

1. Purpose

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the Alliance Final Test System. This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

2. Background

The Alliance Final Test System is used to test Alliance products of the following part numbers: WAT270008, WAT270880, WAT270886, WAT069885, WAT069887, WAT069889, 186271819, 186271821, 186269501, 186269502, 186269503, 186269504, 186269505, 186269506, 186269507, 186269508, N2971010, and the applicable refurbished equivalent part numbers. During the test, the heater/cooler, fluidic, and chemistry performance of the unit are tested. Upon completion a Final Test Record is completed by the operator according to WAT000867.

This system was designed before test equipment was designated with a "TE" identification number. All documentation will be stored in the VAL001270 directory of SAP; this does not affect the system or validation requirements.

3. Description of Change

A new duplicate test system, Alliance Final Test System #6, is being installed at the Flextronics Contract Manufacturer Site in Singapore to increase production capacity. This does not affect the existing Alliance Final Test Systems or the system controls and test methods.

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?	☒	☐

4.1.2. Software/Firmware	No	Yes
If the change affects software, does the change affect the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
If the change is due to firmware, is the test system used to download firmware?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
If the change is mechanical, electrical, pneumatic, and/or hydraulic in nature, does the change alter the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocating to a different facility?	☒	☐

4.2. Medium Risk Assessment

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

4.2.1. Duplicate System or Process	No	Yes
Is the change a duplicate system, test method, or process?	☐	☒

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4.2.2. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐
4.2.3. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☒	☐

4.2.4. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
If the change is due to firmware, is it an instrument firmware update?	☒	☐

4.2.5. Equipment/Process Moves	No	Yes
If the change is a move of the equipment, test method or process, will it be relocated within the Milford site?	☒	☐

4.3. An answer of Yes to any of the questions in Section 4.1 above results in a high risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

4.4. An answer of Yes to any of the questions in Section 4.2 above results in a medium risk and the associated qualification or requalification requirements, as defined in 730001835, Process Validation Procedure for Milford Site.

5. Hazard Assessment:

No hazards are potentially introduced to the environment, operator, assembler, service technician or end user.

6. Verification, Qualification and/or Validation:

6.1. Complete the tables below based on the qualification or requalification recommendations:

6.1.1. 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?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This system is classified as fit for use. This change does not affect the test method or test system design and there is no custom software, therefore an EDV is not required.		

6.1.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☐	☒
Comments/Justification The Alliance Final Test System #6 will be qualified using the pre-approved Installation Qualification Protocol 735004135. The other duplicate systems (#1-5) are classified as fit for use and are not affected by this change.		

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6.1.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification This test equipment does not utilize an external measurement device and is not subject to operator induced variation. This change does not require a TMV as defined in the Process Validation Procedure 730001835.		

6.1.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
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.)	☒	☐
Comments/Justification OQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.1.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
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.)	☒	☐
Comments/Justification PQ is not required because 100% of critical to quality (CTQ) attributes are verified.		

6.2. Electromagnetic Interference (EMI) Assessment:

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

7. IMPLEMENTATION ASSESSMENT:

- The new equipment will be entered into the onsite Flextronics Calibration Database. There is no impact to documentation or facilities/utilities.
- The qualification of this equipment has a high impact on production schedules, as the increased capacity will enable production to better meet quarterly goals.
- The equipment will be installed by Flextronics personnel. The IQ will be executed by Flextronics personnel according to the pre-approved Installation Qualification Protocol 735004135.
- No additional training will be required.

8. APPROVALS

Responsibility	Name	Title	Signature	Date
Author	Emma Pierce	Test Validation Engineer		06 Jun 2018
Reviewer	Michael Cotter	Principal Test Engineer		07 Jun 2018
Approver	Andre Kopoyan	Senior Operations Quality Engineer		07 Jun 2018