Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	Ana Baxter	**Date**	01-22-2019

A. Requested deviation applies to (Technical Procedure – include specific section):

Technical Procedure for Balances - Version 12
5.1.2.1.1, 5.1.2.2.1, 5.1.2.3.1

B. Requested deviation:

Expand the number of QC checks for each type of balance (table top, bulk, and analytical).

5.1.2.1.1 - Require the monthly QC check be performed on table top balances using 0.1g, 1g, 2g, 5g, 10g, 20g, 50g, 100g and 1000g weights.

5.1.2.2.1 - Require the monthly QC check be performed with three reference standard weights.

5.1.2.3.1 - Require the monthly QC check on analytical balances be performed using the 0.01g, 0.02g, 0.05g, 0.1g, 0.5g, and 1g weights.

C. Necessity for the deviation:

The intent henceforth is to calculate the drug chemistry section uncertainty of measurement values using QC data collected monthly throughout the year, from January through December. The number of QC checks needed each month must be increased in order to obtain and keep a larger number of data points, as compared to the number collected from the 10-day uncertainty study. The values chosen for the table top balances are those close to threshold weights, and reference standard weights that each lab maintains.

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

An increase to the number of monthly QC checks being performed on the balances will not have a negative affect on the quality of casework being performed in the drug chemistry section.

Approved	☑	Yes	☐	No	Duration	1 year, or until next procedure update
Signature	Amanda Battin Venable Digitally signed by Amanda Battin Venable Date: 2019.01.23 09:50:07 -05'00'				Date	01-23-2019

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	☑	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	☑	No

Restrictions/limitations:

☑	Authorized	☐	Rejected	Signature	Katy Schell Digitally signed by Katy Schell DN: cn=Katy Schell, o=North Carolina State Crime Laboratory, ou=Department of Justice, email=kschell@ncdoj.gov, c=US Date: 2019.01.23 15:55:35 -05'00'	Date	1/23/2019

Form approved for use by: Timothy G. Suggs Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdoj.gov, c=US Date: 2014.12.19 09:01:52 -05'00'

Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	Katy Schell	**Date**	04/27/2018

A. Requested deviation applies to (Technical Procedure – include specific section):

Technical Procedure for Balances-Drug Chemistry sections **5.5.2.3** and **5.6.1**

B. Requested deviation:

5.5.2.3 Rescind all examples in this section
5.6.1 Amend the third bullet in the list to read "The corresponding calculated expanded uncertainty for that measurement reported to the same number of decimal places as the readability of the balance used and a statement of the level of confidence". In addition, amend the example in the fourth bullet in the list to add "Measurement uncertainty of reported net weights is at a 99.7% level of confidence."

C. Necessity for the deviation:

Adjustments to the above listed procedure are necessary to include the coverage probability (99.7%) on the laboratory report.

D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)
Comments(to include merits and impacts):

The adjustments outlined above will provide consistency across all regional laboratories and clarification as to our current practices of reporting. By including a statement of the coverage probability on the laboratory report the customer will be provided with transparent, up-front knowledge as to the level of confidence associated with net weight measurements.

Approved	✓	Yes	☐	No	Duration	Until the next procedural revision
Signature	Kathleen M. Schell Digitally signed by Kathleen M. Schell DN: cn=Kathleen M. Schell, o=North Carolina State Crime Laboratory, ou=Drug Chemistry Section, email=Kschell@ncdoj.gov, c=US Date: 2018.05.14 16:46:10 -04'00'				Date	05/14/2018

E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)

Acceptable within general QA guidelines and good laboratory practice?	✓	Yes	☐	No
Significant negative impact to Crime Laboratory Quality System?	☐	Yes	✓	No

Restrictions/limitations:

✓	Authorized	☐	Rejected	Signature	Timothy G. Suggs Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdoj.gov, c=US Date: 2018.05.15 08:11:24 -04'00'	Date	5/15/2018

Form approved for use by: Timothy G. Suggs Digitally signed by Timothy G. Suggs DN: cn=Timothy G. Suggs, o=North Carolina State Crime Laboratory, ou=Quality Manager, email=tsuggs@ncdoj.gov, c=US Date: 2014.12.19 09:01:52 -05'00'

Technical Procedure for Balances – Drug Chemistry

1.0 Purpose - This procedure specifies the required elements for the calibration and use of individual, analytical, and bulk balances.

2.0 Scope - This procedure applies to all electronic balances in the Drug Chemistry Sections of the State Crime Laboratory.

3.0 Definitions

- **Calibration -** Checking or adjusting (by comparison with a standard) the accuracy of a measuring instrument. Calibrations are performed by approved service contractors for all balances in the State Crime Laboratory Drug Chemistry Section.
- **Performance verification** - The initial confirmation of the reliability of a previously or externally validated method or instrument.
- **Primary reference standard weights–** Reference standard weights which have documentation issued by an approved vendor authenticating the calibration status.
- **Quality control (QC) Check -** Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents
- **Reference Standard –** Measurement standard designated for the calibration of other measurement standards (reference standards or equipment)
- **Secondary reference standard weights** – Reference standard weights, used in the course of casework, that have the calibration status verified by comparison to primary reference standard weights.

4.0 Equipment, Materials and Reagents

4.1 Equipment

- Section balances (individual, analytical, and bulk)

4.2 Materials and Reagents

- Weighing boats
- Paper, boxes, plastic bags or other weighing vessels
- Reference standard weights

5.0 Procedure

5.1 Standards and Controls

5.1.1 New balances

5.1.1.1 New balances shall be installed and leveled according to manufacturer's specifications. A calibration shall be performed by an outside vendor prior to use.

5.1.1.1.1 Initial calibration by the vendor shall be documented in Resource Manager in FA by Section personnel.

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5.1.1.2 Prior to being used for casework, all new balances in the Drug Chemistry Section shall undergo the procedure for the yearly balance study (see the Procedure for Measurement Assurance).

5.1.1.2.1 This procedure shall be performed by the Balances Coordinator (or designee) and documented as the Performance Verification in Resource Manager in FA.

5.1.2 QC Check

5.1.2.1 Table Top Balances Assigned to Forensic Scientists

5.1.2.1.1 The Forensic Scientist shall perform a monthly QC check on the table top balance using the 0.10, 1.00, 10.00, 100.00, and 1000.00 gram reference standard weights.

5.1.2.1.2 Results of the QC check shall be documented in the Resource Manager section of FA.

5.1.2.1.3 Acceptable ranges for reference standard weights used for QC checks shall be calculated by adding and subtracting the values for Highest Expanded Uncertainty at 99.7 % Confidence Level for each model. See the Drug Chemistry Measurement Assurance Yearly Report for current values.

5.1.2.1.4 The user shall ensure the balance is clean, level, and properly functioning before use each day it is used for casework.

5.1.2.1.5 A QC check using one reference standard weight shall be performed on the balance before casework is performed each day.

- Results of these daily QC checks shall be recorded and maintained by the Forensic Scientist in possession of the balance.
- These checks are only required for days when the balance is used for casework**.**

5.1.2.2 Bulk Balances

5.1.2.2.1 Bulk balance(s) shall have a monthly QC check performed by the Balances Coordinator (or designee) using two reference standard weights.

5.1.2.2.2 Results of the QC check shall be recorded in the Resource Manager section of FA.

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5.1.2.2.3 Prior to each use for casework, bulk balance(s) shall have a QC Check performed by the Forensic Scientist using one reference standard weight.

Note: In the case where only one set of weights is obtained by the laboratory (bulk balance weights), they shall be considered primary weights that may be used for casework.

5.1.2.2.4 A reference standard weight should be selected based on the weight of the item of interest.

5.1.2.2.5 Results of the one point check shall be recorded in the case file.

5.1.2.2.6 Acceptable ranges for reference standard weights used for QC checks shall be calculated by adding and subtracting the values for Highest Expanded Uncertainty at 99.7 % Confidence Level for each model. See the Drug Chemistry Measurement Assurance Yearly Report for current values.

5.1.2.3 Analytical Balances

5.1.2.3.1 Analytical balances shall have a monthly QC check performed by the Balances Coordinator (or designee) using three reference standard weights.

5.1.2.3.2 Results of the QC check shall be recorded in Resource Manager in FA.

5.1.2.3.3 Prior to each use for casework, analytical balance(s) shall have a QC Check performed by the user using one reference standard weight. A reference standard weight should be selected based on the weight of the item of interest.

5.1.2.3.4 Results of the one point check shall be recorded in the case file.

5.1.2.3.5 Acceptable ranges for reference standard weights used for QC checks shall be calculated by adding and subtracting the values for Highest Expanded Uncertainty at 99.7 % Confidence Level for each model. See the Drug Chemistry Measurement Assurance Yearly Report for current values.

5.1.2.4 QC Checks are to be performed for all balances according to working instructions for each specific balance type.

5.1.2.4.1 If results are within the range for the model, the balance may be used for casework.

5.1.2.4.2 If the results are outside these parameters, the balance shall not be used until all necessary steps have been taken to bring the balance into compliance.

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- Steps may include cleaning, leveling, re-taring, or contacting the Section Balances Coordinator who can then contact an approved ISO accredited outside vendor.

5.2 Calibrations

5.2.1 Calibration for all Drug Chemistry Section balances shall be done on a yearly basis by an approved ISO accredited outside vendor.

5.2.1.1 Yearly calibrations shall be documented in Resource Manager in FA by Section personnel.

5.2.1.2 Certificates of Calibration issued by the approved ISO accredited outside vendor shall be maintained in Section records by the Balances Coordinator.

5.2.2 Recertification for primary reference standard weights used in the Drug Chemistry Section shall be completed every three years by an approved ISO accredited outside vendor.

5.2.3 Secondary reference standard weights shall be checked once during each calendar year against the primary reference standard set of weights. See the Procedure for Measurement Assurance for requirements of a successful recheck and documentation procedures.

5.2.4 Reference standard weights calibration certificates shall be filed and maintained by the Balances Coordinator in each Laboratory.

5.2.5 When a Drug Chemistry Section balance has been placed out of service (e.g., maintenance/calibration, or malfunction), correct operation shall be demonstrated by a monthly QC Check.

5.2.5.1 This evaluation shall be conducted according to the monthly QC Check as outlined above.

5.2.5.2 This evaluation shall be done prior to the balance being used for casework and it shall be documented in Resource Manager in FA.

5.2.5.3 Laboratory personnel shall examine the effect(s), if any, of a malfunction on analysis results and implement the Procedure for Corrective Action as required.

5.2.6 Balances that have been used for casework, but are not currently assigned to a Forensic Scientist, are placed out of service. Balances not in service at the time of the yearly balance study are not included in the data collection process.

5.2.6.1 The procedure for the yearly balance study (see the Procedure for Measurement Assurance) shall be performed by the Forensic Scientist being

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assigned the balance and documented as a Quality Control Check before the balance is placed back into service.

5.3 Sampling - See Drug Chemistry Section Administrative Procedure for Sampling.

5.4 Application of Procedure on Evidence

5.4.1 Choose desired units of measure according to balance instructions. (Record weights from bulk balances in kilogram units only. Do not use the pound setting on the bulk balances. See "Calculations" **5.5** below for conversion factors.)

5.4.2 Tare the weighing boat or other weighing vessel that will hold the evidence.

5.4.3 Remove the tared weighing vessel from the balance.

5.4.4 Remove evidence from packaging material, if possible, and place in/on the tared weighing vessel.

5.4.5 Return the tared weighing vessel with evidence to the balance pan and record weight observed from the balance.

5.4.6 Note in the FA case file if gross weights are recorded.

5.4.7 For net and gross weights received, record in the FA case files all digits displayed by the balance.

5.4.8 For returned weights, replace the weighing boat or other weighing vessel back on the balance without taring and record all digits displayed by the balance.

5.4.9 Record the weight of material to be returned in the FA case file.

5.5 Calculations

5.5.1 When a trafficking amount of Marijuana is reported for a single item of evidence, the weight shall be reported in grams or kilograms with the appropriate uncertainty of measurement, and converted to pounds since the NC General Statutes are written with threshold levels of pounds.

5.5.1.1 When multiple populations are present in a single item where a threshold is present AND all items are weighed on the same balance, the reported weights of all populations in the item shall be added together and the final amount converted to pounds as directed below. Results of the conversion of all units analyzed in each item shall be reported as "The total weight of all material analyzed for Item X = XX.X pounds."

5.5.2 When conversion of grams or kilograms to pounds is needed, the following conversion factors shall be used as needed:

5.5.2.1 1000 grams = 1 kilogram

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5.5.2.2 1 pound = 0.45359237 kilograms

5.5.2.3 Truncate the value for pounds to the tenths decimal place and report original weight and Uncertainty of Measurement information in grams or kilograms.

Examples:
Item 1
Marijuana – Schedule VI.
Net weight of material – 5,216.31 (+/- 0.XX) grams. (11.4 pounds)

Item 1
Marijuana – Schedule VI.
Net weight of material – 23.72 (+/- 0.XX) kilograms. (52.2 pounds)

Item 1
1a) Three plastic bags
Marijuana – Schedule VI.
Net weight of material – 2,216.31 (+/- 0.03) grams.
1b) Four paper bags
Marijuana – Schedule VI.
Net weight of material – 2385.05 (+/- 0.04) grams.
Total weight of all material analyzed for Item 1 = 10.1 pounds.

5.6 Reporting

5.6.1 When net weights are reported, the following shall be included on the report:

- A notation that a net weight is being reported.
- All digits displayed on the balance.
- The corresponding calculated uncertainty for that measurement.
- Example for an individual top-loading balance:
  Cocaine – Schedule II
  Net Weight of Material – 1.25 (+/- 0.0X) gram(s).
  (See the Procedure for Measurement Assurance for current uncertainty.)

5.6.2 When only a gross weight can be obtained due to sample matrix, the following shall be included on the report:

- A notation that a gross weight of contents and packaging is being reported.
- The truncated value for the digits displayed on the balance.
- No measurement assurance values (calculated or reported).
- Example for sticky black substance wrapped in plastic:
  Material containing Heroin – Schedule I.
  Gross weight of contents and packaging – 1.2 grams.

5.6.3 Uncertainty of Measurement – The uncertainty of measurement shall be calculated by the following formula:

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$U_{final} = \sqrt{(U_{balance})^2 \times N}$
Which can be simplified to

$U_{final} = \sqrt{N} \times U_{balance}$

Where
U_{final} = Final uncertainty for the measurement process
$U_{balance}$ = Total Expanded Uncertainty
N = number of weighings
(See the Procedure for Measurement Assurance for current Uncertainty values.)

6.0 Limitations

6.1 If the balance does not read to the hundredths place due to units chosen (e.g., bulk balances) or due to the quantity of material being weighed, record in the case file all digits displayed on the balance.

6.2 Bulk balances are calibrated on a yearly basis only up to a 50 kilogram capacity. For this reason, bulk balances shall not be used to weigh any single item that weighs more than 50 kilograms.

6.2.1 If the bulk balance has capabilities above 50 kilograms, a sign shall be placed near the bulk balance location stating 50 kilogram maximum capacity for casework purposes.

6.3 Table top balances equipped with dual ranges are calibrated on a yearly basis in the lower range only. For this reason, table top balances are to be used in the lower range only.

7.0 Safety - Make sure balance is plugged in and is not near a source of water.

8.0 References

Operator Manuals for each balance model.

Moffat, A.C., et al., eds. *Clarke's Isolation and Identification of Drugs*. 2nd Edition. London: Pharmaceutical Press, 1986.

Butcher, K.S, et al., ed. *The International System of Units (SI) – Conversion Factors for General Use*. National Institute of Standards and Technology, NIST Special Publication: U.S Department of Commerce, May 2006: 11.

Virginia Department of Forensic Sciences. Controlled Substances Procedure Manual. Document 221-D100 Revision 7, February 6, 2012.

9.0 Records

- Certificates of Calibration for balances
- Certificates of Calibration for reference weights
- QC Check entries in Resource Manager section of FA

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10.0 Attachments - N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document - Technical Procedures L-01 through L-05 combined for conversion to ISO Standards.
02/15/2013	2	**4.1** - Added equipment models for Western Regional Laboratory. **5.1.1.1** - Added "A calibration shall be performed by an outside vendor prior to use." **5.1.2.1.5 -** Section added requiring a daily QC check with one reference standard weight. **5.1.2.2.4** and **5.1.2.3.3** - modified statements to represent all three laboratories. **5.1.2.4 -** Removed work instructions applicable to only Raleigh Laboratory. **5.5.1.2** - Removed example and made statement applicable to all three laboratories reference rounding and reporting.
05/10/2013	3	**5.3** - Revised name of Sampling Plan from Technical to Administrative Procedure **5.5.1.2** – Replaced "round" with "truncate"
05/22/2013	4	**Definitions –** Added primary and secondary reference standard weights definitions **5.2.2 and 5.2.3** - Added reference primary/secondary weights and recheck schedule **5.2.4** Added in each Laboratory **Original 5.2.2.1** – Deleted
07/31/2013	5	**5.1.1.2, 5.2.3, 5.6.3** – Updated name of Procedure for Measurement Assurance **5.6.1** – Added bullet point for reporting of net weights **5.6.2** – Added requirements for reporting of gross weights
11/15/2013	6	Added issuing authority to header.
04/18/2014	7	**5.2.6** - Added section to clarify putting unassigned balances back into service
08/29/2014	8	**Equipment List –** Edited/rearranged to reflect current data. **5.1.1.2.1, 5.1.2.2.1, 5.1.2.3.1, 5.1.2.4.2, 5.2.1.1, 5.2.4 –** Changed Balances Key Operator to Balances Coordinator. **5.1.2.1 and 5.1.2.3** – Added references in these sections and their subparagraphs for "table top balances", and "Toxicology Unit." Changed "Forensic Scientist" to "user" to accommodate Chemistry Technicians as well as Forensic Scientists. **5.1.2.2.3 -** Clarified bulk balance primary standard weights. **5.1.2.3.4** – Added reference to Resource Manager for

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		Toxicology Unit. **5.5** – Clarified procedure for conversion/reporting kilograms to pounds.
02/27/2015	9	**4.1 –** Removed specific balance model numbers to avoid changes in procedure when equipment changes. **5.1.1.1.1** – Added requirement that initial vendor calibration be documented in the FA system. **5.1.1.2.1** – Added requirement that initial Performance Verification be documented in the FA system. **5.1.2.1, 5.1.2.1.1, 5.1.2.1.5, 5.1.2.3,** and **5.1.2.3.4** – Removed references to Toxicology Balances. **5.1.2.1.5** – Edited daily balance check requirement to one check only, deleted "paper log." **5.2.1.1** – Added requirement that yearly vendor calibration be documented in FA system. **5.4.1** – Added "bulk" **5.4.7** – Added "net and gross" to record all digits displayed. **6.1** – Renumbered original single limitation. **6.2, 6.2.1** – Added 30 kg/50 kg maximum capacity to all bulk balances. **6.3** – Added limitation to lower range only for table top balances.
05/15/2015	10	**5.6.2 –** Changed reporting of only gross weight when sample matrix prevents complete removal of packaging.
10/19/2015	11	**Header -** Revised issuing authority **5.5 –** Added caveat for single item and conversion factor for grams to pounds
07/01/2016	12	**5.2.3** Delete specific month **5.2.5** Change performance verification to monthly QC check **5.5.1.1 -** Added details when multiple populations are present. **5.5.2.3 –** Added example for reporting for multiple populations

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