

For the PCM II Tester (TE82817-2)

**PREPARED BY**

| Name        | Role                 | Signature | Date |
|-------------|----------------------|-----------|------|
| Luo HuaZhen | Senior Test Engineer |           |      |

The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

**REVIEWED BY**

| Name       | Role                    | Signature | Date |
|------------|-------------------------|-----------|------|
| Matt Brule | Principal Test Engineer |           |      |

The "Reviewed By" signature[s] denotes agreement with the details of the planned testing and/or deliverables to be performed.

**APPROVED BY**

| Name         | Role                             | Signature | Date |
|--------------|----------------------------------|-----------|------|
| Kah Chin Tan | Senior Quality Assurance Manager |           |      |

The "Approved By" signature denotes that this system change risk assessment and resulting planned process validation activities has been approved.

## 1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Pump Control Module, PCM II Tester (TE82817-2), and to define the resulting deliverable(s) required to maintain the system process validation.

## 2. BACKGROUND

The PCM II Tester (TE82817-2), facilitates the functional test of the following part numbers: 186002449, 800000178, 279001290, 800000224. The system downloads firmware and verifies the electrical and mechanical functionality of the unit under test. Upon completion, a Final Test Record is automatically generated and printed for the operator to collect.

## 3. DESCRIPTION OF CHANGE

The computer in use at the PCM II Tester (TE82817-2) located in CEI Singapore has been replaced with a new PC. The new computer uses the same operating system, Windows XP, and there was no change to the custom test software. This change does not affect TE82817-1 located in Milford NPI.

## 4. RISK ASSESSMENT

### 4.1. High Risk Assessment

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

| 4.1.1. Specification                                                  | No                                  | Yes                      |
|-----------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a test specification value being modified and/or added? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.1.2. Software/Firmware                                                                                                                | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change due to firmware downloaded to the UUT by a test system?                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a flash file update?                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is it a change to an existing, or the addition of a new, PCB Test Sequence?                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)                                                                                                              | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.1.4. Equipment/Process Moves                                                          | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a move of the equipment, test method or process, to a different facility? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

### 4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

| 4.2.1. Replacement of Non-Identical                                                       | No                                  | Yes                      |
|-------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change due to a replacement of a system component with a non-identical equivalent? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.2.2. Computer Related or Replacement of Custom PCBs          | No                                  | Yes                                 |
|----------------------------------------------------------------|-------------------------------------|-------------------------------------|
| Is the change an update to the PC operating system?            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Is the change a computer or printed circuit board replacement? | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |

| 4.2.3. Software/Firmware                                                                   | No                                  | Yes                      |
|--------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?    | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a test system instrument firmware update (i.e. update to a stack component)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.2.4. Equipment/Process Moves                                                        | No                                  | Yes                      |
|---------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a move of the equipment, test method or process, within the local site? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

4.3. This change results in a Medium Risk Assessment and the associated process validation requirements, as detailed in Section 6.0.

## 5. HAZARD ASSESSMENT:

There are no hazards potentially introduced to the environment, operator, assembler, service technician or end user due to this change.

## 6. VERIFICATION, QUALIFICATION AND/OR VALIDATION:

| 6.1. Equipment Design Verification (EDV)                                                                                                                           | No                                  | Yes                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?                                                               | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change?                                                                         | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>An EDV is not required because this change does not affect the way the system controls or measures a specification or PSC result. |                                     |                          |

| 6.2. Installation Qualification (IQ)                                                                                                                                                                                                                                                                                                                                                                            | No                       | Yes                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-------------------------------------|
| Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change?                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| <b>Comments/Justification</b><br>A functional test will be performed on the PCM II Tester (TE82817-2) located in CEI Singapore to verify the custom test software and instrument firmware versions, as well as to verify the functionality of the system. In lieu of a formal IQ Report, the objective evidence will be attached to the provided Objective Evidence Completion form and submitted for approval. |                          |                                     |

| 6.3. Test Method Validation (TMV)                                                                                                                                             | No                                  | Yes                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does a TMV need to be executed due to this change?                                                                                              | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>TMV is not required because this system does not utilize external measurement equipment and this change does not involve Operator influence. |                                     |                          |

| 6.4. Operational Qualification (OQ)                                                                                                                       | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>An OQ is not required because 100% of critical to quality attributes are verified.                                       |                                     |                          |

| 6.5. Performance Qualification (PQ)                                                                                                                      | No                                  | Yes                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br>A PQ is not required because 100% of critical to quality attributes are verified.                                       |                                     |                          |

**6.6. Electromagnetic Interference (EMI) Assessment:**

This change only affects test equipment; therefore, there is no impact to product EMI.

**7. IMPLEMENTATION ASSESSMENT:**

- There is no impact to documentation, calibration, or facilities/utilities.
- There is no impact to any other qualified, verified, or validated process, test method, or equipment.
- The production schedule for this system is currently stopped awaiting validation.
- This change will be implemented by Test Engineering; the qualification activities will be executed by a Test Engineer.
- No additional training be required.
- Product used for qualification or tested prior to approval of qualification activities shall be quarantined.
- Should any predefined deliverable to unable to be obtained the deviation should be addressed as an additional attachment to the Objective Evidence Completion Form.

**VALIDATION ASSESSMENT  
OBJECTIVE EVIDENCE COMPLETION**  
For the PCM II Tester (TE82817-2)

**PREPARED BY**

| Name        | Role                 | Signature | Date |
|-------------|----------------------|-----------|------|
| Luo HuaZhen | Senior Test Engineer |           |      |

The "Prepared By" signature denotes that the document accurately provides the required objective evidence.

**REVIEWED BY**

| Name       | Role                    | Signature | Date |
|------------|-------------------------|-----------|------|
| Matt Brule | Principal Test Engineer |           |      |

The "Reviewed By" signature[s] denotes agreement that the required objective evidence is provided and accurate.

**APPROVED BY**

| Name         | Role                             | Signature | Date |
|--------------|----------------------------------|-----------|------|
| Kah Chin Tan | Senior Quality Assurance Manager |           |      |

The "Approved By" signature denotes that the objective evidence has been reviewed and approved for overall quality and completeness.

**ATTACHMENTS:**

Attachment 1: Cover sheet of the test procedure listing the custom test software version

Attachment 2: BOM for the unit under test listing the required firmware version

Attachment 3: Operator training record

Attachment 4: Passing Test Record