National Cancer Institute-Frederick, Frederick, MD Biopharmaceutical Development Program	STANDARD OPERATING PROCEDURE	Effective Date APR 22 2010	Procedure Number 21500
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Title: General Policies and Procedures for Balances

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SOP References: 00110, 21508, 21526, 21531, 21901	**Supersedes:** Rev03

Purpose: This procedure describes the general policies and procedures applicable to balances, including purchasing requirements, calibration policies, performance of weight checks, maintenance of weights, balance tolerances, general use procedures, and documentation.

Scope: This procedure applies to BDP personnel who use balances for GMP and GLP purposes. Historically, the word “balance” described a weight-measuring device that compared a sample, placed in a pan suspended from a beam, with a standard weight suspended from the other end of the beam. However, this word has evolved to now commonly refer to both balances and scales (weight-measuring devices that do not necessarily use a balance beam). For the purposes of this SOP, the word “balance” will be used to describe weight-measuring devices in the BDP, whether they are traditional balances or not.

Contents:

1.0 Authority and Responsibility

1.1 The Program and Technical Director, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

1.2 BDP Personnel using balances are responsible for adhering to this procedure.

1.3 Equipment owners, with assistance from QA, are responsible for determining the range and tolerance limits for their unit based on its use.

1.4 The Quality Engineering Group, or designee, is responsible for:

1.4.1 Assisting equipment owners in determining the appropriate range and tolerance limits for their balances based on intended use.

1.4.2 Assisting equipment owners in updating Master Equipment File (MEF) information for range and tolerance.

1.4.3 Assisting equipment owners in selecting appropriate weight sets.

1.4.4 Affixing range/tolerance labels to each balance. If the label cannot be affixed to the unit itself, it is affixed to the unit's logbook.

1.5 Biopharmaceutical Quality Assurance (BQA) is responsible for quality oversight of this procedure.

2.0 Purchasing Requirements for Balances and Weight Sets

2.1 Balances and weight sets are critical equipment and must be procured and received according to ***SOP 00110, Master Equipment Files (new SOP number assigned is 21520)***.

2.2 Recommendations for Purchase of Balances

2.2.1 Select balances to meet the range and tolerance required for anticipated weighing activities.

2.2.2 Purchase balances without an autocalibrate function.

2.3 Recommendations for Purchase of Weight Sets

2.3.1 Weights must be traceable to NIST Standards.

2.3.2 Select weights that are provided with a signed and dated Certificate of Quality (that states the weight's weight and the acceptable tolerance).

2.3.3 Purchase check weights that cover the stated range of the balance. Use the following table to specify the appropriate ASTM E617 class for the check weights. Generally, select a class of check weight that provides accuracy at least 2-3 times the accuracy claimed for the balance. For example, if the balance weighing tolerance is claimed to be ± 3%, the certified check weight accuracy needs to be 1.0% to 1.5% (3X or 2X the balance's stated value). Consult the Quality Engineering Department for the selection of check weights outside of these table parameters or to use check weights certified to other classification schemes.

ASTM E617 Class Of Check weight For Various Weights And Weighing Tolerances

Stated weighing tolerance	0.1%			0.5%			1.0%			2.0%			3.0%			5.0%		
Accuracy of checkweight (compared to weighing accuracy)	2X	3X	4X	2X	3X	4X	2X	3X	4X	2X	3X	4X	2X	3X	4X	2X	3X	4X
1 mg	0	0	0	0	0	0	0	0	0	1	0	0	2	1	0	3	2	2
2 mg	0	0	0	0	0	0	1	0	0	2	2	1	3	2	2	4	3	3
3 mg	0	0	0	0	0	0	2	1	0	3	2	2	4	3	2	5	4	3
5 mg	0	0	0	1	0	0	3	2	1	4	3	3	5	4	3	5	5	5
10 mg	0	0	0	2	2	1	4	3	2	5	4	3	5	5	4	5	5	5
20 mg	1	0	0	3	3	2	5	4	3	5	5	4	5	5	5	6	5	5
30 mg	2	1	0	4	3	3	5	4	4	5	5	5	6	5	5	7	6	5
50 mg	2	2	1	4	3	3	5	5	4	6	5	5	6	6	5	7	6	6
100 mg	3	2	2	5	4	4	5	5	5	6	5	5	7	6	5	7	7	7
200 mg	3	3	2	5	5	4	6	5	5	7	6	6	7	7	6	7	7	7
300 mg	4	3	3	5	5	5	6	6	5	7	6	6	7	7	7	7	7	7
500 mg	4	4	3	6	5	5	6	6	6	7	7	6	7	7	7	7	7	7
1 g	5	4	4	6	5	5	7	6	6	7	7	7	7	7	7	7	7	7
2 g	5	4	4	6	6	6	7	7	6	7	7	7	7	7	7	7	7	7
3 g	5	5	4	6	6	6	7	7	6	7	7	7	7	7	7	7	7	7
5 g	6	5	4	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7
10 g	6	6	6	7	6	6	7	7	7	7	7	7	7	7	7	7	7	7
20 g	6	6	6	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7
30 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
50 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
100 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
200 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
300 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
500 g	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
1 kg	7	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
2 kg	7	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
3 kg	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
5 kg	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
10 kg	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
20 kg	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7

3.0 Range and Tolerance

3.1 Definitions

3.1.1 Range is the range of weights that the balance can weigh with its purported accuracy (tolerance) and precision.

3.1.2 Tolerance, also known as the statement of accuracy, is the allowable deviation from a known measurement value, based on the accuracy of the unit under test.

3.2 A balance's range and tolerance are documented in the equipment's Master Equipment File (***SOP 00110, Master Equipment Files***). As appropriate, the MEF must be updated to document revised range/tolerance requirements.

3.3 The range and tolerance for a balance are stated on a label (see below) affixed to each unit or its equipment log by the Quality Engineering Department.

NOTE: Different tolerances may be established for different weight ranges.

BALANCE#_____
This balance is to be used for weighing within the following parameters.

RANGE:_____
TOLERANCE:_____

RANGE:_____
TOLERANCE: _____

OWNER:_____PH#_____
Reference SOP 21500

3.4 Selection of Appropriate Range and Tolerance

3.4.1 The user-defined range and tolerance (from the range/tolerance label)may be less restrictive than or equal to the manufacturer's claim, but ***not more restrictive***.

3.4.2 Selection of Appropriate Range

3.4.2.1 The range of weights that can be measured must be based on the ranges for the anticipated use of the instrument.

3.4.3 Selection of Appropriate Tolerance

3.4.3.1 Tolerances are to be established to match the weighing operations. Stated policies on process tolerances, tolerances cited in MPRs, or weighing instructions expressed using significant figures (***SOP 21901, Significant Figures and Rounding of Numbers***) can be used to determine an appropriate tolerance for a particular balance.

NOTE: Balances may NOT be used outside of the range and tolerance indicated on the label.

4.0 General Use Procedures

4.1 Confirm that the range/tolerance label is appropriate for the weighing operation to be performed.

4.2 Confirm that the balance is within its calibration expiration.

4.3 Ensure that the balance is level. If the built-in bubble indicator is outside the target, the balance is not level and the legs must be adjusted so that the balance is level.

4.4 Clean the balance before use (see Section 7.0 for details) to ensure there is no dirt or extraneous material remaining from the last weighing operation.

4.5 Some balances have a selection for “scale.” As a general rule, set the scale to “grams” for weights greater than 1 gram, and set to “milligrams” for weights less than 1 gram.

4.6 Verify that any “warm-up” period (if applicable to the balance model) has occurred.

4.7 Complete or verify complete any pre-weighing checks (see Section 5.0 for details).

4.8 “Autocalibration” capabilities, if present, **MUST NOT BE USED**. They must be disabled or the unit placarded to alert users not to use the autocalibrate function.

4.8.1 If the autocalibrate function is inadvertently used, the BQA Calibration Department must be notified immediately. Balances must be put out of service until recalibrated.

4.9 Select an appropriate sized, dry weighing container and place in the center of the balance pan; press the “tare” button.

4.10 Dispense the material into the weighing container using clean utensils.

4.11 If the balance has doors, close the doors.

4.12 Once the reading is stable, it can be recorded in a logbook or worksheet; be sure to use the appropriate significant figures.

4.13 Remove the weighing container from of the balance pan.

4.14 Clean the balance according to Section 7.0.

5.0 Pre-Weighing Checks

5.1 Maintenance of Weights

5.1.1 Weights must be stored to protect them from the environment (i.e., avoiding extremes in temperature and humidity).

5.1.2 Weights must be handled using forceps or gloved hands, or by the manufacturer's specifications, to avoid degradation of the weight.

5.1.3 Check weights must be calibrated at established intervals and used only if they are within their calibration period.

5.1.4 Weights must be handled and stored so as to minimize risk of becoming magnetized, as follows:

- Do not use or store weights in or around equipment with large motors such as air conditioners, water systems, refrigerators, or freezers.
- Do not use or store weights around magnetic equipment such as stir plates.
- Do not use or store weights around rotating machinery such as centrifuges, filling machines, or vial washers.
- Do not use or store weights within 10 feet of power lines carrying 100 amperes or more.

5.2 Check Weight Procedure

5.2.1 A weight check is performed on each balance each day of use, or after a balance has been moved, to confirm that the balance is within defined tolerance requirements.

5.2.1.1 At least two weights, generally covering the intended weight range, must be weighed. When weighing items over 20 kg, only a 20 kg weight needs to be used to check weigh the balance.

5.2.2 Use appropriate weighing techniques (Section 4.0).

5.2.3 Record the nominal weight of the check weight to one (1) decimal place greater than you wish to report.

5.2.4 Record the balance reading.

5.2.5 Confirm that the difference between the nominal weight and the balance reading is within the stated balance tolerance (from the range/tolerance label).

5.2.6 Successful completion clears the balance for that day's use. Balances for which the weight checks demonstrate unacceptable performance must be placarded "Out of Service" and communicated to the BQA Calibration Department, as per ***SOP 21526, Engineering Event Management and Status Placarding***.

6.0 Sources of Error in Weighing

The following events can cause weighing inaccuracies and should be avoided.

6.1 Weighing in open rooms – drafts can affect the consistency of a balance.

6.2 Spilled material/dirt on the balance pan – spilled material or dirt on the pan can affect weighing accuracy and is a potential source of contamination.

6.3 Hot or cold samples – hot or cold samples can cause air currents within the weighing chamber and affect weighing accuracy. Weigh samples at ambient temperatures.

6.4 Hygroscopic materials – hygroscopic materials absorb water and can increase in weight as they are being weighed due to the absorption of water.

6.5 Dirty utensils – dirty utensils can be a potential source of product contamination.

6.6 Avoid weighing containers containing a magnetic stir bar. The magnetic field generated may cause unpredictable effects on the electronic balance.

7.0 Cleaning

7.1 Use a brush or wipe to remove large particles or spilled material.

7.2 Use WFI or Septihol to wipe the balance.

7.3 For operations involving biohazardous material, wipe the balance with Cavicide followed by Septihol after use.

8.0 Documentation

8.1 An equipment logbook must be established for each balance that supports CGMP activities according to ***SOP 21531, Equipment/Facility Logs***. An equipment logbook is recommended for balances that support R&D activities.

8.1.1 Equipment logs are comprised of the Weight Check Datasheet and Activity Log (Form 21500-01). This form captures information for weight checks and can be customized by preprinting the balance description, ID number, etc. on the form. Record use, maintenance, cleaning, and calibration in the activity/comments section.

9.0 Investigating Product Impact for Out-of-Calibration Balances

9.1 Balances are calibrated at an established interval to confirm that they are performing within specification to the manufacturer's stated range and tolerance (or user-defined range and tolerance).

9.2 Failure to Meet Range/Tolerance

9.2.1 During periodic calibration, failure of a balance to meet the stated user-defined range or tolerance will be documented, and the balance brought into compliance (or placarded "Out of Service"). QA will notify the equipment owner and will require that an investigation into the potential product impact be conducted (See ***SOP 21508, Equipment Calibration Program***).

9.2.2 During periodic calibration activities, failure of a balance to meet the manufacturer's range or tolerance requirements will be documented, and the balance brought into compliance (or placarded "Out of Service"). No investigation of potential product impact will be required if the stated user-defined range and tolerance are met.

9.2.3 Failure to Meet User-defined Tolerance Claims for Pre-weighing Checks

During weight check, document the failure of a balance to meet the stated user-defined tolerance for a given range in the equipment log, and placard the unit as "Out of Service."

- The individual detecting the failure will notify: 1) the BQA Calibration Department, 2) the equipment owner, and 3) any users of the balance since the last weight check.

ATTACHMENT I

This form has been formatted to fit this page.

NCI-Frederick
Form No.: 21500-01
SOP No.: 21500
Revision 04:

BALANCE WEIGHT CHECK DATASHEET AND ACTIVITY LOG

Description:_____ BDP ID Number:_____ Calibration Due Date: _____

Stated Range*[1]:_____ Stated Tolerance*[1]: _____

Stated Range*[1]:_____ Stated Tolerance*[1]: _____

(*[1]from range/tolerance label on equipment) (*[2]Not required for non-GMP Production weighing)

Date	Weight MEF#	Nominal Weight	Balance Reading	Pass? (Y/N)	Performed By/Date	Checked By/Date*[2]

Date	Time	Activity/Comments	Initials/Date

Reviewed By/Date:_____