsible for reviewing the documents to ensure they are identifiable and legible as they use them and submitting document change requests to update documents or obtaining new copies as necessary.

5.5.2 Documents are revised to update or clarify information using the Document Change Request form, F-750-005.

5.5.3 Revisions to procedures and the description of changes are indicated in the table in the revisions section at the end of the procedure. For example, the letter A in the table and at the end of the procedure number represents the initial issue for a procedure.

5.5.4 The document control coordinator uses the document revision checklist, form F-750-006 to ensure that all steps are completed.

5.5.5 When changes to the QMS are needed, they are carried out in a planned and systematic manner and consideration is given to the integrity of the QMS.

5.5.6 Revisions to documents go through the preceding document approval, identification, and distribution steps. Document changes are approved by an individual in the same function that performed the original review and signed the original document indicating approval.

5.5.7 All changes authored by other individuals have the document owner as a reviewer/approver.

5.6 Obsolete Document Disposition

5.6.1 To prevent the unintended use of obsolete documented information, one copy of the obsolete document is retained and marked “Archive Copy”.