ERL MAINTENANCE SUPPORT SDN BHD

Co. Reg. No. 199901023674 (498574-T)

E-MAS

Effective Railway Operations; Reliable System Maintenance

PROJECT & ENGINEERING DEPARTMENT

MEASURING INSTRUMENT VALIDATION MANAGEMENT PROCEDURE

Ref. No. E00.OMD.M01000.BT.1001.B

Release

Released: f	Ham Mow Wai	Maintenance	16.03.22	
Checked:	Jayarajah Savarimuthu	Rolling Stock & Engineering	16.03.22	
Checked: f	Anthony Arokianathan	Wayside	16.03.22	
Checked:	Noel Devan	Systems	2 March 2022	
Checked:	Abdul Halim Baharom	Infrastructure	2.03.22	AB HALIM 039
Checked:	Norazman Abu Hassan	Rolling Stock	23.02.22	
Checked:	Gan Lee Hong	Procurement	23.02.2022	
Checked:	Haryati Khalil	CEO Office	22.02.2022	
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Checked:	Muhamad Dzulfaqar Yusoff	Project & Engineering	17/02/2022	f
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	Name	**Dept.**	**Date**	**Signature**

Amendments or additions to this procedure must be indicated with a vertical black line in the adjacent left margin.

Change Record and Configuration Control

Revision	Date	Modification	Name
B	17-2-2022	Adding checked personnel for releasing the procedure.	Amir
A	1-6-2021	New Release.	Imran

Planning Of Changes Reference For Revision: E00.OMD.M01000.BT.1001.B					
Issues To Consider	**Checked** *(Please mark X)*				**Remarks**
1) Are there any negative impact?	YES		NO	X	
2) Will the integrity of QEMS be affected?	YES		NO	X	
3) Resources available?	YES	X	NO		
4) Allocation or relocation of responsibilities and authorities required?	YES		NO	X	

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1 Purpose

This document describes the management for calibration, verification and self-test of measuring instrument and equipment owned by PNE department.

The objective of validation in this document is to ensure such instrument and equipment is producing reliable measurement reading and guidance to handle doubtful issues in measurement.

2 Scope, Distribution & Access

This document is managed by the PNE Department. The distribution and access shall be available to all PNE staff via the EDMS and through the E-MAS portal.

3 Abbreviation, Terminology and Definition

3.1 Abbreviations

Asterisk (*)	Refer to the latest version
EDMS	Electronics Document Management System
E-MAS	ERL Maintenance Support Sdn. Bhd., Co. Reg. No.199901023674 (498574-T)
HOD	Head of Department
PNE	Project and Engineering
ESD	Engineering and System Development
ERC	Electronic Repair Centre
DWE	Depot and Workshop Equipment
WS	Working Standard Device

Table 3.1 – Abbreviation List

3.2 Terminology and Definitions

Note

1) International vocabulary of basic and general terms in metrology (VIM) 2004 [http://www.geste.mecanica.ufrgs.br/medterm/ISO_VEM.pdf]

3.2.1 Validate, Validation and Validated

“The confirmation through examination of a given item and provision of objective evidence that it fulfils the requirements for a stated intended use”. Item 2.28 in Note 1.

This term will be used as general wording representation for calibration, verification and self-test in this document, depending on situation and requirement.

3.2.2 Calibration

"An operation that establishes the relation, obtained by reference to one or more measurement standards, that exists under specified conditions, between the indication of a measuring system and the measurement result that would be obtained using the measuring system". Item 2.22 in Note 1.

This term will be used as a comprehensive validation process which covers more parameters compared to verification.

3.2.3 Verification

"The confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements". Item 2.27 in Note 1.

This term will be used as a general validation process which substitutes the calibration in a limited manner within this document.

3.2.4 Self-Test or Functional Check

A diagnostic test that a system performs on itself based on built-in function or with the aid of external devices.

3.2.5 Correction

The modification applied to a quantity value obtained from measurement, to compensate for a systematic effect. Item 2.32 in Note 1.

3.2.6 Working Standard

"Measurement standard that is used routinely to calibrate, verify, or check measuring systems, material measures, or reference materials" Item 5.6 in Note 1.

Working Standard Devices (WS) is the reference instrument used for the validation process.

3.2.7 Working Instrument

The measurement instrument for measuring a physical quantity.

3.2.8 Error of Measurement

Difference of quantity value obtained by measurement and true value of the measurand. Item 3.10 in Note 1.

Error is expressed in percentage (%) value in this document. The following is the error calculation for this document:

$$\% \text{ error} = \frac{\text{Measured Value} - \text{True Value}}{\text{True Value}} \times 100\% \qquad \text{……Equation 3.1}$$

4 Abbreviation, Terminology and Definition

Please refer to the following records for instruments listed for measurement validation:

1) PNE ERC Calibration Monitoring Record[1].
2) PNE DWE Equipment Calibration Monitoring Record[2].

Other measurement instruments such as ruler and callipers owned by PNE are for general use and may not be included in the list and may not be validated. It shall not be used for critical measurements.

In case such critical measurement is required but PNE does not possess such instrument, it shall be loaned from other sources.

5 Validation Requirement and Intervals

The following are used as a guideline for the calibration or verification fundamentals:

1) Measurement parameter or function
2) Usage frequency
3) Acceptable measurement error
4) Regulatory and legal requirement

Any of these may rule out others depending on practicability.

5.1 Measurement Parameter or Function

The user has to determine the usage parameter or function of the measuring instruments based on their work requirements and conditions. If the said instruments are being used for a particular work, the requirement will cover only for that particular work.

5.2 Usage Frequency

The user shall decide the interval based on the usage. The following provides the general guideline for validation interval. However, it is subjected to availability and practically. This, however, does not apply to the digital multimeter.

Usage Frequency	Calibration	Verification	Self-Test
Daily	Once in 3 years	Annually	Weekly or Monthly
Once a month	Once in 3 years	Annually	Weekly or Monthly
Occasionally	Once in 3 years	Annually	Weekly or Monthly
Rarely used equipment	To verified before use	To verified before use	Before every usage

Table 5.1 – Validation interval based on Usage Frequency

5.3 Acceptable Measurement Error

The user has to determine the acceptable measurement error in which suitable for the application.

In general, PNE set the acceptable measurement error to less than 5% for all applications in validation activities.

If “Accuracy” term arises, it shall be the inverse of the error value as depicted in equation 5.1. For example, if the error is 5%, then the accuracy will be 95%.

Accuracy% = 100% - Error % …. Equation 5.1

5.4 Regulatory and Legal Requirement

Some measuring instruments are required by regulatory bodies to be validated according to the regulations and/or acts. The validation parameters should be observed accordingly.

5.5 Deciding When to Perform the Validation

1) For general ruling, the measurement instruments should be verified annually and sent for calibration once every 3 years. However, the following could play an important factor in deciding the interval.

2) If the measurement error is more than 3%, it shall be verified every 6 months to monitor the trending: -

   a) If the error increased to 4% or higher, that instrument should be sent for calibration. The next validation period will be based on a recommendation from the calibration result.
   b) If the error maintains, slightly fluctuate or remain below 4%, it shall be verified every 6 months.
   c) If the error decreased to 3% or lower, the general ruling should be observed.
   d) If the error reaches 5%, please refer to Section 9 – Dealing with Defective Instrument.

3) If the total cost for calibration (including shipping, tax and miscellaneous) is more than 10% from the instrument value, the general ruling should be observed. If lower, it shall be calibrated annually. However, it shall not violate item 2 above.

4) If the facility to perform such validation is abroad, for example out of Malaysia, the general ruling should be observed. However, it shall not violate items 2 and 3 above.

5) For multimeters, it can be verified internally without the need to send for external calibration. However, if the unit was in a doubtful state, it is then advised to send it for external calibration.

6 Handling of Validation Matters

The validation requirement and interval as mention in Section 5 shall be determined by the users and recorded in Calibration/Verification Requisition Form[3].

6.1 Calibration and Verification Process Flow

Please refer to Calibration and Verification Flow[4].

6.2 Self-Test Process Flow

Self-test process may vary from instrument to instrument. Please refer to relevant material.

6.3 Monitoring the Validation Deadline

ERC Supervisor is responsible for monitoring all registered measurement instrument owned by ERC and ESD Team.

DWE Supervisor is responsible for monitoring all registered machineries owned by DWE Team and alert the user when a particular machinery reaches the validation deadline and make arrangement for the validation process.

6.4 Evaluating the Validation Result

For the instrument owned by PNE, the respective PNE's Supervisors and Technical Executives are responsible for evaluating and analysing the validation result.

For In-house Multimeter Verification, the user is responsible for evaluating the validation result. In general, section 5.3 should be observed when deciding the result. If the error exceeds the acceptable value, section 9 shall be observed.

6.5 Record Keeping

User shall keep their own record. This can be done via digital or physical copies.

All digital copies shall be stored in EDMS. No retention period is required.

All physical copies shall be kept properly within the workspace of the user. It is recommended that it be converted to digital copies. Retention period for all physical copies is 3 years.

6.6 Calibration and Verification Sticker

It is recommended that the external calibration entity to paste the sticker to the instruments that they calibrate. If this is not available, the user is allowed to use internal calibration / verification sticker that states the next calibration date based on the calibration certificate provided by the calibration party.

All working instrument which successful verified internally shall have the Verification Sticker[5], paste somewhere within the main structure of that instrument.

7 In-House Multimeter Verification

Due to economical reason, all multimeters are to verified in-house which overriding the requirement for calibration mention in Section 5.2 and 5.5 item 1. However, if the unit met criteria mention in Section 5.5 item 2(a), it then shall be sent for calibration.

ERC Team is providing in-house verification service for multimeters and other instruments which have a similar function. This service is made available to all maintenance department within E-MAS.

Please refer to the Multimeter Verification Procedure[6] for details.

Only Working Standard (reference) unit shall be sent for external calibration annually, not bind to the requirement for calibration mention in Section 5.2.

8 Traceability

The measuring instruments shall be calibrated with reference standards that are traceable to National or International Standard. Typically, the reference standard is traceable to National Metrological Lab (NML) – SIRIM.

All working instrument shall inherit the traceability from the working standard used in the verification process.

9 Dealing with Defective Instrument

Any instrument which having validation error more than the predetermined acceptable value shall either be corrected, repaired or prohibit from usage unless the HoD issue a memo overriding section 5.5 item 2. This can only be allowed if the intended usage allows lower accuracy requirement.

All correction should be recorded. The correction shall re-establish the highest accuracy possible.

Any instrument that been repaired and affecting the measuring function shall be validated before it can be used again. Replacement of display, connector and casing do not require the validation.

Instruments which labelled as “Prohibited from Usage” shall not be made accessible to the user. However, it should be kept properly for further action.

The HoD shall decide either to repair or write-off if the instrument are out of accuracy after calibration or verification.

10 References

1) International vocabulary of basic and general terms in metrology (VIM) 2004.
2) Quality and Environmental Management Systems Manual[7].

10.1 Reference to Document Referred

No	Document Name	Document Number	Document Type
1	PNE ERC Calibration Monitoring Record	E00.OMD.M11411.DQ.1001.*	Monitoring Table
2	PNE DWE Equipment Calibration Monitoring Record	D00.OMD.M12980.DC.1001.*	Monitoring Table
3	Calibration/Verification Requisition Form	G00.OMN.M11411.DQ.0001.*	Form
4	Calibration and Verification Flow	E00.OMD.M11411.CC.1001.*	Process Flow
5	Verification Sticker	G00.OMD.M11411.QK.1001.*	Verification Sticker
6	Multimeter Verification Procedure	E00.OMD.M01000.CZ.1029.*	Procedure
7	Quality and Environmental Management Systems Manual	G00.OMQ.M11421.AF.1009.*	Manual

Table 10.1 – List of Reference to Document Referred