

Title: Change Control

Filename: 220v4.lwp

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Reference: SOP 101: Control of Standard Operating Procedures and Test Methods  
SOP 2250: Analytical Instrument Qualification and Facility Equipment Maintenance  
SOP 140: Documentation of Training and Qualification of Employees  
SOP 250: Internal, Third Party, and Vendor Audits.

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	11-18-02	Original
2.	11-13-03	Sec. 4.4: Added
3.	10-14-09	Re-engineered system to require completion of a change control form for tracking change control in the laboratory.
4.	MAY 31 2011	Electronic database for management of change control system implemented. Responsibilities and activities clarified throughout.
5.		

Prepared by

Date

Technical Review

Date



04/15/11



4-18-11

QA Approval/Date:



05/31/11

## 1.0 SUMMARY AND SCOPE

The purpose of this SOP is to define how changes (including repairs) to quality critical equipment, facilities, processes, computerized systems, controlled documents (such as standard operating procedures and test methods), compendial revisions, critical service providers, and critical reagents/ consumables or their vendors is reviewed by Department Managers and the Quality Assurance Unit (QAU) to assure that laboratory systems remain suitable for their intended use. A risk assessment of the proposed change is performed prior to implementation and client notification, qualification, and validation activities are performed as deemed necessary. Verification of impact of the change is performed before the change control process is closed.

1.1 Prior to the implementation of a change, a Change Control database entry (Appendix) is created to document proposed changes to equipment, facilities, processes, computerized systems, controlled documents (such as validated test methods), compendial revisions, critical service providers, and critical supplies or their vendors.

1.2 Exclusions from the scope of this SOP

1.2.1 Like-for-like equipment components, reagent, and consumable item changes do not require a change control entry. A “like-for-like” replacement is defined as when an equipment component, reagent, or consumable item requires replacement and the manufacturer and model/part number are identical or of the same design and functional specification as the item currently used. Reagents from alternate approved vendors with certified purity or concentration equivalent to current reagents are included in this category, as well as routine preventative maintenance of equipment, as described in the SOP for the operation of the equipment and documented in the instrument logbook.

1.2.2 Software computer system changes that do not affect instrumentation operation, electronic file integrity, or data calculation (e.g. routine Windows operating system, McAfee, Adobe Reader, Java, and Flash upgrades; personal computer software upgrades for word processing and business functions; adding a new user on a non-instrument workstation; and adding additional RAM memory or a larger hard drive to a non-instrumentation computer) do not require change control. These changes are requested and tracked to completion via the corporate “IT Ticket” system on ExovaNet.

1.2.3 Creation or minor revisions of logbook templates, sample preparation worksheets, or forms in order to improve documentation practices does not require a change control entry, as long as no changes in the test method itself are implemented. QA oversight is provided through the issuance of the logbook (refer to SOP 2260) or document (refer to SOP 101) and through normal data review activities.

- 1.2.4 Periodic review and revision of general SOPs (101-2999) and SOPs for non-validated methods do not require a change control entry. This does not apply to major revisions that change an analytical approach or have the potential to impact data. This assessment is verified during the Technical and QA review of SOP revisions, per SOP 101.
- 1.2.5 Creation of a new SOP or worksheet template following the validation of a method do not require a change control entry. These activities are tracked as part of the method validation job and QA oversight is provided during the review of data acquired in accordance with the method.
- 1.2.6 The transfer of staff from one functional group to another or the addition of an employee does not require a Change Control Form. Training assessment will be performed per SOP 140.
- 1.3 Change control entries are evaluated for potential data impact during technical review prior to changes being implemented. In addition, the QAU approves change control entries prior to implementation to verify that appropriate follow up actions with regards to client notification, qualification, calibration, validation, training, or SOP revision have been identified.
- 1.4 Change control entries are evaluated after the change has been implemented for potential data impact by a technical reviewer. The QAU closes change control forms when appropriate follow up actions have been verified as completed with regards to client notification, qualification, calibration, validation, training, or SOP revision.

## 2.0 RESPONSIBLE PARTIES

- 2.1 Change Initiator: The person who is requesting the change is responsible for completing the first section of the change control form and ensuring the form is approved prior to implementing the change. Purchase Orders (template given as Fig. 1) are completed in a manner that indicates if a Change Control is required. The initiator of the change is responsible for ensuring that change controls are closed in a timely manner and that the “Assigned to”, “Date Due”, “Summary of Activities” and “Status Update” fields are completed in a timely manner as activities are performed.
- 2.2 Technical Review: The Technical Director or the associated Department Manager (Group Leader) must approve change controls to ensure that the potential for data impact and actions to be taken for requalification of the system following the change have been adequately assessed. The Technical Director or the associated Department Manager (Group Leader) will close change controls upon acceptance of the justification for closure and the review of any associated objective evidence.

- 2.3 Quality Assurance: Proposed changes require pre-approval by a member of the QAU, following approval of the risk assessment of the potential impact of the change. In order to close the change control, the QAU will review the appropriateness and completeness of the actions performed as part of the change control process, including, as applicable, client notification, requalification, recalibration, revalidation, training, or revision of SOPs.
- 2.4 The General Manager is responsible for approving Purchase Orders related to vendor changes, computer systems, facilities, and equipment or other purchases over \$1000.
- 2.5 The Office Manager, or their designee, is responsible for completing the Purchase Order process and verifying that a change control entry has been initiated, when applicable.
- 2.6 Evaluation of the regulatory impact of changes, following the notification of proposed changes, is the responsibility of our clients.

### 3.0 PROCEDURE

- 3.1 The change initiator completes the top portion of the Approval section of the electronic Change Control Form (Appendix I), including a description of the change to be implemented and the justification for the change. Submit to the QAU for scanning into the Change Control any supporting documents such as copies of data, investigations, compendial or literature references, equipment specifications, or vendor communication.
- 3.2 The initiator obtains approval by their Department Manager or the Technical Director of the intended change. The initiator is responsible for ensuring that the change is not implemented until both technical and QAU approval have been obtained.
  - 3.2.1 The technical reviewer will categorize the change as major or minor:
    - Major Change* – A change that has the potential to impact the qualified or validated state of equipment, computerized systems, utilities, facility, or test methods. This includes, but is not limited to, the physical move, modification, or repair of analytical instrumentation; changes in specifications or testing methods; software changes that impact data calculation or security of a computerized system; and changes in the supplier or specification of critical supplies, reagents, utilities, or services.

*Minor Change* – A change that does not impact the qualified or validated state of equipment, computerized systems, utilities, facility, or test methods. This includes changes to documentation procedures; software changes that do not impact data calculation, quality systems, or security; test method changes that do not have the potential for affecting the accuracy, precision, sensitivity, or specificity of the method; and rewording of documents for clarification or formatting purposes. Changes deemed to be minor require justification as to the decision that revalidation/requalification is not required and that there is no potential for data impact.

- 3.2.2 The technical reviewer will complete the “Actions to be taken” section, indicating the appropriate follow up actions with regards to client notification, qualification protocols, calibration, validation, training, or SOP revision.
- 3.3 A member of the QAU will verify the risk assessment performed by the technical reviewer and verify that appropriate follow up actions with regards to client notification, qualification, calibration, validation, training, or SOP revision have been identified before approving the change control.
- 3.4 Document and test method change control
- 3.4.1 For document changes that do not require a change control form, such as creation of new SOPs, reformatting, correction of typographic or grammatical errors, rewording or adding wording for clarity, or addition of quality control parameters, no client pre-notification is required and clients will be notified of the change in SOP revision number as it appears on their Laboratory Reports. Clients requesting a specific revision number on their Analytical Request Form will be notified that a new revision is in effect when samples are received (refer to SOP 1500).
- 3.4.2 For major changes to a test method that include introducing new testing steps, revision of one or more steps, or changes to the specifications for quality control, clients in regulated industries that have validated the method in their products will be notified before the revised SOP becomes effective. The change will be implemented when client approval is obtained for immediate implementation or 30 days following client notification.
- 3.4.3 If any significant changes are made to documents (i.e. other than pagination, spelling, minor clarifications, or typographic/grammatical corrections) during routing for approval or training, prior signatories to the document must sign the revised document.
- 3.4.4 Refer to SOP 101 for procedures used to create and revise SOPs.

### 3.5 Equipment, Facilities, Utilities, and Computerized System Changes

- 3.5.1 For minor equipment, facilities, utilities, or computerized system changes that do not impact the qualified state of the system, the test method, or impact other systems, no client notification is required.
- 3.5.2 For major equipment, facilities, utilities or computerized system changes that may impact the qualified state of the system, the test method, or impact other systems, the need for client notification will be assessed by the QAU and the technical reviewer based on a regulatory assessment and the potential impact to data.

### 3.6 Compendial and other standard method changes

- 3.6.1 Periodically, changes to USP or other compendial methods are implemented. Upon notification, proposed changes will be reviewed by the Technical Director, or their designee, for potential impact. A Change Control will be created if changes are identified that affect the analyses performed for our clients. Any SOPs that need to be updated will be referenced in the Change Control.
  - 3.6.2 Standard method changes (ACS, EPA, CPSC, etc.) are released to industry through technical literature to which the laboratory subscribes. When notification is made of a change to a method performed by the lab, the Technical Director or department manager will initiate a Change Control. Any SOPs that need to be updated will be referenced on the Change Control.
- 3.7 The change control request will be evaluated, based on an assessment of the risks and potential benefits of the change, to determine whether the change is appropriate. If the change is denied by the Technical Reviewer or QAU, this will be noted in the database entry and the change control will be closed.
- 3.8 In order to close a change control, objective evidence (such as calibration data, computer screen shots, an executed qualification or validation protocol, or a signed SOP documenting review and training) should be given to the QAU for scanning into the change control database, as appropriate.
- 3.9 Progress towards the completion of Change Controls will be reviewed during the weekly management meetings.
- 3.10 Business changes, such as those associated with the addition of certifications, a change in company location, or a change in ownership may be announced to clients through the newsletter, individual client letters, or news publications.



Change Control Database Entry Screenshots

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Change Control

List

Approval

Closure

Look For:

Opened By  Not Approved  Not Closed  Assigned To

Select Current Record

NUMBER	GROUP	SUMMARY	DATE OPENED	DATE APPROVED	DATE CLOSED	ASSIGNED TO	DUE DATE
2011087	ICPMS	New Template for Validated Method	04/11/2011	/ /	/ /	MHH	05/31/2011

First Prev Next Last Add List Close

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**Change Control**

List: **ICPIMS** Approval: Closure

Group: **ICPIMS**

Summary: **New Template for Validated Method**

Change Type:

- Document
- Equipment
- Facilities
- Vendor
- IT
- Materials
- Test Method

Reason:  New  Deletion  Move  Repair  Modification

Details of Change: **Create template for validated method.**

Justification: **Method validation complete.**

**QAU ASSESSMENT**

Risk Assessment:  Minor  Major

Client Pre-Notification Required:

Client Notification Details: By: **[User]** Date:  **/ /**

Action Required:  Yes  No

Actions to be Taken: **Submit print-out of completed template**

**TECHNICAL REVIEW**

Technical Review:  **/ /** Date:  **/ /**

**APPROVALS**

QAU:  **/ /** Date:  **/ /**

Buttons: First, Prev, Next, Last, Add, List, Close

Change Control

List Approval

Group: ICPMS  
Assigned To: MHH  
Date Due: 05/31/2011

Summary of Activities

Status Update

QA Assessment

Client Notification + 30 Days  Changes Being Effective Date: / /

Justification for Closure

Technical Review

CLOSURE

AUDIT

QAU

QAU 2011087

Scan View

LMS	04/12/2011-15:54:01	TAP:	/ /	QAP:	/ /	TOI:	/ /	QOI:	/ /
LMS	04/12/2011-12:25:40	TAP:	/ /	QAP:	/ /	TOI:	/ /	QOI:	/ /
LMS	04/12/2011-12:24:49	TAP:	/ /	QAP:	/ /	TOI:	/ /	QOI:	/ /

First Prev Next Last Add List Close



SOP Review Log

<u>Reviewed by</u>	<u>Date</u>	<u>Approved by</u>	<u>Date</u>
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____
9.	_____	_____	_____
10.	_____	_____	_____

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