

Title: Sustaining Test Equipment Procedure

Document No: 730001836

Version No: 02

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1. PURPOSE

The purpose of this procedure is to define the process used to maintain, upgrade and track test equipment after it has been released for production usage. This includes the process for repairs, upgrades and duplication of production test equipment.

2. SCOPE

The scope of this procedure is all production test equipment purchased, designed and/or constructed by the Waters Test Engineering Department in Milford MA.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
TE	Test Equipment or Test Engineering
Test Equipment	Equipment, that is typically comprised of hardware and software, and is required to perform a non-destructive test that demonstrates the product meets applicable specifications.
OESR	Operations Engineering Service Request
OFI	Opportunity For Improvement – OESR status to assist in prioritizing requests.
Qualification	The documents and activities that ensure specified test equipment is installed properly and functional requirements are fulfilled. This is accomplished by executing protocols developed to verify the test equipment.
N/A	Not Applicable
ERP	Enterprise Resource Planning
SAP	Systeme, Anwendungen und Produkte (Systems, Applications and Products), ERP software
Calibration	A process to ensure that equipment is capable of producing accurate results. This includes verifying measurements and/or making adjustment(s) to ensure measurement accuracy.
PM	Preventive Maintenance: The servicing, for the purpose of maintaining equipment in satisfactory working order, by performing systematic inspection, detection, and correction of potential failures. PM activities may include tests, measurements and parts replacement.
NIST	National Institute of Standards and Technology (NIST) is a measurement standards laboratory and an agency of the United States Department of Commerce.
UUT	Unit Under Test
CAL	Calibration or Preventative Maintenance Procedure document type in SAP
PCB	Printed Circuit Board
ICT	In-Circuit board Test using various measurement techniques to ensure electronic components are properly assembled and meet designated tolerances.
URL	Uniform Resource Locator
FCT	Functional Circuit board Test, typically performed in the last phase of PCB production, as a final quality control, to ensure that the UUT fulfills its functional specifications. FCT consists of simulating the operational environment to check functionality, including: communication, driving loads, generating and reading signals necessary to make the UUT work properly.
Supplier	Any facility which provides component, subassembly or instruments, including component and subassembly vendors as well as contract manufacturing facilities.
Consigned Test Equipment	Test Equipment owned, leased or rented by Waters Corporation, provided to a non-Waters supplier for use in their process. This may include custom designed or standard, commercially available equipment, fixtures, known good boards or assemblies. For purposes of this document, consigned test equipment also includes support collaterals, such as documentation and software.

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4. ROLES AND RESPONSIBILITIES

Role	Responsibilities
Test Engineering Manager	• Ensure implementation of this procedure and affiliated Standard Operating Procedures. • Assign Test Engineering staff to approved projects. • Review and/or approve documentation deliverables.
Test Engineering	• Support, service and maintain test equipment. • Develop product test solutions. • Develop and qualify test equipment required to implement production testing at Waters or its suppliers. • Write, review and/or approve all necessary documentation deliverables. • Provide test equipment training. • Work with various engineering functions towards problem resolution.
Test Engineering Technician	• Support Test Engineers in test equipment support activities. • Write and/or review documentation deliverables. • Support, service and maintain test equipment. • Work with various engineering functions towards problem resolution.
OESR Originator (Originator)	• Identify Operations Engineering service need. • Complete/update OESR form. • Email completed OESR form to OESR Coordinator. • Support OESR Coordinator and Assignee in service request resolution.
OESR Coordinator (Coordinator)	• Support, facilitate and manage Service Requests. Maintain the OESR database.
OESR Assignee (Assignee)	• Communicate with the Originator and Coordinator. Plan and execute solution, working with Test/Validation Engineers for qualification/requalification, as required. Update relevant documents and summarize OESR activities.

5. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730001833	Test Engineering Management Policy
730001834	New Test Equipment Development Procedure
730001835	Process Validation Procedure for Milford
730001799	Operating Procedure, Calibration and PM
730001292	Release and Revision of Non-Catalog Tool
730000483	Global WI/Operating Procedure Template
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy

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6. FORMS

6.1. Records

Test equipment design records will be captured in SAP or in a physical folder (legacy test equipment) in Test Engineering department. Test specification and procedure documents, as well as Test Equipment PM/Calibration procedures will be stored and maintained in SAP.

Doc. No:	Document Title
Various	Test Equipment Design Records
730002013	Template, Test Specification and Procedure
730002014	Template, Cal and PM Procedure
Various	OESR Form
N/A	OESR Database
N/A	Calibration Database
N/A	Test Equipment List

7. HEALTH & SAFETY

No Health & Safety-specific considerations.

7.1. Equipment/Materials of use Required

Not Applicable.

8. PROCEDURE

8.1. OESR

The Operations Engineering Service Request (OESR) process will cover test equipment service, including test equipment upgrades & enhancements, as well as duplication and repairs.

The Originator, upon identifying a service need, will complete and email the OESR to the Coordinator. The Coordinator will record, categorize and assign the request.

Categories include:

- Repair: Test equipment that has an issue and requires to be fixed.
- Upgrade: Test equipment is working but needs enhancement to improve ergonomics, yield, safety, capability or repeatability.
- Duplicate: Test equipment works, but does not satisfy production demand (capacity).
- New: New test equipment for current (existing) product.
- Doc Only: Administrative (Documentation) change only
- Other: Request does not fall into the other categories.

The Assignee shall gather information as needed, plan and execute the solution, update test equipment records and assess qualification requirements. The Assignee may close the OESR and notify Coordinator when complete. Alternatively, the Assignee may notify the Coordinator for closure. The Coordinator shall notify the Originator when the OESR is closed.

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Roles	Tasks/Instructions
Originator	8.1.1. Complete OESR Form. 8.1.2. Save and Email OESR Form. See section 10, Appendix - OESR Form.
Coordinator (or TE Manager)	8.1.3. Evaluate submitted form to determine if it is complete. 8.1.4. If necessary, return to Originator for more information, otherwise: 8.1.5. Record, categorize and assign OESR. 8.1.6. Email updated OESR form to Originator and Assignee.
Assignee	8.1.7. Receive OESR notification via email. 8.1.8. Determine if request status represents an Opportunity for Improvement (OFI). If so, then notify Coordinator, otherwise: 8.1.9. Evaluate record, determine if any changes are required. If so, then return to Coordinator, otherwise: 8.1.10. If OESR is categorized as 'Other' and is a request to obsolete or remove a piece of test equipment, then follow 'Calibration and Maintenance of Measurement and Test Equipment' procedure (730001799) and then proceed to step 8.1.17. 8.1.11. If OESR is categorized as 'New', then follow the New Test Equipment Development Procedure (730001834) or Release and Revision of Non-Catalog Tool Procedure (730001292) and then proceed to step 8.1.17. 8.1.12. If necessary, request more information until resolved. 8.1.13. Plan and execute resolution to service request.
Originator/Assignee/Coordinator	8.1.14. If resolution is acceptable, then determine if change will require qualification/requalification. If so, then follow Test Equipment Qualification Procedure (730001835). If qualification is not required, then provide justification in OESR and proceed to step 8.1.16. 8.1.15. Determine if resolution is acceptable. If not, revisit resolution to ensure that all stakeholders are satisfied.
Assignee	8.1.16. Update Records (SAP, Tester Folder, Test Equipment List, Test Engineering Computer List, etc.). 8.1.17. Summarize action taken on OESR form. Include attachments, if necessary. 8.1.18. Close OESR. Alternatively; email Coordinator for record closure.
Coordinator	8.1.19. Verify that records have been updated. 8.1.20. Change OESR status if necessary (to OFI or Closed). 8.1.21. Notify Originator of OESR status change.

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8.2. Equipment Repair

The OESR process will manage repairs to production equipment. The Assignee shall execute the solution, closing the request or notifying the Coordinator when complete. Repair effectiveness will be verified and documented on the OESR form. The Coordinator will verify that the repair has been completed and reopen the request, if necessary.

Roles	Tasks/Instructions
Assignee	8.2.1. Gather data, plan and execute solution. 8.2.2. Refer to document 735001835 to determine if qualification is required. 8.2.3. If qualification is not required, then provide justification. 8.2.4. Update records (SAP, Test Equipment list, Test Engineering Computer list, etc.). 8.2.5. Summarize response on OESR record, including attachments, if necessary. Document repair effectiveness including verification activity on OESR record. 8.2.6. Close OESR or Email Coordinator for closure.
Coordinator	8.2.7. Verify that OESR has been completed, closing OESR if necessary. 8.2.8. Notify Originator that OESR has been completed.

8.3. Asset Management

The OESR process will manage requests for the addition, removal or update of equipment in the Operations Engineering inventory with database/program changes handled by document 730001799 (Operating Procedure, Calibration and PM). When equipment is added, removed or upgraded, records shall be updated accordingly (SAP files, Equipment Design Files, Test Equipment List, Test Engineering Computer List, Calibration Database). It is the responsibility of the Assignee to update these records. The Coordinator shall ensure that equipment records have been updated.

Roles	Tasks/Instructions
Assignee	8.3.1. Refer to document 730001799 (Operating Procedure, Calibration and PM). 8.3.2. Update Records, as appropriate. 8.3.3. Summarize action taken on OESR record. Include attachments, if necessary. 8.3.4. Close OESR or email Coordinator for closure.
Coordinator	8.3.5. Verify that records have been updated, closing OESR if necessary. 8.3.6. Notify Originator that OESR has been closed.

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8.4. New Equipment Development

The OESR process may cover new equipment requests. Requests for new equipment (for existing products only) will be managed via the OESR process and tracked in the OESR database. The equipment development will follow document 730001834 (New Test Equipment Development) or 730001292 (Release and Revision of Non-Catalog Tool). Once the OESR has been assigned, if categorized as 'New', then equipment development will be governed by document 730001834 or 730001292.

Roles	Tasks/Instructions
Assignee	8.4.1. Refer to document 730001834 (Test Equipment Development) or 730001292 (Release and Revision of Non-Catalog Tool). 8.4.2. Assess the qualification requirements per 730001835 (Process Validation Procedure for Milford) and perform required qualification. 8.4.3. Summarize Action Taken on OESR form. Include attachments, if necessary. 8.4.4. Close OESR or email Coordinator for closure.
Coordinator	8.4.5. Verify that records have been updated, closing OESR if necessary. 8.4.6. Notify Originator that OESR has been closed.

8.5. Changes to Test Equipment (non-OESR)

Test equipment may require revision, not triggered by an OESR. Examples may include UUT changes, new part numbers, revised specifications, etc. A development project may be the trigger for these changes. When these changes are made, records shall be updated accordingly (SAP files, Equipment Design Files, Test Equipment List, Test Engineering Computer List, Calibration Database). Qualification/requalification should be assessed and performed per 730001835 (Process Validation Procedure for Milford).

8.6. Control of Consigned Test Equipment

The Waters Test Engineering department will provide test equipment to suppliers, as required to meet the quality requirements and needs of Waters Corporation. Consigned test equipment remains owned and controlled by Waters with changes governed by section 8.8, Changes to Consigned Test Equipment. Changes to consigned test equipment are not permitted without Waters' knowledge, except as described in step 8.8.7, Supplier changes to test equipment that do not require approval from Waters.

Roles	Tasks/Instructions
Waters Test Engineering	8.6.1. Waters Test Engineering shall maintain a tracking log or system for the ongoing identification and location of consigned test equipment. 8.6.2. Any replacement, major refurbishment or major modification(s) of consigned test equipment are the responsibility of Waters Test Engineering. See section 8.8.
Supplier	8.6.3. Suppliers are responsible for the proper storage and basic maintenance of consigned test equipment. Basic maintenance includes cleaning, normal replacement of consumable items or the implementation of hardware or software updates at the request of Waters Test Engineering. 8.6.4. Suppliers are responsible for the qualification of consigned test equipment (working with Waters Test Engineering) upon installation, or after a physical move/relocation per 730001835, Process Validation Procedure for Milford. 8.6.5. Suppliers are responsible for the regular calibration and/or preventive

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	maintenance of Waters consigned test equipment per Waters calibration procedures and traceable to NIST standards, where applicable. Cost of equipment repair (not adjustment) for any consigned item which fails calibration is the responsibility of Waters; unless the failure is the direct result of supplier mishandling, unauthorized modification or damage in shipping. Costs for equipment repairs required during calibration should be quoted to Waters Test Engineering before work is authorized or performed by the supplier. At Test Engineering's discretion, Waters may choose to have any item returned for repair or replacement in lieu of repair. Calibration records for all consigned test equipment are to be filed, or otherwise locally maintained by the supplier, with copies provided to Waters Test Engineering. 8.6.6. Suppliers shall be responsible for any test equipment misplaced, lost or damaged (excluding normal wear); unless such damage is caused by implementing modifications at the request of Waters Corporation.
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8.7. Return of Consigned Test Equipment

Roles	Tasks/Instructions
Waters Test Engineering	8.7.1. Waters Test Engineering may request the return of obsolete test equipment no longer required for production. Alternatively, the supplier or purchasing may request that Test Engineering accept obsolete test equipment.
Supplier	8.7.2. Supplier shall return test equipment to Waters Corporation upon request from Waters Test Engineering. Equipment must be packaged in an acceptable manner for shipment, consistent with the size, weight, fragility and type of equipment being shipped.

8.8. Changes to Consigned Test Equipment

Waters may request changes to consigned test equipment at supplier facilities. Additionally, it is understood that some flexibility must be afforded suppliers in making minor changes to better fit their production process or accommodate anomalies among test systems, particularly in the area of In-Circuit Test (ICT) fixtures. The limits of acceptability to Waters Corporation for these are detailed herein.

Roles	Tasks/Instructions
Waters Test Engineering	8.8.1. Waters Test Engineering Dept. must approve any changes in consigned test equipment configuration, hardware, software or procedure; with the sole exception of those changes where supplier flexibility is specifically identified and afforded within section 8.8.7 of this document.
Waters Test Engineering/ Suppliers	8.8.2. If the need arises, Waters Test Engineering may request a supplier to implement changes to consigned test equipment. Additionally, suppliers may request changes to better fit their unique equipment or process requirements. 8.8.3. These changes will be handled by the OESR process, managed by the OESR coordinator/Test Engineering Manager. 8.8.4. Suppliers will implement changes upon request from Waters Test Engineering Department. If a supplier does not have the technical expertise, information, capacity or equipment to implement requested changes, Waters Test

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	Engineering Department will work with supplier for resolution. 8.8.5. Waters Test Engineering may elect to have consigned test equipment shipped to a third party or back to Waters for implementation of equipment upgrades or changes. Supplier will ensure that equipment is suitably transferred for updates/changes as requested. 8.8.6. Waters is responsible for any material or labor costs for upgrades and changes outside the normal level of technical support afforded by its business relationship with the supplier, e.g., minor hardware or software changes are considered by Waters to be 'maintenance items' and are expected to be performed upon request and at no cost to Waters. If, at any time a supplier perceives the cost of a requested equipment change or update to exceed this level, the supplier shall quote the implementation cost to Waters Test Engineering for consideration. 8.8.7. Supplier changes to test equipment that do not require approval from Waters a) Equipment modifications of a minor nature made in the course of test equipment maintenance or repair activities. Examples include, but are not limited to: • ICT or FCT probe cleaning or replacement, re-crimping or soldering loose or damaged wires • "Identical" replacements of defective or failed components in test equipment • Replacement of consumable items such as filters, columns & detector lamps or connectors, cables or contacts, ferrules used in UUT interfaces b) ICT software modifications may be made to accommodate temperature/humidity changes and minor equipment anomalies, as per industry practice. Waters may audit the supplied test software to ensure compliance with this standard and seek corrective action with the supplier in any case of deviation.
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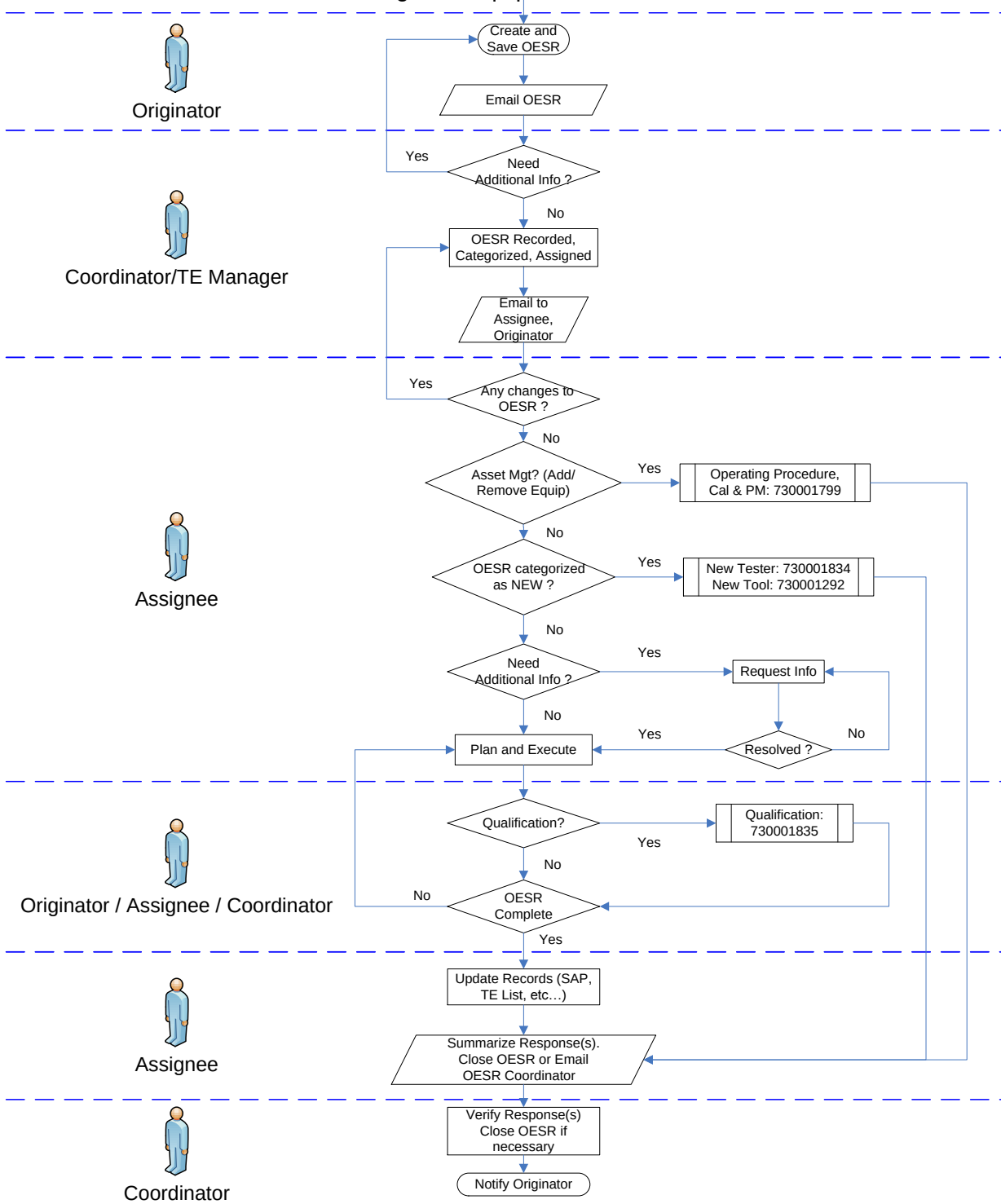
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9. OESR FLOWCHART

Operations Engineering Service Request (OESR) Process For Existing Test Equipment and Products



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10. APPENDIX - OESR DATABASE INSTRUCTIONS

10.1. To access the OESR database, using a web browser, navigate to the OESR page at the following address: <http://10.2.241.78/fmi/webd#OESR>.

10.2. Log into the OESR system (login = OESR, password = password). See Figure 1.

Figure 1

10.3. Click 'Create New OESR Record'. See Figure 2.

Figure 2

10.4. Complete the form and click 'Save'. Note: form cannot be saved until all required fields are populated. See Figure 3.

Figure 3

10.5. Click 'EMAIL OESR' to notify Test Engineering. See Figure 4.

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OESR Form

Operations Engineering Service Request



Log Number

Response Pg. 01 Pg. 02 Pg. 03

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All fields are mandatory.
Put N/A if not applicable

☐ Test Engineering ☐ Manufacturing Engineering



Originator	Name:	Date	
Phone Ext		Department	
Request (US, Int'l)		Plant Location	
TE / Tool No.	-	Associated Part No.	
TE Tool Name		Test Software Rev.	
Pole No.		DIR: ASP/TSP/OTHER	No.: Rev.:

Summary of problem(s) (as detailed as possible and include attachment if required):

Milford Operations Engineering use only

Category	☐ Repair ☐ Upgrade ☐ Duplicate ☐ New ☐ Doc_Only ☐ Other		
Assignee 1		Date Received	
Assignee 2			
Qualification Required	☐ Yes ☐ No (Please explain in Summary of action taken)		

Summary of action taken (as detailed as possible and include attachment if required):

Date Completed		STATUS	OPEN
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Recommendation

Figure 5 – OESR Form – for reference only

OESR URL: <http://10.2.241.78/fmi/webd#OESR>

Note: If the OESR system is down, the manual form may be used (in the \\finserv2\TE\OESR\ folder). Populate the top section and email to Ops_Eng_Support@waters.com.

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DOCUMENT HISTORY

VERSION:	02	ORIGINATOR:	Michael Cotter	Change ID:	N/A
SUMMARY OF CHANGE: UPDATE DOCUMENT TO: VERSION 02 INCORPORATING THE FOLLOWING CHANGES: REMOVE REFERENCES TO OBSOLESCENCE AND ASSET MANAGEMENT FROM PURPOSE AND PROCEDURE SECTION AS THESE ARE ADDRESSED IN DOCUMENT 730001799. IN ASSET MANAGEMENT SECTION (8.3) INSERT THE WORDS 'REQUESTS FOR' PRIOR TO 'ADDITION, REMOVAL OR UPDATE OF EQUIPMENT'. THE OESR WILL FACILITATE THE REQUEST BUT THE ACTUAL WORK IS GOVERNED BY 730001799. ADD A NEW OESR STATUS (OFI) USED FOR OPPORTUNITIES FOR IMPROVEMENT DESCRIBE A NEW OESR CATEGORY (DOC_ONLY) USED FOR DOCUMENTATION ONLY CHANGE REQUESTS CHANGE THE OESR TASKS/INSTRUCTIONS, ALLOWING ASSIGNEE OR COORDINATOR TO CLOSE OESR. UPDATE OESR FLOWCHART TO INCLUDE QUALIFICATION PRIOR TO CLOSING OESR. ADD A NEW SECTION (REVISION OF TEST EQUIPMENT WITHOUT OESR). DESCRIBE DELIVERABLES FOR THESE CHANGES. REMOVE REQUIREMENT TO PRINT HARD COPY OF OESR AND STORE IN EQUIPMENT FOLDER. REMOVED THE BIENNIAL INSPECTION OF ICT TEST FILES. ADD QUALIFICATION TO THE TASKS/INSTRUCTIONS IN MULTIPLE PLACES.					