

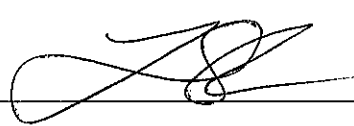
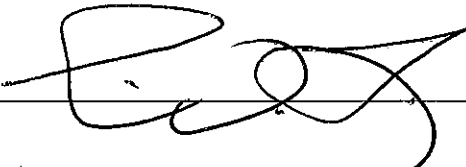
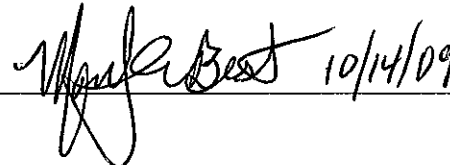
Title: Change Control

Filename: 220v3.lwp

This document does not contain proprietary information.

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

<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.	OCT 14 2009	Re-engineered system to require completion of a change control form for tracking change control in the laboratory.
4.		
5.		

<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	09/15/09		09.15.09
QA Approval/Date:	 10/14/09		

1.0 SUMMARY AND SCOPE

The purpose of the this SOP is to define how changes to equipment, facilities, processes, computerized systems, controlled documents (such as standard operating procedures and test methods), compendial revisions, critical service providers, and critical supplies or their vendors is reviewed by department managers and the Quality Assurance Unit (QAU) to assure that 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 is performed as deemed necessary. Verification of effectiveness is performed before the change control process is closed.

- 1.1 Prior to the implementation of a change, a Change Control Form (Appendix) is filled out to document proposed changes to equipment, facilities, processes, computerized systems, controlled documents (such as standard operating procedures and test methods), compendial revisions, critical service providers, and critical supplies or their vendors.
- 1.2 Like-for-like equipment components, reagent, and consumable item changes do not require a change control form. 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.
- 1.3 Change control forms are evaluated by the QAU to determine the appropriate follow up actions with regards to client notification, qualification, calibration, validation, training, or change in SOPs.

2.0 RESPONSIBLE PARTIES

- 2.1 Change Initiator: The person who initiates the change is responsible for completing the first section of the change control form. Purchase Orders (template given as Fig. 1) are completed in a manner that indicates if a Change Control is required.
- 2.2 Proposed changes require pre-approval by a member of the QAU. The QAU will perform risk assessment and determine the actions necessary to complete the change process, such as client notification, qualification, calibration, validation, training, or change in SOPs.
- 2.3 In addition, the General Manager must approve Purchase Orders related to vendor changes, computer systems, facilities, and equipment or other purchases over \$1000. The Technical Director or Department Manager must approve change controls relating to test methods, equipment, software, reagents/consumables, and controlled documents.

2.4 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 page 1 of the Change Control Form (Appendix I). They 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 the 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 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; 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 The initiator receives approval by their Department Manager of the intended change. Department Managers do not require secondary approval to submit a Change Control.

3.3 Like-for-like equipment component, reagent, and consumable item replacements do not require a change control form.

3.4 The QAU will assign a sequential number to the Change Control Form, documented in the Change Control Spreadsheet.

3.5 Document and test method change control

3.5.1 For minor changes such as creation of new SOPs, format, grammar, correction of typographic errors, rewording or adding wording for clarity, addition of quality control parameters, or expansion of the scope of the document, only the author of the document and QA need to approve the change control. No client notification is required and clients will be notified of the change in SOP revision number as it appears on their Laboratory Reports.

- 3.5.2 For major changes to a document or test method that include introducing of 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 or have requested pre-notification will be notified a minimum of 30 days before the revised SOP becomes effective.
- 3.5.3 Any significant changes made to the context (i.e. other than pagination, spelling, typos, grammatical corrections, etc.) of the document during routing for approvals or training will need to be reviewed and approved by the original signatories to the document.
- 3.5.4 Refer to SOP 101 for procedures used to create and revise SOPs.
- 3.6 Equipment, Facilities, Utilities, and Computerized System Changes
- 3.6.1 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; the change control may be approved by the department manager and QA. No client notification is required.
- 3.6.2 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 change control is additionally approved by the Technical Director or their designee. The need for client notification will be assessed by the QA Officer, or their designee, based on a regulatory assessment and the potential impact to data.
- 3.7 Include all information requested on the form, including the justification for the change, and attach any supporting documents such as copies of data, investigations, compendial or literature references, equipment specifications, vendor communication, etc.
- 3.8 The change control request will be evaluated with the requestor of the change, the department manager (if different than requestor), and a decision will be made by QA, based on an assessment of the risks and benefits of the change, on whether the change is appropriate.
- 3.9 A plan for accomplishing the change will be approved by QA, following consultation with the Technical Director, General Manager, and department manger(s), as appropriate, including the appropriate follow-up action(s), schedule, and protocols.
- 3.10 Compendial and other standard method changes
- 3.10.1 In November, February, and June of each year, changes to USP are posted to the on-line version. A Change Control Form will be opened by the Technical Director or their designee and the proposed changes will be reviewed for potential impact. Any SOPs that need to be updated will be referenced on the Change Control Form.

- 3.10.2 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 Form. Any SOPs that need to be updated will be referenced on the Change Control Form.
- 3.11 If changes require calibration, qualification, validation, training, or SOP change(s), supporting documentation must be given to the QAU to close the change control.
- 3.12 The transfer of staff from one functional group to another or the addition of an employee requires a Change Control Form. Training assessment will be performed per SOP 140.
- 3.13 Progress towards the completion of Change Controls will be reviewed during the weekly management meetings.
- 3.14 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 Form

Group: _____

C - _____

Change type: Document Equipment Computer System Facilities Vendor
 Reagent/Consumable Test Method/Specification Staff
 Other _____

Reason: New Deletion Modification Repair Move

Classification: Major Minor

Details of change: See Attachment _____

Justification for Change/Classification: _____

Requestor/Date: _____ Manager Approval/Date: _____

QAU ASSESSMENT

Risk Assessment: No data impact Potential data impact Likely data impact

Client Pre-notification Required: No Performed by/Date: _____

Client notification details: _____

SOP/Qualification/Validation Action Required: Yes No

Actions to be taken: _____

APPROVALS

QAU/Date: _____ Technical Review/Date: _____

Change Control Closure Request

Group: _____

C - _____

Summary of activities: See Attachment _____

Additional Activities Required: None _____

Requestor/Date: _____ Manager Approval/Date: _____

QAU ASSESSMENT

Client notification + 30 days: N/A Changes Being Effective Date: _____


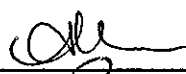
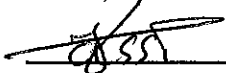

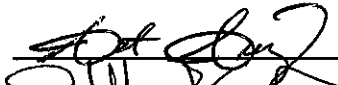







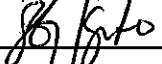


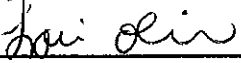




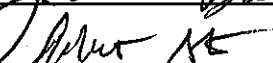
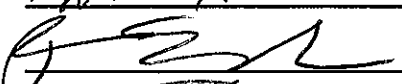
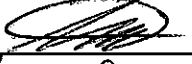



Verification of Activities and Effectiveness: N/A Yes (Attach objective evidence)

Comments: _____

APPROVALS

QAU/Date: _____ Tech. Dir. or GM/Date: _____

The following people have read this SOP and are currently using these procedures in the laboratory:

<u>Signature</u>	<u>Date</u>	<u>Signature</u>	<u>Date</u>
	10.06.09		10/12/09
Susanna Lippso	10.06.09		10/13/09
	10/06/09	Janet Z. Alvarez	10/13/09
	10/7/09		10/14/09
	10/07/09		10/14/09
	10-7-09		10/14/09
	10-8-09		10/14/09
Maurya Amara	10/8/09		10/14/09
	10/9/09	Ammanda Elchert	10/14/09
Doni Albanese	10-9-09		10/14/09
	10-09-09		
	10-09-09		
	10-09-09		
	10-09-09		
	10-12-09		
	10-12-09		
	10-12-09		
	10/12/09		
	10/12/09		
Charles Jells	10-12-09		
	10-12-09		
	10-12-09		