



Re: International OESR 193232 Acquity CMA tester TE is down
due to test PC cannot boot up 

Emma Pierce to: HuaZhen Luo
Cc: Matt Brule, Kah Chin Tan, Edwin Koh

12. 04. 2019 04:33

Hi Luo,

Thanks for writing up the VAF! Matt and I reviewed it and have some corrections:



TE83026-08APR2019-VAF_Edits.pdf

I think there is some confusion about the purpose of the VAF routing sheet. The VAF (pages 1-4) is meant to be completed and approved as an assessment of the change and to document the planned validation activities. The **unsigned** routing sheet (page 5) is meant to be reviewed as part of the VAF (pages 1-4) so that the required attachments can be agreed upon **before execution**. Signatures on page 1 show that everyone involved has agreed to the planned deliverables (including the attachment list on page 5); signatures on page 5 show that the deliverables have been completed, reviewed, and approved. It might help to think of the routing sheet as the cover sheet of a report such as an IQR- the VAF should be approved before the IQ is executed and the IQR submitted for approval. Apologies if this is not an adequate explanation, please let me know if you still have questions.

There is also some confusion about the test equipment itself. TE83026 is not the same system as TE0083026. The TE83026 systems are in the process of being updated to TE0083026 systems. This is an important distinction because an EDV has only been completed for the TE0083026 CM-S program. The CM-A and CM-Aux test programs on TE83026 systems do not have EDVs. To make the VAF assessment align with the current situation please remove the first sentence (crossed out in red) in the comments of section 6.1 on page 3.

Some miscellaneous notes:

- VAF titles do not include the system (or "dash" number) specifically. Even though this VAF affects only TE83026-1 the VAF title should still be "TE83026-08APR2019-VAF" The SAP # is correct as "TE008302601"
- Please use "TE83026-1" instead of "TE83026-01" I believe the .docx copy uses a field to populate this so fixing it once in the body and once in the header will fix it everywhere but I've circled all the instances just in case
- Please use the nomenclature "Sigma Quest Data Archive" and "Venture Contract Manufacturing Site" across all validation documentation for consistency with documents generated by the Milford team
- Some of the attachments and screen captures you included are not necessary. It isn't wrong to include extraneous objective evidence but it is better (and potentially less confusing to an auditor) to only provide pertinent information and eliminate any redundancy. I've added comments on the scanned copy but please let me know if you'd like any further explanation.
- Thank you for ensuring the traceability between the operator training record and the test record by adding the operator ID numbers! However by adding the IDs yourself you are making a change to their signature which is messy to record according to Good Documentation Practices. Please have the operators fill in their own ID numbers when completing the training form.

After making corrections to the VAF (pages 1-5) please scan a copy with your signature only on page 1 for Matt and I to review. I will return a signed scanned copy for approval by KC. Once the VAF has been approved you can execute the required work and send the routing sheet with your signature (page 5) and the attachments for Matt and I to

review, which I will also scan and send to KC for approval. Upon approval of the attachments as documented on the routing sheet the equipment is considered qualified and ready for use.

Please let me or Matt know if you have any validation or equipment questions!

Thanks,
Emma

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Test Validation Engineer



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HuaZhen Luo	Hi Matt, Thanks for fixing this SigmaSur...	11-04-2019 02:01:50
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From: HuaZhen Luo/Waters
To: Matt Brule/Waters@WATTS Waters Sales
Cc: Emma Pierce/Waters@WATTS WATERS SALES, Kah Chin Tan/Waters@WATTS WATERS SALES, Edwin Koh/Waters@WATTS WATERS SALES
Date: 11-04-19 02:01
Subject: Re: International OESR 193232 Acquity CMA tester TE is down due to test PC cannot boot up

Hi Matt,

Thanks for fixing this SigmaSure upload issue. We can download the test records from server now.

And I have prepared the attached VAF for this repair as attached.

Please kindly review and sign off on Page 1 & 5 if everything is okay.

[attachment "TE83026_1-08APR2019-VAF with Objective Evidences.pdf" deleted by Emma Pierce/Waters]

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Matt Brule	Hi HuaZhen, Again I apologize for the de...	11.04.2019 05:17:30
HuaZhen Luo	Hi Matt, Noted with thanks. I will as...	04/10/2019 03:16:38 AM
Matt Brule	Hi HuaZhen, I apologize, I did not get t...	10.04.2019 05:41:25
HuaZhen Luo	Hi Matt, I tried to download the test...	04/09/2019 05:31:02 AM
HuaZhen Luo	Hi Matt/Emma, I have drafted a VAF based...	08.04.2019 17:39:46

Matt Brule	Hi HuaZhen, THANK YOU!!!!	06.04.2019 04:48:02
HuaZhen Luo	Hi Matt, Yes, I asked them to keep th...	04/05/2019 05:29:30 AM
Matt Brule	HuaZhen, Also, if the old TE83026-1 is s...	05.04.2019 05:41:17
HuaZhen Luo	Hi Matt, The ID is Te-1 and password...	04/01/2019 09:05:36 PM
Matt Brule	HuaZhen, I cannot log in to the PC. Ple...	01.04.2019 23:21:17
HuaZhen Luo	Hi Matt, The tester TE83026-1 is down...	04/01/2019 03:26:38 AM