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1 PURPOSE

- 1.1 The purpose of this Quality Management System (QMS) work instruction is to:
- 1.1.1 Inform users of Measurement and Test Equipment (M&TE) of potential quality problems originating from Out-of-Tolerance (OOT) conditions. When found to be OOT, M&TE are identified, reported, and the impact assessed in a timely manner. Immediate notification is provided to the user’s Supervisor, Manager, Manufacturing Engineer, Metrologist and/or Calibration Quality Engineer depending on the area.
 - 1.1.2 Provide a method of assessing the impact on measurement, testing, and/or manufacturing processes when M&TE is found OOT after recalibration. The overall intent, beyond ensuring credible measurements, calibration, and performance data to our customers, is to meet or exceed the requirements of ISO 9001 and ISO/IEC 17025.


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2 SCOPE

- 2.1 The scope of this QMS Work Instruction (WI) applies to all “Active” M&TE identified in the Met/Team Database. In addition, the notification process for external customer M&TE (identified as “Inactive” asset) is also summarized in this procedure.
- 2.2 This WI procedure applies to MTS Calibration Organization Personnel (MTSCOP) when issuing an OTN during the calibration of M&TE.

3 ACRONYMS AND DEFINITIONS

- 3.1 Acronyms
 - CA – Corrective Action
 - FSE- Field Service Engineer
 - ILAC- International Laboratory Accreditation Cooperation
 - M&CL- Metrology and Calibration Laboratory
 - M&TE- Measurement and Test Equipment
 - MTSCOP- MTS Calibration Organization Personnel
 - NAFS – North American Field Service
 - OOT- Out-of-Tolerance
 - OTN- Out-of-Tolerance Notification
 - PMU- Potential Measurement Uncertainty
 - QMS- Quality Management System
 - RSS- Root Sum Square
 - SQG- Service Quality Group
 - UUT – Unit Under Test
 - WI- Work Instruction
- 3.2 Definitions
 - 3.2.1 Customer/User- Anyone who is either the user of, or is responsible for, any equipment potentially affected by the M&TE OOT condition. This includes anyone within the MTS organization, as well as any outside customer who is the owner/user of potentially affected equipment.
 - 3.2.2 M&TE - Electrical and mechanical devices used to measure or control electronic

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and physical properties for purposes of product build, evaluation, acceptance, and test. Devices require re-calibration per [WI 604A, Recalibration Process](#). Also see [MFG_050, Corporate Measurement and Test Equipment \(M&TE\)- Asset Control and Identification](#).


- 3.2.3 OOT condition- A condition when a performance or operating parameter exceeds the permissible error, usually manufacturer's specification.
- 3.2.4 Simple acceptance/shared risk method- The MTSCOP provides measured values and applicable uncertainty to the customer for evaluation. It is the customer's/user's responsibility to assess the impact that the reported measurement uncertainty has on the measured value. Using this method, In-Tolerance and OOT are the two possible outcomes reported by the MTS M&CL. [ILAC-G8](#) defines this as Simple Acceptance- A decision rule in which the acceptance is the same as the tolerance limit.

4 GRAPHIC

N/A

5 RESPONSIBILITIES


- 5.1 Calibration and Metrology Supervisor/Manager or Principal Engineer
 - 5.1.1 Reviews the open OTN for complete record disposition.
 - 5.1.2 Reviews and approves completion of OTN.
 - 5.1.3 Maintains this document, authorizes changes, and ensures MTS Calibration Organization operations comply with all elements.
- 5.2 MTSCOP
 - 5.2.1 Validates OOT condition with a reproducibility run of the OOT parameter(s). Validation data of the OOT is recorded with the original calibration data and identified as such.
 - 5.2.2 Identifies, documents and labels M&TE found to have an OOT condition.
 - 5.2.3 Prepares the OTN.
 - 5.2.4 Segregates OOT equipment from other equipment if not currently being worked on.

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- 5.2.5 Performs or arranges for the repair, adjustment, or replacement of OOT units.
- 5.2.6 Performs recalibration of corrected units prior to return to service.
- 5.2.7 Provides support to the M&TE user in assessing the OOT and follows up with M&TE user to ensure prompt assessment.
- 5.2.8 Updates the Met/Team Database.
- 5.2.9 Ensures closure of the OTN in Met/Team.
- 5.3 Customer/User/Responsible Person (Supervisor/Manager, Metrologist, Calibration Quality Engineer, Manufacturing Engineer of M&TE)
 - 5.3.1 Assesses the impact, accepts all decision-making accountability of all OOT conditions when documented on the OTN received from M&CL per this WI. Determines when resumption of work can commence after the OTN is complete.

6 PROCEDURE

- 6.1 Simple acceptance/shared risk decision rule
 - 6.1.1 When declaring in-tolerance or OOT conditions, MTSCOP utilizes the simple acceptance decision rule, unless customer specifies an alternative method. In-Tolerance and OOT condition are the two possible outcomes using this method. When parameter(s) are certified to be within specified tolerances, the measured value(s) shall fall within the appropriate specification limit and the uncertainty of the measured value shall be stated and provided to the customer for evaluation. The uncertainty is NOT included in the assessment. With written agreement from the customer, alternate decision rules may be used. This applies to accredited calibrations.
- 6.2 Procedure
 - 6.2.1 During use or normal calibration, a unit may be found to be OOT. An OOT condition exists when a parameter exceeds a defined permissible error, usually a manufacturer's specification.
 - 6.2.2 Any M&TE is suspected to be OOT:
 - 6.2.2.1 If proper functioning is subject to doubt.
 - 6.2.2.2 If calibration seal integrity has been violated.


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- 6.2.2.3 If it appears to have been damaged, overloaded, or mishandled.
- 6.2.2.4 If it has exceeded its designated calibration interval.
- 6.2.2.5 If it displays any malfunction.
- 6.2.3 Validating an OOT
 - 6.2.3.1 Validation of OOT is required by acquiring an additional reproducibility run by the MTSCOP.
 - 6.2.3.2 Validation data of the OOT is recorded with the original calibration data and identified as such.
 - 6.2.3.3 Validation data is for M&CL records only unless requested by the customer.
 - 6.2.3.4 If applicable, additional data points should be taken to identify where within the range of the UUT the OOT occurs. For example, if an OOT is identified at 50%, but not at 40% or 60%, additional data points would add clarity to the extent of the OOT.
- 6.2.4 Action(s) may include one or all the following:
 - 6.2.4.1 Adjustment of the parameter and recalibration.
 - 6.2.4.2 Repair and recalibration.
 - 6.2.4.3 Adjustment of calibration intervals.
 - 6.2.4.4 Removal of the item from use and/or available inventory.
 - 6.2.4.5 Limited Use, if agreed upon with the user.
- 6.2.5 OOT M&TE that is not returned to service is identified, labeled, and segregated from other units.
- 6.2.6 For all “Active” and “Recalled” M&TE, the M&CL OTN is issued from the Met/Team database if the unit is OOT. Instructions for generating an OTN from the Met/Team database are in [WI 1800, Met/Team Database for Users](#).
- 6.2.7 Applicable data sheets are attached and delivered (electronically or physically) to the MTS customer/user Supervisor/Manager/Manufacturing Engineer/Metrologist within one working day.
 - 6.2.7.1 When the customer/user is for NAFS, it is emailed within one working day to the SQG Metrologist and Calibration Quality Engineer.

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- 6.2.7.2 When the customer/user is in Manufacturing, it is emailed within one working day to customer/user and Manufacturing Engineer.
- 6.2.8 The Met/Team assigns a unique number to the OTN, and this number is stored in the database. The OTN contains the following:
 - 6.2.8.1 Username (This could be the department Supervisor/Manager).
 - 6.2.8.2 Location (If applicable).
 - 6.2.8.3 OTN#.
 - 6.2.8.4 Print date.
 - 6.2.8.5 MTS asset number.
 - 6.2.8.6 Manufacturer.
 - 6.2.8.7 Model number.
 - 6.2.8.8 Description of unit.
 - 6.2.8.9 Cal date and previous cal date.
 - 6.2.8.10 Out of Tolerance Notes.
 - 6.2.8.11 Calibration Technician reporting the OOT condition.
 - 6.2.8.12 Section for the user to document impact assessment/analysis.
 - 6.2.8.13 Section for asset user or responsible person printed signature and date.
 - 6.2.8.14 Data sheets including As Found and As Left data for those parameter/s found to be OOT as noted on OTN.
 - 6.2.8.15 Section for approval printed signature and date.
- 6.2.9 OTN Met/Team database entry for Internal Customer\User

An OTN is entered into the Met/Team database the same as any calibration history except, a 21, 22, 23, or 25 is placed in the Rel field. This allows tracking of the open OTN's.
- 6.2.10 Rel Field Codes for Out-of-Tolerance:
 - 6.2.10.1 21 Received Out-of-Tolerance, Returned In-Tolerance.
 - 6.2.10.2 22 Received Out-of-Tolerance, Returned Out-of-Tolerance.
 - 6.2.10.3 23 Received Out-of-Tolerance, Returned Inoperative.

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6.2.10.4 25 Received Out-of-Tolerance, Inactive.

- 6.2.11 If an asset is OOT and sent out for repair and returned for calibration, a Y in the Closed OTN field is required to avoid duplication of identical OTN’s within the database.
 - 6.2.12 A brief explanation as to the OOT condition is recorded in the OTN notes field in Met/Team database. “See calibration report” in the OTN notes field may be needed to adequately explain the OOT condition.
 - 6.2.13 It is the responsibility of the M&CL Supervisor/Manager or Principal Engineer to review and approve the OTN after the user has assessed the impact of the OTN.
 - 6.2.14 Upon approval of the OTN, the MTSCOP shall update the “OTN Closed” field in the Met/Team database by entering “Y”. It is also necessary to annotate the OTN closed date and MTSCOP initials in the “Out of Tolerance” field of the calibration record to show when the OTN was closed and by whom.
 - 6.2.15 The “Open” OTN report is reviewed each month by the M&CL Supervisor/Manager or Principal Engineer to ensure forms are returned, and the OOT incident is “Closed” in a timely manner.
- 6.3 External Customer Owned Equipment
- 6.3.1 External customer devices are considered inactive M&TE. All OOT conditions are identified on the calibration data on the calibration report making it readily apparent to the user. We do not expect acknowledgement nor assessment results in these cases.
- 6.4 Asset OOT with no OTN generated for External Customer
- 6.4.1 If the asset was OOT and a 21, 22, 23, or 25 is entered in the rel field, but an OTN will not be issued, a Y is entered in the OTN closed field so the open OTN report will not identify this asset as an open OTN.
- 6.5 Quality Records
- 6.5.1 The MTSCOP records the required information. Forms are scanned and filed in the M&CL mspdata1 directory. All MTSCOP has access to the file.
- 6.6 Issuing OTN
- After determining an OOT condition, the M&CL issues an OTN.
- 6.7 Customer/User Assessment of OTN

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6.7.1 Upon receiving the OTN, the responsible person evaluates the impact of the OOT condition/parameter on measurement, manufacturing, calibration, and/or testing processes performed with that M&TE since its last calibration.

6.7.2 Timeliness of this assessment is critical. A two-week time frame would be reasonable to review:

6.7.2.1 Where the instrument was used.

6.7.2.2 What it was used for.

6.7.2.3 When it was in service.

6.7.2.4 Impact of the OTN.

6.8 OTN Requirements

6.8.1 The OTN process and associated records are critical to MTS' ability to consistently deliver the highest quality products and services. The M&TE Customer/User, in the case of an OOT condition, provide the following information on the OTN as a minimum:

6.8.1.1 Complete description involving the course of action taken along with the specific corrective action taken.


6.8.1.2 Copies of all written correspondences, electronic and printed, sent to any customer (i.e., e-mails, form letters, memos, etc.).

6.8.1.3 List of all potential customers or processes involved, in addition to a brief statement of the resolution for each one.

6.8.1.4 Printed name of individual completing OTN and date.

6.9 OTN evaluation/assessment

6.9.1 If the responsible person determines the impact is of little or no risk to product performance or process, and no corrective action is required, they complete the OTN received from the M&CL, stating no further assessment or action is required. The responsible person also needs to briefly describe the methodology used to determine the impact of the OOT condition. The responsible person returns the OTN to the M&CL for review and approval. If the impact of the OOT condition could potentially impact product performance the responsible person must immediately initiate a course of action to identify all product and customers affected and implement a corrective action process. The corrective action process may include any of the following: product recall, recalibration, performance re-

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verification, data correction factor, new adjustment procedure, or other corrective actions as required.

6.9.1.1 NAFS: the Metrologist will work with the responsible person to assess the impact.

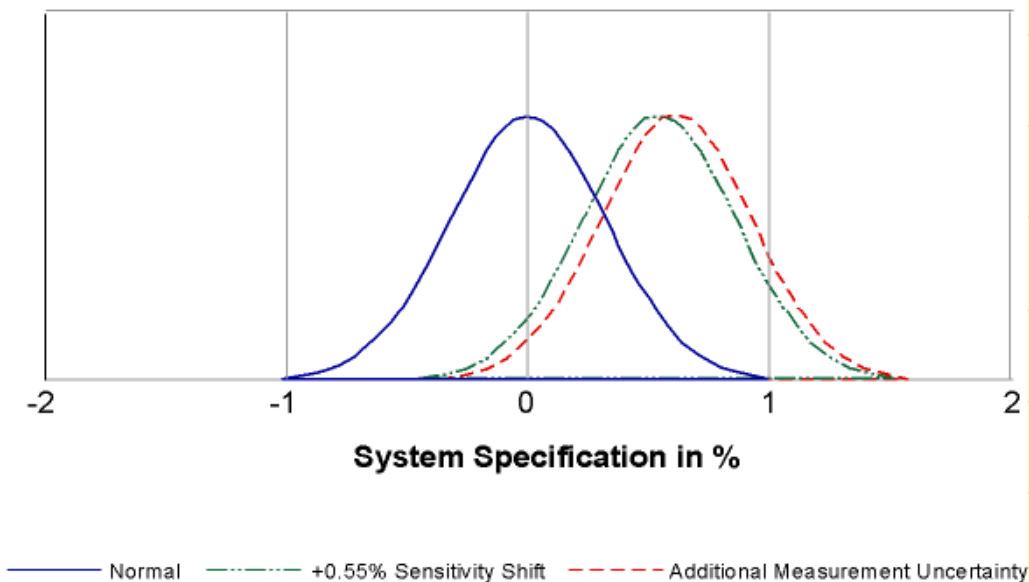
6.9.1.2 Manufacturing: An assigned Manufacturing Engineer may work with responsible person to assess the impact.

6.10 Example of Impact Assessment

6.10.1 An OTN was issued for a torque transducer. The MTS M&CL recalibration process found the sensitivity percent change exceeded the $\pm 0.25\%$ tolerance. The largest percent change observed for the torque transducer was $+0.55\%$ of the measured torque.

6.10.2 The torque transducer is used to calibrate an MTS torsional system with a specification of $\pm 1.0\%$ of applied torque. Using the theory of normal distribution, we will assume that 95% of the system measurements will perform within $\pm 1.0\%$, with the system calibrated to nominal. See Figure 1.

**Assessing OTN Using Normal Distribution
RSS Method**





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Figure 1

- 6.10.3 A bias shift of +0.55% may have shifted the distribution curve of the system calibration performed by as much as +0.55% as shown in Figure 1.
- 6.10.4 Furthermore, it is important to assess the impact of additional uncertainty components related to the overall calibration process. All calibration processes should have an established measurement uncertainty.
- 6.10.5 The added uncertainty when calibrating a torque measuring system may include, but may not be limited to, the following additional sources of measurement uncertainty (reference [QMS 706, Measurement Uncertainty](#)):
 - 6.10.5.1 Reported measurement uncertainty of the torque standard transducer.
 - 6.10.5.2 Signal conditioner DCV output measurement uncertainty using a voltage measuring instrument such as a digital multimeter.
 - 6.10.5.3 Environmental effects such as temperature.
 - 6.10.5.4 Mechanical fixturing effects.
 - 6.10.5.5 Operator contributors.
 - 6.10.5.6 Repeatability, resolution, and reproducibility
- 6.10.6 The combined amount of uncertainty due to these contributors must be evaluated and stated within some level of confidence, typically 95%. These measurement uncertainty contributors may be combined to produce a total measurement uncertainty using two methods. Utilizing one method, each contributor can be combined by the method of RSS. Utilizing a second method, a direct sum method, would tend to be overly conservative when establishing a value of uncertainty for a calibration process. Therefore, it is suggested that the RSS method of combining the various measurement uncertainty components be utilized.
- 6.10.7 In evaluating the impact on calibration data produced with an OOT reference standard, we must include the system calibration process uncertainty in our overall assessment. Throughout a range of calibration, the amount of measurement uncertainty differs. The uncertainty is usually larger as a percentage of the measurement at the low end of a range. One could assess the measurement uncertainty at each data point acquired throughout the range and this would be valid. However, this process can also be quite time consuming. Using the maximum measurement uncertainty component for the calibration process is

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acceptable and will in many cases yield a slightly conservative value to the assessment. This is especially true if the reference standard OOT is at the upper portion of a normal range of calibration data.

6.10.8 If the calibration process is determined to have a maximum measurement uncertainty of $\pm 0.25\%$ of applied torque for a confidence level of 95%, we need to include this by the RSS method to determine the full impact of the reference standard OOT on the calibration data supplied for the system. For this example, the resultant assessment adjustment to the data will become:

$$PMU = (\text{Square Root of } ((0.55\%)^2 + (0.25\%)^2)) = 0.60\%$$

6.10.9 Figure 1 visually displays the results of combining these uncertainties by the RSS Method.

6.10.10 Tracking which customers might be affected by a reference standard OOT, is aided by utilizing MTS tools, such as the Zero Tracking Log that contains a record of each customer site where the reference standard was used.

6.10.10.1 Starting with the latest entry on the Zero Tracking Log, the data for all calibrations performed with the reference standard for the customer listed, must be assessed.

6.10.10.2 Review all the data produced with the reference standard and compensate the data by the combined measurement uncertainty.

6.10.10.3 If the system calibration data is found to be out of acceptable tolerance when compensated, corrective action must follow.

Example of calculation:


Calibration Data Point Error(s) + PMU = x

Is $x < \pm 1\%$?

6.10.11 At the very least, when corrective action is required, the customer must be notified of the potential OOT condition. The customer may elect to leave the system as is. In such cases, appropriate written records shall be made of this decision for future reference.

6.10.12 Calibration data cannot simply be compensated or corrected by the determined OOT corrections, resulting in a new calibration report re-issued to the customer.

6.10.13 Corrective action may include verifying a calibration by performing a spot check throughout the calibrated ranges of the system. If the spot check shows that the

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system is not performing within specification and reflects an OOT condition, a full recalibration is required. The system user shall be notified so they may assess the impact of the OOT condition.


- 6.10.14 The tracking of customers affected is continued until it can be determined that the system calibrations were no longer affected by the reference standard OOT.
- 6.11 Once the impact assessment is completed and appropriate action has been taken, the OTN form is completed with enough detail and supporting documentation to provide confidence the resolution.
- 6.12 The completed OTN is returned to the M&CL for approval and closure and retained as a record. The OTN can be completed and closed with a CA still open. The CA number will be referenced on the OTN form.

7 ASSOCIATED QUALITY RECORDS

Required Record	QMS Web Location
Met/Team database	N/A
OTN (completed)	QMS Home Page
Training Record	QMS Home Page

8 REFERENCE FORMS / TEMPLATES / DOCUMENTS

Form / Template / Document Title	QMS Web Location
OTN Form	Met/Team database report generator
WI 604A, Recalibration Process	QMS Web Page
WI 1800, Met/Team Database for Users	QMS Web Page
QMS 706 Measurement Uncertainty	QMS Home Page
MFG_050, Corporate M&TE - Asset Control and Identification (SABA 0000004275)	QMS Home Page
ILAC – G8	On File


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9 CURRENT REVISION TRAINING REQUIREMENTS


SABA Course	Awareness	Read & Test	Functions or groups that require this training
MFG_CAL001_OV RVW	X		MTSCOP

10 REVISION HISTORY & APPROVAL


Revision History			
Rev	Description of Change	Author	Effective Date
H	<p>Added Principal Engineer as an option for approving OTN.</p> <p>Added clarification that an assigned ME may work with responsible person to assess OTN.</p> <p>Changed Customer/User to responsible person in 6.7.1 and 6.9 to encompass anyone involved with making the decision.</p> <p>Document Reviewed, minor edits made.</p>	Dave Kreitlow	18-Dec-2023
G	<p>Added in Metrologist and CQE in Section 1.1.1, 5.3, 6.2.7.</p> <p>Added CA and UUT into Section 3.1.</p> <p>Changed all MC&L to M&CL.</p> <p>Section 6.2.6 Changed WI 800 to WI 1800 and added in “Recalled” assets.</p> <p>Added steps in to 6.9.1 & 6.9.2 for NAFS</p> <p>Added step in 6.12 for the ability to close out the OTN while the CA is still open.</p>	Tiia Plath	21-Jun-2022

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F	<p>Section 6.2.8 change:</p> <p>When the customer/user is a NA FSE, it is emailed within one working day to the FSE Service Manager, NA SQG Calibration Quality Engineer, and NA Metrologist, and the FSE.</p>	DJ	13-Apr-2022
E	<p>Merged QMS 604C, <i>Out-of-Tolerance Notification</i>, and QMS 604D, <i>Out-of-Tolerance Assessment</i>, into WI 604C.</p> <p>Eliminated duplication from merging.</p> <p>Changed from a QMS document to a WI due to QMS alignment project and content being specific to Metrology and Calibration Laboratory.</p>	DK	15-Dec-2021
D	<p>Document Review. Added Simple Acceptance terminology (per ILAC G-8) as synonymous with Shared Risk Method. Minor editorial changes.</p>	DK	03-Sep-2020
C	<p>Document Review. Minor editorial changes.</p>	DK	08-Aug-2019
B	<p>Changed Document ID from QMS505C to QMS 604C to align with new ISO 17025 Revision.</p>	DK	03-Jan-2018
A	<p>Document Review- Converted format to new corporate template, including letter revision. No additional changes.</p>	DK	07-Jun-2017
31	<p>Document Review.</p> <p>Added “NA Quality Manager” to “When the user is a NA Field Service Engineer (FSE), it is emailed within one working day to the FSE Supervisor/Manager, NA Quality Manager, NA Technical Manager, and the FSE.”</p>	DK	03-Jun-2016

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30	Added to Section 6.2: If applicable, additional data points should be taken in an attempt to identify where within the range of the UUT the OOT occurs. For example, if an OOT is identified at 50%, but not at 40% or 60%, additional data points would add clarity to the extent of the OOT.	DK	05-May-2015
29	Document Review. Minor editorial changes made.	DK	06-Feb-2015
28	Document Review. No Changes needed.	DK	03-Jan-2014
27	Document Review. Minor additions to what is included on the OTN.	DK	08-Jan-2013
26	Ensured consistency with term “Out of Tolerance Notification” (i.e. removed the word “form” after OTN). Section 8 replaced OTN location from QMS Web Page to “Metrology Data Base (Met/Track Report Generator)”. Section 9 added reference to WI 800. Document Review.	DK	13-Jan-2012
25	Added requirement to validate Out of Tolerance calibration data with a reproducibility run. Document Review	DK	29-Mar-2011
24	Converted from SOP to QMS Procedure- Minor grammatical changes Document Review	DK	29-Jun-2010
23	Added Key Words. Minor editorial changes. Document Review	DK	20-May-2009
22	Clarified Database entries	DK	25-Apr-2008
21	Adopted as 505C- Document Review	DK	24-Mar-2008
20	Document Review- Minor Editorial Changes	DK	13-Apr-2007
19	Added technical manager for NA Field Service OTN distribution	DK	02-Dec-2006
18	Document Review- Minor Editorial Changes	DK	16-Feb-2006
17	Document Review-Removed Users from Responsibilities of Supervisor/Manager & Users of M&TE	DK	24-Feb-2005
16	OTN issued to M&TE Supervisor/Manager instead of user	DK	15-Oct-2004

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15	Minor edits for clarification.	DK	29-Dec2003
14	Renamed from a corporate QMS procedure to a locally controlled standard procedure.	DK	30-Sep-2003
13	Changed owner from Chuck Madden to Dave Kreitlow	DK	07-Aug-2003
12	Changed owner from Gaylord DeGroot to Chuck Madden and changed Title. Change to process overview to incorporate a decision rule for out- of-tolerance conditions.	CM	01-May-2002
11	Changed to incorporate ISO17025 requirements and provisions of external customers	GD	31-Oct-2002
10	Changes needed to utilize Met/Track 5.0 and changes to OTN form #0299.	GD	25-Feb-2009
9	Minor edit for clarification. Added Service Managers in distribution of OTN form. Under responsibilities added users of M&TE.	GD	04-Dev-1997
8	Added QMS #0417 to Related Documents section	GD	22-Aug-1996
7	Clarification of Quality Records	GD	16-May-1996
6	Added item 2 - when user is Field Service Engineer; item 6 - removed 1180; item 9 - added heading; removed 1180 from Related Documents section.	GD	16-Jan-1996
5	Item 4 - added second sentence. Item 5 - Changed the distribution of the OTN form. Added item 9 - customer owned equipment	GD	17-Jul-1995
4	Responsibility change in item 4. Under Responsibility section, moved Chief Inspector responsibility to Metrology Technician and deleted Chief Inspector	GD	14-Dec-1994
3	Added QMS Doc Numbers to Related Documents section	GD	01-Nov-1994
2	Minor edits for clarification / ease of reading	GD	26-Sep-1994
1	Placed into control	GD	27-Jul-1994

	<p align="center">QMS Work Instruction MTS Systems Corporation – MTS Test</p>	<p>Document ID: WI 604C</p>	<p>Rev.: H</p>
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<p>Work Instruction Owner(s) – list Functions, not persons: MTS Calibration Organization</p>			

Required Approvers for Current Revision	
Name	Function
Dave Kreitlow	Calibration and Metrology Principal Engineer