

<u>Balance Sensitivity</u>	<u>Drift Tolerance Average Wt. (n=10) Limit (\pm g)</u>
0.1	0.2
0.01	0.02
0.001	0.002
0.0001	0.001
0.00001	0.0002
0.000001	0.00002

6.3.6 Balance Check Failures

6.3.6.1 Failures during balance checks are to be noted in the back of the QA balance logbook in the Balance Maintenance Log. The balance is labeled as “Out of Service” and the QAU is notified.

6.3.6.2 The QAU will open an NCR investigation and consider the following possible causes:

- the balance has been turned off and is not yet equilibrated
- the balance door was open
- excessive air currents in the laboratory
- improper leveling
- nearby vibrations
- hysteresis of the mechanical parts

6.3.6.3 If the QAU is unable to remedy the situation, an outside service will be called to inspect the balance. The balance will be not be placed back in service until properly calibrated.

6.3.6.4 As part of the NCR investigation, potentially affected data is reviewed. A determination will be made on whether or not clients need to be notified following an impact assessment. Appendix B may be used as a part of the NCR investigation.

6.3.7 Change Control for Balances

Any changes that will affect the performance of balance require submission of a change control form according to SOP 220. These changes may include moving a balance from one bench to another, moving the balance for cleaning purposes, or changing settings that will affect the performance such as repeatability settings.

6.4 Records - The working QA Logbook, Balance Measurement Uncertainty Worksheets, balance calibration records, and weight calibration records are stored in the QA office.

APPENDIX A

Balance Measurement Uncertainty Worksheet

Balance ID: _____

Analyst: _____

Date Tested: _____

Room Location: _____

Replicate	Test#1	Test#2	Test #3
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
Weight (g):			
STD Dev:			
3XSTD Dev : Weight			
Pass/Fail			

Acceptance Criteria: NMT 0.001

Minimum Weight For Assay: _____

APPENDIX B

Balance Failure Investigation

Balance ID: _____ Room Location: _____ Date of Failure: _____

Type of failure: _____ Failing Result: _____ Tolerance: _____

Date of Investigation: _____ Investigator Initials: _____ NCR#: _____

Replicate	Check Wt
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
Avg Weight (g):	
STD Dev:	
High Accuracy Check:	
Tolerance:	
Low Accuracy Check:	
Tolerance:	

Was the balance level? _____ Was the balance clean? _____

Were there excessive air currents or vibrations? _____

Comments: _____

Corrective Action: _____

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APPENDIX C

Measurement Uncertainty Calculation for Top Loading Balances

Balance ID: B-28
 Analyst: JLH
 Date Tested: 10-2-09

	<u>Test #1</u> 5.00g	<u>Test #2</u> 10.00g	<u>Test #3</u> 1.00g
#1	5.00	10.00	1.00
#2	5.00	10.00	1.00
#3	4.99	10.01	0.99
#4	5.00	10.00	1.00
#5	5.01	10.01	1.00
#6	5.00	10.00	1.00
#7	4.99	10.00	1.00
#8	5.00	10.00	1.00
#9	5.00	10.00	1.00
#10	4.99	10.00	1.00
STD Dev:	0.006325	0.004216	0.003162
(3 x STD Dev)/Amt Wt:	0.0038	0.0013	0.0095

Balance ID: B-31
 Analyst: JLH
 Date Tested: 10-2-09

	<u>Test #1</u> 5.00g	<u>Test #2</u> 10.00g	<u>Test #3</u> 1.00g
#1	5.00	10.00	1.00
#2	5.00	9.99	1.01
#3	5.01	9.99	1.02
#4	4.99	10.00	1.01
#5	5.00	10.00	1.01
#6	4.99	10.00	1.01
#7	4.99	10.00	1.00
#8	5.00	9.99	1.01
#9	5.00	9.99	1.00
#10	5.00	10.00	1.00
STD Dev:	0.006325	0.005164	0.006749
Result			
(3 x STD Dev)/Amt Wt:	0.0038	0.0015	0.0202