

Title: Change Control

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Reference: SOP 101

<u>Rev. No.</u>	<u>Date Revised</u>	<u>Revision Summary</u>
1.	11-18-02	Original
2.	11-13-03	Sec. 4.4: Added
3.	11-29-04	Added equipment location change to section 2.2.
4.		
5.		

	<u>Prepared or Reviewed by</u>	<u>Date</u>	<u>Approved by</u>	<u>Date</u>
1.	_____	_____	_____	_____
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1.0 SCOPE AND APPLICATION

Change control is a procedure by which changes are reviewed by senior level managers to insure that systems remain qualified for their purposes. Any changes or additions made to SOP documents, equipment, instruments, facilities, or software which are subject to 21 CFR Part 11, 210, or 211 are subject to this change control procedure.

2.0 SUMMARY

2.1 Changes to SOP documents are made according to SOP 101.

2.2 Changes, replacements, or additions made to equipment, software, or facilities are made through purchasing and QA using the Requisition /Purchase Order Form. If an instrument is moved from one location to another location within the laboratory, it is documented on the Requisition /Purchase Order Form and given to QA for review.

2.3 Changes brought about by internal development (not made through purchasing) must notify QA using the Requisition/Purchase Order Form, noting that the change does not include a purchase.

2.4 All changes go through QA to determine the appropriate follow up to qualification, calibration, validation, or change in SOPs.

2.5 Major changes such as that required by certifications, company location, or ownership may be announced through the newsletter, individual client letters, or news publications.

3.0 RESPONSIBLE PARTIES

3.1 Change Initiator. The person who initiates the change is responsible to notify QA for proper review and approval using the attached form.

3.2 QA will determine the proper follow up procedures necessary such as qualification, calibration, validation, or change in SOPs.

3.3 Group Leaders. Purchases <\$1000 and changes to SOPs, equipment, or software require the approval of a Group Leader.

3.4 President or Lab Director must approve major changes to equipment, software, or facilities, and purchase over \$1000.

4.0 PROCEDURE

- 4.1 The change initiator notifies their Group Leader and QA of an intended change using the attached Requisition/Purchase Order Form, supplying the information at the bottom of the form.
- 4.2 QA determines the appropriate follow-up action, schedule, and protocol.
- 4.3 QA obtains the approval of the President or Lab Director on major changes.
- 4.4 If changes require calibration, IQ/OQ, validation, or SOP change, a copy of the Requisition/Purchase Order is placed into a binder for tracking purposes. Once the required work has been completed, the copy is removed from the binder and attached to the completed work and filed with the instrument.

The following people have read this SOP and are currently using these procedures in the laboratory:
(QAU, Group Leaders, Lab Director, President, QA Officer)

Signature

Date

