



FW: Fw: Action Required: Validation for OESR #182921

Joel Mamalateo Deduyo

to:

HuaZhen Luo

27.02.2019 17:08

Cc:

Nallajanula Phani Bhushan, Edwin Koh

Hide Details

From: Joel Mamalateo Deduyo <joelmamalateo.deduyo@flex.com>

To: HuaZhen Luo <HuaZhen_Luo@waters.com>

Cc: Nallajanula Phani Bhushan <phanibhushan.nallajanula@flex.com>, Edwin Koh <Edwin_Koh@waters.com>

Hi Hua Zhen,

With reference to below inquiry:

1. How does your training system track updates to documents?

REPLY: Training system track update to document as per ECO release to Flex. Once Waters ECO received, Flex shall generate in-house ECO to track the customer document reference to respective changes.

2. Are the revisions of your documents somehow offset from the revisions in SAP?

REPLY: Yes, Waters SAP document used for a particular time before project transfer example is in Rev B, but for Flex documentation still in initial release to Flex And shall register Flex Doc Rev A.

3. If so is there something you can provide to show that Rev H in the system is the same as Rev L in SAP?

REPLY: Pls refer to below sample procedures:

Flex received the ECO 9221407 for 735002155 Rev H and shall create a corresponding document as per Flex ECO process and document control.

WATERS SAP DOC:

Details	TSP	H	735002155	07	Acquity QSM Final Instrument Test	RG	9221407	05-Jul-2018
---------	-----	---	-----------	----	-----------------------------------	----	---------	-------------

FLEX ECO SGSWATE001651 and Doc # WAT-RW-SWM00021 Rev F:

- WAT-RW-SWM00021 Rev F Test Procedure For Acquity QSM Pump (735002155) is Flex cover page detailing the revisions for Waters TSP 735002155, this document will be routed containing Waters SAP TSP 735002155 Rev H and personnel shall be trained using this document.

Document Title: Test Procedure For Acquity QSM Pump (735002155)	Engineering Change No.: SGSWATE001651	Document # WAT-RW-SWM00021	Organization: Kallang
Revision: F	Document Owner: Joel Mamalateo Deduyo	Customer: Waters Corporation	Effective Date: FlexQ – On File

REVISION HISTORY

REV.	ECN	DESCRIPTION OF CHANGE	ORIGINATOR	RELEASE DATE
F	SGSWAT E001651	1. Update to new format. 2. Update as per customer document reference: ECO # 9221407, 735002155, change of customer document revision from G to H	Shajeeth Ahamed R	FlexQ – On File

Rev.	Description of Change	DC Workflow Number
	1. Update to new format. 2. Update as per customer document reference: ECO # 9221407, 735002155, change of customer document revision from G to H	DC-RW069554
F	Reason for Change Change initiated by customer ECO9221407.	Release Date 16-Jul-2018 10:17:29-AM (GMT +8:0)

The same goes on with the other document.

Flex received the ECO 9221398 for 735002010 Rev L and shall create corresponding document as per Flex ECO process and document control.

WATERS SAP DOC:

Details	TSP	L	735002010	10	AcQuity BSM Pump Automated Final Test	RG	9221398	05-Jul-2018
---------	-----	---	-----------	----	---------------------------------------	----	---------	-------------

FLEX ECO SGSWATE001650 and Doc # WAT-RW-SWR00017 Rev G:

WAT-RW-SWR00017 Rev G Test Procedure For Acquity BSM Pump (735002010) is Flex cover page detailing the revisions for Waters TSP 735002010, this document shall be routed containing Waters SAP TSP 735002010 Rev L and personnel shall be trained using this document.

Document Title: Test Procedure For Acquity BSM Pump (735002010)	Engineering Change No.: SGSWATE001650	Document #: WAT-RW-SWR00017	Organization: Kallang
Revision: G	Document Owner: Joel Mamalateo Deduyo	Customer: Waters Corporation	Effective Date: FlexQ – On File

REVISION HISTORY

REV.	ECN	DESCRIPTION OF CHANGE	ORIGINATOR	RELEASE DATE
G	SGSWATE001650	1. Update to new format. 2. Update document as per customer reference: ECO 9221398. Uprev 735002010 Rev. K to 735002010 Rev. L	Shajeeth Ahamed R	FlexQ – On File

Rev.	Description of Change	DC Workflow Number
	1. Update to new format. 2. Update document as per customer reference: ECO 9221398. Uprev 735002010 Rev. K to 735002010 Rev. L	DC-RW069547
G	Reason for Change	Release Date
	Change initiated by customer ECO9221398.	16,Jul,2018 10:18:12-AM (GMT +8:0)

Flex QMS shall release corresponding document once training conducted to respective personnel.

Best Regards,



direct: +65.6507 5982
mobile: +65.9685 8678
main: +65 6507 6507
fax: +65 6507 5958

Joel Mamalateo Deduyo
Senior Engineer, Test Engineering
joelmamalateo.deduyo@flex.com

1, Kallang Place
Singapore, 339211 Singapore

www.flex.com

From: HuaZhen Luo <HuaZhen_Luo@waters.com>
Sent: Wednesday, February 27, 2019 9:04 AM
To: Joel Mamalateo Deduyo <joelmamalateo.deduyo@flex.com>
Cc: Nallajanula Phani Bhushan <phanibhushan.nallajanula@flex.com>; Edwin Koh <Edwin_Koh@waters.com>
Subject: RE: Fw: Action Required: Validation for OESR #182921

Hi Joel,

Please help to review/answer the questions posted from Milford validation team regarding training record, Thanks

We're a little confused over here with the operator training records, can you help clarify? The training record for 735002155 lists revision F but the cover sheet and SAP are revision H and the training record for 735002010 lists revision G when the cover sheet and SAP are revision L. The date of training in each case roughly lines up with the release of the most recent document but it isn't clear that the operator has been trained to the correct (most recently released) revision.

How does your training system track updates to documents? Are the revisions of your documents somehow offset from the revisions in SAP? If so is there something you can provide to show that Rev H in the system is the same as Rev L in SAP?

Once we understand how operator training is tracked we can move forward with the qualification for TE82943-14.

Luo HuaZhen
Senior Test Engineer



[T] +65 6593 7044
[F] +65 6873 0820
[W] www.waters.com
[E] huazhen_luo@waters.com



Waters Pacific Pte Ltd
1 Science Park Road
#02-08 The Capricorn
Singapore Science Park II
Singapore 117528

From: Joel Mamalateo Deduyo <joelmamalateo.deduyo@flex.com>
To: HuaZhen Luo <HuaZhen_Luo@waters.com>, Nallajanula Phani Bhushan <phanibhushan.nallajanula@flex.com>
Cc: Amy Xu Xia Jie <amyxu@flex.com>, Desmond Ann <Desmond_Ann@waters.com>, Edwin Koh <Edwin_Koh@waters.com>, Kah Chin Tan <Kah_Chin_Tan@waters.com>, Kevin Teo <Kevin_Teo@waters.com>, Wei Xiang Loh <Wei_Xiang_Loh@waters.com>, Yeehwa Chan <Yeehwa_Chan@waters.com>, Yin Ying Soo <Yin_Ying_Soo@waters.com>, Zack Lin <Zack_Lin@waters.com>
Date: 11.02.2019 10:36
Subject: RE: Fw: Action Required: Validation for OESR #182921

Hi Hua Zhen,

We are testing QSM Plus today and send the result in the afternoon. For the meantime, attached is the training for the two procedures.

WAT-RW-SWR00017 Rev G Test Procedure For Acquity BSM Pump (735002010)

- Equivalent to 735002010 Rev L

WAT-RW-SWM00021 Rev F Test Procedure For Acquity QSM Pump (735002155)

- Equivalent to 735002155 Rev H

Rgds,



direct: +65.6507 5982

mobile: +65.9685 8678

main: +65 6507 6507

fax: +65 6507 5958

Joel Mamalateo Deduyo

Senior Engineer, Test Engineering

joelmamalateo.deduyo@flex.com

1, Kallang Place

Singapore, 339211 Singapore

www.flex.com

From: HuaZhen Luo <HuaZhen_Luo@waters.com>

Sent: Friday, February 1, 2019 11:47 AM

To: Nallajanula Phani Bhushan <phanibhushan.nallajanula@flex.com>

Cc: Amy Xu Xia Jie <amy.xu@flex.com>; Desmond Ann <Desmond_Ann@waters.com>; Edwin Koh <Edwin_Koh@waters.com>; Joel Mamalateo Deduyo

<joelmamalateo.deduyo@flex.com>; Kah Chin Tan <Kah_Chin_Tan@waters.com>; Kevin Teo <Kevin_Teo@waters.com>; Wei Xiang Loh

<Wei_Xiang_Loh@waters.com>; Yeehwa Chan <Yeehwa_Chan@waters.com>; Yin Ying Soo <Yin_Ying_Soo@waters.com>; Zack Lin <Zack_Lin@waters.com>

Subject: Re: Fw: Action Required: Validation for OESR #182921

Hi Joel,

Please get 3 models tested on this system each for this qualification and send me the complete test results as Objective Evident for this qualification.

3 Mfg part numbers:

186015080 QSM Plus;

186015001 BSM;

186015018 QSM;

Please let me know if you have any questions. Thanks

Luo HuaZhen

Senior Test Engineer

[T] +65 6593 7044

[F] +65 6873 0820

[W] www.waters.com

[E] huazhen_luo@waters.com



Waters Pacific Pte Ltd

1 Science Park Road

#02-08 The Capricorn

Singapore Science Park II

Singapore 117528

From: HuaZhen Luo/Waters

To: "Phani Bhushan Nallajanula" <PhaniBhushan.Nallajanula@flex.com>

Cc: Edwin Koh/Waters@WATTS WATERS SALES, Desmond Ann/Waters@WATTS WATERS SALES, Yeehwa Chan/Waters@WATTS WATERS SALES, Yin Ying Soo/Waters@WATTS WATERS SALES, Zack Lin/Waters@WATTS WATERS SALES, Kah Chin Tan/Waters@WATTS WATERS SALES, 'Flextronics' <JoelMamalateo.Deduyo@flex.com>, Kevin Teo/Waters@WATTS WATERS SALES, Wei Xiang Loh/Waters@WATTS WATERS SALES, Flextronics <amy.xu@flex.com>

Date: 01.02.2019 10:15

Subject: Fw: Action Required: Validation for OESR #182921

Hi Phani,

Please stop using BSM/QSM Tester TE82943-14 and put 'Do Not Use' sticker on it until qualification is completed.

Please quarantine all FGs tested on this tester until the validation is completed. If the unit is urgent for shipment requirement, please re-test on other BSM/QSM testers and release for shipment after Final test passed on other BSM/QSM testers except TE82943-14.

I'm drafting the validation document and will send it to you shortly.

Please let us know if there is any impact to today and next week shipment.

Thanks

Regards,

Luo HuaZhen
Senior Test Engineer



[T] +65 6593 7044

[F] +65 6873 0820

[W] www.waters.com

[E] huaazhen_luo@waters.com



Waters Pacific Pte Ltd
1 Science Park Road
#02-08 The Capricorn
Singapore Science Park II
Singapore 117528

----- Forwarded by HuaZhen Luo/Waters on 01.02.2019 09:31 -----

From: Emma Pierce/Waters
To: HuaZhen Luo/Waters@WATTS WATERS SALES
Cc: Tetiana Morse/Waters@WATTS WATERS SALES, Kah Chin Tan/Waters@WATTS WATERS SALES
Date: 01.02.2019 01:04
Subject: Action Required: Validation for OESR #182921

Hi,

I was looking into this OESR from November for TE82943-14. I checked with Bill Bates and it seems that the work done to repair the computer was equivalent to a PC replacement, which requires a partial requalification. Upon its repair in November this system should have been removed from service and all parts tested on it quarantined until validation was completed. Please put a DO NOT USE sticker on TE82943-14 as soon as possible and stop all testing on this system until validation can be completed. In the future, please try to be aware that computer repairs need to be risk assessed as changes to the equipment.

The information in this email is confidential, and is intended solely for the addressee(s). Access to this email by anyone else is unauthorized and therefore prohibited. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited and may be unlawful.

Legal Disclaimer :

The information contained in this message may be privileged and confidential.

It is intended to be read only by the individual or entity to whom it is addressed or by their designee. If the reader of this message is not the intended recipient, you are on notice that any distribution of this message, in any form, is strictly prohibited. If you have received this message in error,

please immediately notify the sender and delete or destroy any copy of this message! [attachment "WAT-RWSWM00021 Rev F.pdf" deleted by HuaZhen Luo/Waters] [attachment "WAT-RW-SWR00017 Rev G.pdf" deleted by HuaZhen Luo/Waters]

The information in this email is confidential, and is intended solely for the addressee(s). Access to this email by anyone else is unauthorized and therefore prohibited. If you are not the intended recipient you are notified that disclosing, copying, distributing or taking any action in reliance on the contents of this information is strictly prohibited and may be unlawful.