

QMS Tier 2
QMS – Procedure

Subject: Calibration System

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Calibration System
Procedure

1.0 PURPOSE AND SCOPE

1.1 Purpose

1.1.1 The purpose of this procedure is to define the calibration, maintenance and control of measuring and test equipment used to determine acceptability of materials/products at our Company (ATS).

1.1.2 This procedure includes the process for conducting internal and external calibration activities.

1.1.3 When customer or employee owned measuring and test equipment is used to determine acceptability of materials/products shipped to ATS Customers, the measuring and test equipment shall be identified and tracked in the same manner as ATS owned measuring and test equipment.

1.1.4 This procedure calls for the clear identification of all measuring and test equipment used at ATS to prevent unauthorized or mis-use concerns.

1.2 Scope

This procedure shall apply to all measuring and test equipment used in Receiving Inspection, production Assembly/Fabrication, Test and Inspection, and Engineering Design.

2.0 APPLICABLE DOCUMENTS

The following documents are applicable to the extent specified herein:

Industrial/Commercial/Government Documents

ISO 9001	Quality Management System - Requirements
ISO/EC 17025	Laboratory Accreditation

ATS

Document(s)

ATS-PGP-1001	Purchasing System
ATS-PGP-2001	Supplier Evaluation and Approval/Disapproval
ATS-PGP-3001	Receiving Inspection
ATS-QAP-1004	Quality Records
ATS-QAP-1005	Nonconforming Material System
ATS-QAP-1006	Corrective Action System
ATS-QAP-1008	Internal Audits

Form(s)

FORM ATS10-5500
FORM 1601
FORM AQCES-1069
FORM ATS10-2116

Calibration Extension Request
Internal Calibration and Maintenance Record
Defect Report
Calibration Status Report

3.0 GENERAL CALIBRATION INFORMATION

3.1 Responsibilities

- 3.1.1 **Quality Assurance** - is responsible for preparing, implementing and maintaining this procedure. In addition, QA is assigned Calibration Administration responsibilities as defined in this procedure
- 3.1.2 **Calibration Administrator/Operations** - is responsible for following the procedure defined in this document.
- 3.1.3 **Receiving Inspection** - is responsible for following the procedure defined in this document.
- 3.1.4 **Receiving** - is responsible for following the procedure defined in this document.

- 3.2 Receipt and Identification of New and Re-Calibrated Equipment
- 3.2.1 Upon receipt of new company owned Capital Equipment/Assets, the Receiving Department assigns an Asset number. For equipment provided by a customer, the Customer's Asset Number or other unique number shall be used.
- 3.2.2 All measuring or test equipment (herein after called equipment) that will be used for judging acceptability of product/material is then process through Receiving Inspection per ATS-PGP-3001, Receiving Inspection procedure upon receipt.
- 3.2.1.1 The Receiving Inspector will contact the Calibration Administrator who will ensure that the equipment is acceptable and has supporting documentation certifying the equipment is calibrated when specified by the ATS issued Purchase Order. If the Item requires Calibration, the Calibration Administrator shall ensure that the equipment is identified "Held for Calibration" and segregated from use until the Calibration effort is completed.
- 3.2.1.2 If the equipment has been calibrated by a calibration service that ATS has determined meets the requirements of ISO 9001 or ISO 17025 with the necessary NIST traceability, the certification will be accepted. If not, the equipment will be calibrated before it is put into use.
- 3.2.1.3 Equipment received that is nonconforming (i.e. damaged, out of spec., etc) shall be rejected and processed in accordance with ATS-PGP-3001, Receiving Inspection.
- 3.2.2 After acceptance by Receiving Inspection, the Calibration Administrator will be contacted to ensure that the equipment is assigned an Asset Number or unique tracking number (Customer, Employee or Supplier owned equipment) which is used for the Calibration Identification Number (CIN).
- 3.2.3 The equipment CIN or unique tracking number information and Calibration Label shall be attached or marked onto the equipment or its packaging material for identification purposes.
- 3.2.4 When the equipment is exempt from calibration, the equipment will be marked, tagged, or labeled with "Calibration Not Required" or "Reference Only". Defective or out-of-calibration items shall be red tagged or identified/stored in a manner that makes it clear the items are not calibrated and shall not be used for conducting test and inspections on service or products. The item may be painted/marked or labeled with a Yellow color when labeling or tagging is not practical (environment or size issues) to indicate for Reference Only/Calibration Not Required, or red tagged or stored in a clearly posted area to prevent use all together.

- 3.2.5 Personal equipment used for judging material/product acceptability during receiving inspection, inspection, test or engineering design activities is subjected to the same calibration and control requirements as detailed in this procedure.

4.0 CALIBRATION REQUIREMENTS

4.1 Control of Calibrated Equipment

- 4.1.1 All measuring and test equipment that is used to judge acceptability of materials/products shall be calibrated and traceable to standard(s) with NIST traceability. The equipment information is entered into the Calibration Status Report (FORM ATS10-2116) excel spreadsheet. Once entered, the equipment is tracked using the Calibration Status Report (recall) list by the Calibration Administrator. The following information is enter into the Part Information screen:

- a) Part Number
- b) Model Number
- c) Manufactures Name
- d) Serial Number
- e) Work Center Location
- f) Calibration Label Type
- g) Calibration Frequency (interval)
- h) Equipment Status
- i) Service Code
- j) Comments

- 4.1.1.1 Once the equipment successfully completes its calibration requirements, the Calibration Administrator updates the Calibration Status Report (FORM ATS10-2116) excel spreadsheet. When it is necessary to prepare a modified Calibration Status Report list for a batch of equipment placed in the service or production work area, the list shall contain the same information as the Calibration Status Report (FORM ATS10-2116) plus be dated and approved by the person preparing and maintaining the list. See Figure 1 - Calibration Documentation Photo(s).

- 4.1.2 All test equipment that requires periodic calibration will have a label attached to it per Paragraph 6.0 – "Labels" by the Calibration Administrator or his/her assigned personnel that shows the following information:

- a. Date of last calibration approval
- b. By whom calibrated it or Calibration Administrator Name
- c. When next calibration is due

d. Calibration Identification Number (CIN) (Asset Number)

- 4.1.2.1 If the calibrated Item is small and is normally stored in a protective box/case/etc., the label containing the above information may be placed on the Item's packaging/container. In addition, the Item shall be marked/tagged/engraved/labeled/etc. with the CIN number that matches the CIN number on the label placed on the packaging/container. The CIN number may also be engraved or permanently marked/tagged onto the asset for tracking and long with a "Calibrated" sticker that includes the Issued By, Date and Due Date information.
- 4.1.2.2 See paragraph 6.1, Labels for typical calibration system labels used.
- 4.1.3 The Calibration Administrator will maintain a Calibration Status Report (recall listing). This report will be published as required and identifies all items due for calibration. Each department assigned calibration equipment is distributed a copy of the Calibration Status Report and is responsible to ensure that all equipment is collected and returned to the Calibration Administrator for re-calibration. The Department assigned the Calibrated equipment shall deliver the equipment to the Receiving Inspection or Calibration Administrator for processing. Each department supervisor/management person is responsible for reviewing calibrated and non-calibrated equipment in their area and notifying the Calibration Administrator if any equipment needs to be added to the Calibration Status Report.
- 4.1.3.1 User functions shall use equipment that contains a current calibration label or Calibration Extension Request approved by the Calibration Administrator when accepting products/materials for ship to customers.
- 4.1.4 Departments not complying with this requirement will be reported to Quality Assurance for corrective action in accordance with ATS-QAP-1006, Corrective Action(s) System.
- 4.1.5 All calibration expired equipment removed or not physically removed from the work area, shall be identified by the using department to prevent unauthorized use. Typical identification methods include tagging/labeling as "Out of Calibration" or "Do Not Use - Requires Calibration".
- 4.1.6 Any equipment whose accuracy is suspect or found to be functioning improperly will be tagged/labeled with the deficiency and "Out of Calibration" or "Do Not Use - Requires Calibration". Any comments or notes attached to the equipment shall be initialed/signed and dated by the person recording the information. The Item is delivered to or removed from the area by the Calibration Administrator for service as required.

- 4.1.7 Equipment requiring repair or calibration will be identified, segregated and held by the Calibration Administrator until pick-up by the calibration service, or rework/repaired and re-calibrated internally by ATS.
- 4.1.8 The Calibration Administrator maintains the Calibration Status Report with necessary information (i.e. Equipment Status or Comments block on the Part Information screen) of all equipment forwarded to the calibration service for accountability purposes.
- 4.1.9 The Calibration Administrator will update the Calibration Status Report (recall list) status as the equipment is calibrated internally or returned from the calibration service using the Calibration Status Report (FORM ATS10-2116) excel spreadsheet. All items returned from the external calibration service shall be routed through the Receiving Inspection area and held for the calibration Administrator for review and records updating.
- 4.1.10 If equipment requires extensive repair, the repair cost will be reviewed by the responsible department supervisor/manager to determine if the cost justifies the repair. Un-repairable equipment will be dispositioned in the same manner.
- 4.1.11 Internal calibration personnel or the calibration service will report all out of tolerance conditions to the Calibration Administrator. Quality Assurance will evaluate all out of tolerance conditions to determine degree of significance and take appropriate action. In general, an out of tolerance condition of more than 10% of the specified operating tolerance will be considered significant. The out of tolerance parameter will be evaluated in conjunction with how the equipment is used in the actual test environment to determine potential impact on product quality. If a significant out of tolerance condition could have affected performance of equipment delivered to a customer, the customer will be so notified. See paragraph 5.1, Nonconforming Material.
- 4.1.12 The Calibration Administrator will notify the using Department promptly when the equipment is available for reissue.
- 4.1.13 The environment in which the test equipment is used shall be controlled in such a manner that measurement accuracy remains within tolerance. This includes temperature, humidity and overall cleanliness. Each operator is responsible for proper handling and maintenance of equipment under use in order to maintain the continued accuracy of the equipment.
- 4.1.14 All equipment and facilities used for receiving inspection, inspection and test activities will be made available to the Customer representative for verification purpose if required by contract. If necessary, Company personnel will be provided to support the Customer verification activity.

4.2 Calibrating Activity Approval and Requirements

- 4.2.1 All calibration subcontractors are evaluated and approved in accordance with ATS-PGP-1001, Purchasing and ATS-PGP-2001, Supplier Evaluation and Approval/Disapproval. Each Calibration subcontractors is considered a Type 1 Supplier and shall be re-approved annually by Purchasing and Quality Assurance.
- 4.2.2 The calibration service shall furnish a calibration record and/or a certificate for the equipment calibrated to assure that established schedules and procedures are followed to maintain the accuracy of the equipment and supporting standards. The records and/or certificates will be filed in the QA Calibration Records file by CIN/Asset Number and made available for review by authorized Customer personnel.

The Calibration Certificate provided by a Subcontractor shall include or provide the following information:

- a) Equipment/Instrument Description (i.e. part number/model/serial number/CIN, etc.)
- b) Subcontractors Equipment Standard(s) used identification, NIST number and calibration expiration date. When the subcontractor is ISO 9001 or ISO 17025, it is acceptable for the Subcontractor to submit the equipment standards used identification and process method or equipment ID number assigned to conduct the calibration
- c) New assigned Calibration expiration date
- d) Subcontractor written approval and date

Example:

<u>Equipment Part Number Used to Perform Calibration</u>	<u>Expiration Date</u>	<u>NIST No. or Subcontractor Equip./Method ID No. (*)</u>
HP12345	07/09/10	123456778

(*) When the Subcontractor is not an ISO 9001 or ISO 17025 registered company and does not provide an NIST traceable number for the standards used, ATS shall obtain a copy of the Calibration Certificate for the standard(s) used to verify traceability and correct information. This information is filed with the subcontractors provided Calibration Certificate.

- 4.2.3 The Calibration Administrator shall file the certificate of calibration from the subcontractor in the QA Calibration Records file by CIN/Asset number folder. When the supplier (new purchased items) or calibration subcontractor assigns their own calibration tracking number to the equipment, the calibration Administrator shall record the ATS assigned CIN/Asset Number onto the supplier/subcontractor provided certification and initial/sign and date the recorded information in order to provide proper certification traecability.
- 4.2.4 The calibration service will provide an adequate means of protecting the equipment from deterioration during storage and transportation.

4.3 Calibration Intervals

- 4.3.1 The Calibration Administrator will determine calibration intervals based on stability, purpose and degree of usage of each piece of equipment.
- 4.3.2 New equipment for which there exists no calibration history will be initially calibrated at the manufacturer's recommended interval. If not specified, a one (1) year calibration interval will be used and can be adjusted by the Calibration Administrator as required based on the performance of the item.
- 4.3.2.1 Secondary standards such as gauge blocks, pin gauges, mechanical measurement and chemical/material standards that are retained and stored in a protective manner by the Calibration Administrator are typically assigned a 2 to 10 year calibration interval as determined appropriate by the Calibration Administrator.
- 4.3.3 The adequacy of calibration intervals will be evaluated as the equipment is calibrated internally or returned from the calibration service based on the out of tolerance data obtained during calibration. Equipment that requires no, or minimal, adjustments during the previous two calibration periods may have its calibration interval extended at the discretion of the Calibration Administrator. The equipment initial Calibration Frequency (interval) may be adjusted by the Calibration Administrator, as warranted, by reviewing other similar equipment calibration history data.
- 4.3.4 Equipment that consistently requires extensive adjustment will have calibration intervals shortened as required to assure continued accuracy. In these instances, an evaluation of the adequacy of the equipment, the calibration procedures, and the test procedures will be made to identify equipment that does not perform satisfactorily.
- 4.3.5 The equipment Calibration Record files will be kept up-to-date reflecting current calibration intervals for each piece of equipment using the Calibration Status Report (FORM ATS10-2116) excel spreadsheet.
- 4.3.6 The Calibration Administrator may extend the calibration due date of equipment in emergency situations. The length of extension shall be determined by the Calibration Administrator based on the complexity of what is to be tested; and the risk of accepting something bad, or rejecting something good. Calibration due date extensions will be based on the results of previous calibrations reflecting satisfactory stability plus its intended use. See Figure 2 – Calibration Extension Request. The Calibration Extension Request form shall be placed with the equipment's QA Calibration Records file by CIN/Asset Number and a new Calibration Label with the updated information placed on the equipment (old one is removed).

- 4.3.6.1 For equipment with an extended calibration date, the Calibration Administrator shall update the Calibration Status Report
- 4.3.7 When equipment is calibrated internally, the instruction or method is issued as a separate ATS-QAI-16XX, Quality Assurance Instruction.
- 4.3.8 When internal Calibrations occur and data is retained, the Calibration Administrator shall record this data using the Internal Calibration Record form for the applicable equipment CIN/Asset Number.
- 4.3.8.1 The calibration data may also be recorded as a memo providing traceability to the item being calibrated. The memo shall include the assigned CIN/Asset number, variable measurements made and pass/fail requirements, calibration standard CIN/Asset number used that is traceable to the NIST standard, method used for calibration, new expiration date, and date and approval of person performing the calibration.
- 4.4 Control of Subcontractors Calibration System
- 4.4.1 ATS purchase orders issued to subcontractors performing Calibration Services are annotated with the following typical requirements:

"Calibration Services (Subcontractor)

The Subcontractor performing the ATS Purchase Order for Calibration Services shall maintain a Calibration System in accordance with ISO 9001 or ISO 17025. The Calibration standards shall be traceable to the National Institute of Standards and Technology (NIST). The Subcontractor shall maintain part number, serial number and/or calibration ID number records for each calibration performed that provide attribute or variable data, traceability to the instrument(s) used to perform the calibration and traceability to NIST standards.

All defective equipment that requires rework/repair (replacement of materials) shall be in writing to and approved by ATS prior to the activity being performed. The Subcontractor shall retain all replacement/defective materials removed from the item and send them in a bag labeled as defective parts with the Item Calibrated back to ATS.

A Certificate of Calibration shall be issued with each item calibrated. The certificate shall include the following minimum information:

- a) Item P/N, Model, Description Being Calibrated
- b) Traceability to NIST, or Subcontractors method (for ISO 9001 or ISO 17025 registered companies only)
- c) Calibration Date

- d) Recommended Re-calibration Due Date (See ATS PO requirements, typically 1 year)

The Subcontractors Equipment P/N or Description, NIST Traceability Number for each equipment used, and Calibration Expiration Date and Approval signature from the person who is certifying the Certificate information is true and accurate."

4.5 Rented/Leased or Loaned Equipment Control

4.5.1 Equipment Rented/Leased or Loaned to ATS for the purposes of judging final acceptance of material/products will be handled and tracked in the same manner normal ATS calibrated equipment.

4.5.2 All incoming rented/leased or loaned equipment must include a calibration certificate traceable to NIST and calibration sticker with at least 6 months remaining before expiration. If not, the equipment will be returned to the provider or scheduled for re-calibration by the Calibration Administrator.

4.5.3 Each rental/lease/loan service will be responsible for the calibration and maintenance of the rented equipment, unless otherwise specified by a ATS issued purchase order. ATS will observe calibration intervals assigned to the equipment by the respective rental service.

4.6 In-Plant Calibration by Subcontractor

4.6.1 Quality Assurance may direct that the equipment calibration be performed at ATS by an approved calibration service. Such activity will conform to the requirements stated in paragraph 4.0 of this procedure. When calibration activities are performed by ATS, ATS is considered the calibration service provider and is responsible for the same activities as the external calibration service defined in this document.

4.7 Definition for What Needs Calibration

4.7.1 Typically, there are many types and pieces of electronic or mechanical measuring devices used in the areas of Assembly/Fabrication, Test, Receiving Inspection, Inspection or Engineering Design. Not all these items needed to be calibrated. The items that need to be calibrated are those measurement devices that are used to **final accept or reject** customer materials/products based on the Customer order requirements.

4.7.2 When a Customer order defines specific variable or attribute requirements, the Material/Product shall be inspected/tested to ensure each requirement is met. When the **“Final Inspection/Test”** is performed (Test or Quality Assurance), the proper measurement device (10 times better accuracy) shall be selected to make the measurement. The measurement device that is used to judge final acceptance of these requirements shall be calibrated as stated in this document. When a specific requirement

must be verified at earlier assembly levels (because it can not be measured at final inspection/test), the equipment used to make this measurement shall also be calibrated.

- 4.7.3 Measurement equipment that are used at earlier fabrication levels (that are not making final acceptance measurements) need not be calibrated. In order to prevent rejection of acceptable product, Quality Assurance shall define the means that shall be used to ensure that the measurement device provides the right level of accuracy needed without causing the company to be charged for external calibration costs.
 - 4.7.3.1 When similar measurement equipment are used, multiple measurements from each piece of equipment shall be made using the same source and the measurement results compared for differences. When the differences are minimum based on the measurement type, Quality Assurance may authorize this piece of equipment for passing or failing product at earlier fabrication steps before Final Inspection/Test.
- 4.7.4 Measurement equipment that is used to make relative measurements (non-production analysis, line meters or pressure gauges, etc.) and are not used to accept final product shall be labeled “REFERENCE ONLY” or “CALIBRATION NOT REQUIRED”. The item may be painted/marked/tagged Yellow in color when labeling is not practical (environment or size issues) to indicate for Reference Only.
- 4.8 Special Process Equipment/Tool/Fixture
 - 4.8.1 When special equipment/tool/fixture is used during manufacturing to perform fabrication processes (i.e. component lead forming, crimping, drill hole locating, etc.), the equipment/tool/fixture shall be labeled “Calibration Not Required”. When necessary to control these types of equipment/tools/fixtures, Set-Up or First Article Inspection points are established during the normal process flow by Quality Assurance.
 - 4.8.2 When the Assembly/Test operator or Quality Assurance finds that the equipment/tool/fixture is incapable of producing the needed result or is producing nonconforming material, the equipment/tool/fixture shall be labeled “OUT OF CALIBRATION” until repaired or proven to be fixed.
 - 4.8.3 When determined by Quality Assurance that an equipment/tool/fixture is critical to a specific process, Quality Assurance may add the item to the normal Calibration System for control and scheduled calibration purposes. The type of calibration that shall be performed shall be defined by Quality Assurance.
 - 4.8.4 When a Fabrication/Assembly/Inspection drawing aid is printed to scale (i.e. 1:1) and is to be used for process control measurement purposes, the aid's accuracy shall be checked using a calibrated instrument and approved prior to usage. The aid shall be identified with

a part number and revision and Document Control identification number, and contain or be stamped/labeled with the following typical information:

Note:

1. Template is to Scale
2. Verify Lengths Prior to Use

Length Verified by: _____ Date: _____

Template Accurate to: +/- _____

4.8.4.1 A record showing traceability to the CIN/Asset Number used to check the aid is not required. Aids are not tracked using the Calibration Status Report. Aids are removed from usage when destroyed or found not to be effective by the area group leader/supervisor or Quality Assurance. Configuration Management is responsible for issuing controlled copies of drawing aids with part numbers and revisions, and removing obsolete copies from use. See ATS-DCP-1001, Document Control for additional information.

4.8.4.2 The area group leader or supervisor, inspector or Quality Assurance shall verify the drawing aid's accuracy and approve prior to use.

5.0 QUALITY ASSURANCE

5.1 Nonconforming Material

5.1.1 All product discrepancies shall be recorded using a Defect Report (DR) form and submitted for disposition in accordance with ATS-QAP-1005, Nonconforming Material System.

5.2 Audits

5.2.1 Quality Assurance shall be responsible for performing audits as scheduled per ATS-QAP-1008, Internal Audits.

6.0 CALIBRATION SYSTEM LABELS

6.1 Labels

6.1.1 The following are **typical** calibration system labels that are used to support this procedure. Calibration Identification Number is assigned by ATS in accordance with this procedure. Actual visual appearance of the Calibration Labels may vary for subcontractors or suppliers of the labels:

<p style="text-align: center;">CALIBRATED</p> <p>CIN No.: _____</p> <p>Expiration Date: _____</p> <p>Approval: _____ Date: _____</p>

<p style="text-align: center;">OUT OF CALIBRATION</p>
--

<p style="text-align: center;">CALIBRATED</p> <p>Expiration Date: _____</p> <p>Approval: _____ Date: _____</p>

<p style="text-align: center;">REFERENCE ONLY</p>
--

(Use with Asset ID Tag)

<p style="text-align: center;">CALIBRATION NOT REQUIRED</p>
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<p style="text-align: center;">CALIBRATED</p> <p>By: _____ Date: _____</p> <p>Due: _____</p>

(Use with Asset ID Tag)

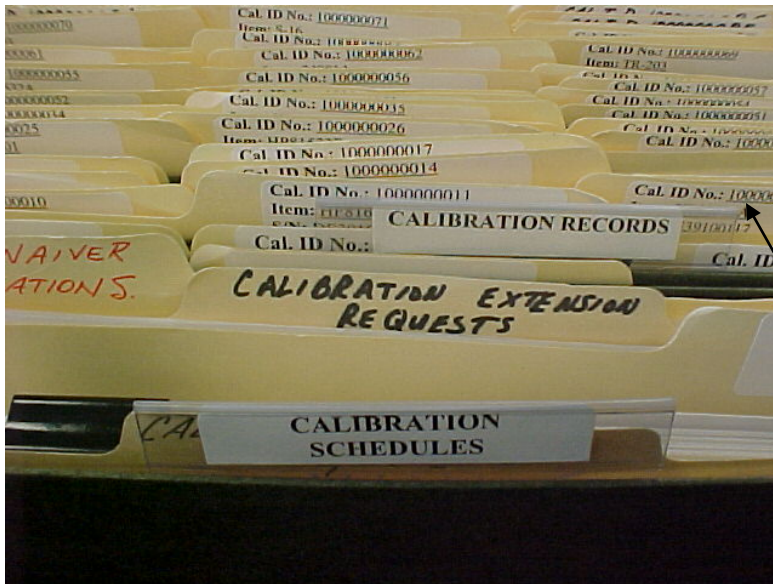
Note:

- 1) When a Subcontractor is used to perform Calibration Services, the Subcontractor's labels may be used if the label contains the information specified in this procedure.

Figure 1 - Typical Calibration Documentation Photo(s)



Calibration Records File



Calibration Record Folder

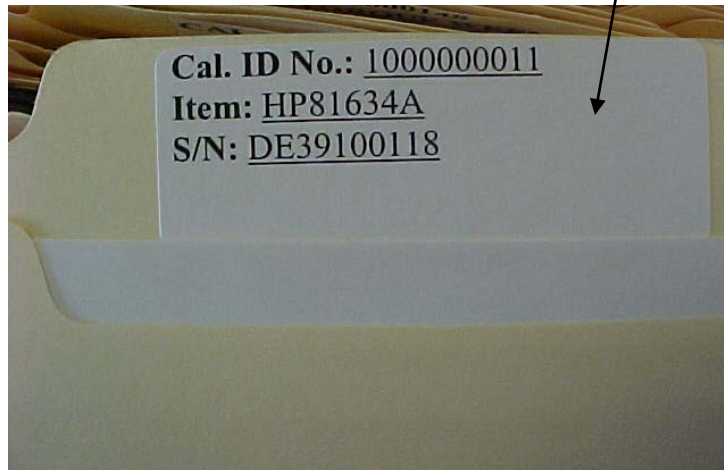


Figure 2 – Calibration Extension Request

Calibration Extension Request

A - GENERAL

Originator Name: _____ Date: _____

To: Calibration Administrator/Quality Assurance Department

Calibration Identification No.: _____ Current Expiration Date: _____

Item Description: _____ Location: _____

B – REASON FOR EXTENTION

___ 1) Equipment is involved in Product Testing/Inspection and
Customer delivery would be impacted if taken out of service. Equipment is in good
Working order.

___ 2) Other: _____

C – EXTENTION AUTHORIZATION JUSTIFICATION

___ 1) The Item has no history of prior calibration accuracy problems.
___ 2) The Item appears to be in good working order with no obvious physical damage
___ 3) Other: _____

D – EXTENTION REQUEST APPROVAL

Requested/Authorized New Expiration Date: _____

Extension Approved by Calibration Administrator: _____ Date: _____