Quality Assurance and Operations Manual

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The Quality Assurance and Operations Manual (CHEM-100) supplements LAB-100 and LAB-200. Use CHEM-100 in conjunction with LAB-100 and LAB-200.

1 DOCUMENT CONTROL

1.1 Document Distribution and Control

1.1.1 Instrument Operation and Systems Support (IOSS) Protocols

Chemistry Unit (CU) personnel will have access to controlled copies of IOSS Protocols on CHEMNET.

1.1.2 Level 3 Documents (Controlled Equipment Manuals)

Controlled equipment manuals (to include electronic versions) are labeled as "controlled" on at least the first page or cover of the manual or directly on the electronic storage device containing the manual. Additionally, the approval signature(s) and date(s) will be recorded on the first page or cover of the manual. For electronic manuals, the signatures and dates are recorded on the *CU Electronic Instrument Manuals Under Document Control Review and Approval Document*. A master list of the Level 3 controlled documents will be maintained in the UC's office.

1.2 Annual Review of CU Controlled Documents

The below personnel will ensure an annual review of the listed documents is conducted and recorded. The annual review will be recorded in a memo issued to the UC by the end of each calendar year. Personnel responsible for more than one area may combine those areas into one memo. The memo will contain the following information:

- Any planned revisions, along with a timeline for submission of the revision(s)
- For any document that does not require revision, a statement indicating such

1.2.1 Technical Leader (TL)

Each TL will issue a memo for their applicable technical procedures, IOSS Protocols, CU Training Manual documents, Level 3 controlled documents, and Level 0 references [e.g., Organization of Scientific Area Committees for Forensic Science (OSAC) registry standards].

1.2.2 IOSS Instrument Manager

The Instrument Manager will issue a memo for the IOSS Protocols, applicable CU Training Manual documents, and applicable Level 3 controlled documents.

1.2.3 CU Quality Assurance Program Manager

The CU Quality Assurance Program Manager will issue a memo for CHEM-100.

1.2.4 CU Training Program Manager

The CU Training Program Manager will issue a memo for the general CU Training Manual documents.

2 EQUIPMENT

2.1 Reagents

2.1.1 Verification of Reagent Reliability

The reliability of a reagent will be verified prior to, or in concurrence with casework. This may be done in any of the following ways:

- When available, follow the reagent verification instructions given in the applicable technical procedure.
- Perform the analysis using suitable reference materials, known materials, controls, and/or blanks and evaluate the outcome.
- Measurement of a chemical property (e.g., pH).
- Apply to an item and evaluate a physical property (e.g., contrast of microstructural phases).

Reagent verification data will be kept in an appropriate location, such as within a reagent logbook, the CU Chemicals and Materials System (CAMS) database, an instrumentation binder, data archive, and/or examination records.

2.1.2 Reagent Preparation Records

For each CU prepared reagent, the following information will be recorded on the *CU Reagent Preparation Log* (CHEM-007) or in the CAMS database. Hard copy log sheets will be maintained in a reagent logbook maintained by each discipline/subdiscipline:

- Date of preparation
- Preparer
- Lot number (will contain initials of preparer and date of preparation)
- Components used to make the reagent and their source and lot information
- Verification result(s)
- Expiration date

2.1.3 Labeling of Reagent Containers

2.1.3.1 Purchased Reagents

Purchased reagents will have the following information recorded on the container:

- Date received
- Date opened

2.1.3.2 CU Prepared Reagents

CU prepared reagents will have the following information recorded on the container:

- Reagent name (using common name or SDS name)
- Lot number (contains the preparer's initials and the preparation date)
- Expiration date

2.1.4 Use of Reagents Beyond Their Expiration Date

A reagent may be used past its expiration date provided that the reagent reliability is verified. The expiration date will not be altered or removed.

2.2 Reference Materials

2.2.1 Certificate of Analysis (COA)

CU's Chemical Inventory Manager (CIM) will be notified of reference material purchases/receipts through the CAMS database, or by receiving a copy of the *Requisition for Suppliers and/or Equipment* form (FD-369, or equivalent) from the CU purchase credit card holder.

The CIM will ensure that a COA is requested/received from the manufacturer, if available. COAs will be retained by the CIM.

2.2.2 Reference Material Verification

A certified reference material (CRM) does not require verification. Additionally, Metallurgy maintains a reference collection that does not require verification. The Metallurgy reference materials are accompanied by certificates that justify the scope of their use, however the certificates for some of the materials do not meet the requirements to allow them to be classified as CRMs.

For all other reference materials, only one sample per manufacturer's lot number must be verified. Subsequent reference materials from the same lot will be considered as having the same verification as the original. The identity of the reference material will be verified prior to, or in concurrence with casework.

Data supporting the verification of the reference material will be provided to the CIM for retention.

2.2.2.1 Discrepancies in Identity

Discrepancies in the identity of a reference material will be discussed with the supplier and the material returned, if applicable. If the material is identified as something other than intended, the CIM must be notified. If the material is retained, the container must be labeled with information indicating the discrepancy. The supporting data will be provided to the CIM for retention.

2.2.3 Synthesis of a Reference Material

When a reference material is not available from a vendor, it may be necessary to synthesize it. The following information will be recorded and provided to the CIM.

- The procedure used to synthesize the material

- The date of synthesis
- The initials of the person who synthesized it
- Storage requirements
- Controlled substance schedule, if applicable

2.2.4 Use of Reference Materials Beyond Their Expiration Date

A reference material may be used past its expiration date provided that the reference material is verified. The expiration date will not be altered or removed.

2.3 Known Materials

A known material is an item acquired for method development, validation, and/or comparison with an evidentiary sample (e.g., commercial products, items received directly from manufacturers).

Known materials will undergo the same relevant analytical examinations that are performed on a questioned sample(s) during casework. The equipment, materials, reagents, and other relevant information may be found in the applicable technical procedure(s) being used. Sufficient information will be recorded in the examination records such that the nature of the known material is established.

2.4 Storage

Specialized storage conditions, as defined by the manufacturer, will be met when applicable. Additional information is provided below.

2.4.1 Controlled Substances

All controlled substances (with the exception of low concentration solutions, such as 1 mg/mL reference material solutions) will be stored in Redacted which is an evidence storage room (ESR) secured for dual-person entry. When entering Redacted the *Access Log – Evidence Storage Facility* form (FD-455) will be filled out unless the entry was recorded in a Laboratory Information System (LIMS).

The initial product weight of a controlled substance will be recorded electronically in the CAMS database. Each time any amount of a controlled substance is removed from its container, the before and after weights of the container will be recorded in the CAMS database.

2.5 Evaluation of External Suppliers of Products and Services that Affect CU Activities

A new external supplier of products and services that affect CU activities will be evaluated upon first use. The *Critical Supplier Assessment Form* (CHEM-002) will be used to record the evaluation. Completed forms as well as a list of approved external suppliers of products and services that affect CU activities are maintained in CU. An external supplier that demonstrates a history of unacceptable performance will be removed from the approved external suppliers list.

3 VALIDATION

3.1 Method Development (Pre-Validation)

Validation starts after a method is acquired and/or developed. If a method needs to be developed in CU (including the modification of an acquired method), the method development will be a planned activity. The *CU Method Development Plan* (CHEM-005) will be completed by the lead scientist and approved by the applicable TL. If the lead scientist is the TL, then another subject-matter expert (SME) will approve the plan. Any changes to the method development plan will be communicated to all personnel involved in the method development.

3.2 Validation Plan

A validation plan will be recorded, reviewed, and approved on the applicable form (listed below) prior to initiating the validation study.

- *Validation Plan and Review, Scope- Physical Properties Only* (CHEM-009)
- *Validation Plan, Scope- Qualitative Procedure* (CHEM-010)
- *Validation Plan, Scope- Quantitative Procedure* (CHEM-011)

3.2.1 Scope

The scope will declare the targeted matrices and analyte(s), specific equipment, and analytical method(s). The scope will generally fall into the following categories:

- Measurement of a physical property
- Screening for the presence or absence of a specified analyte or class of analytes
- Qualitative identification of a specified analyte or class of analytes
- Quantitation of a specified analyte or class of analytes

3.2.2 Performance Characteristics

The performance characteristics will vary depending on the scope. This decision requires professional judgment. For example, some performance characteristics are not relevant to particular sample types, but when applicable and appropriate, the following performance characteristics will be evaluated.

3.2.2.1 Measurement of a Physical Property

- Accuracy

3.2.2.2 Screening for the Presence or Absence of a Specified Analyte or Class of Analytes

- Interferences
- Ionization Suppression/Enhancement
- Limit of Detection
- Processed Sample Stability

3.2.2.3 Qualitative Identification of a Specified Analyte or Class of Analytes

- Carryover
- Interferences

- Ionization Suppression/Enhancement
- Limit of Detection
- Processed Sample Stability

3.2.2.4 Quantitation of a Specified Analyte or Class of Analytes

- Accuracy
- Calibration Model
- Carryover
- Interferences
- Ionization Suppression/Enhancement
- Limit of Detection
- Limit of Quantitation
- Precision
- Processed Sample Stability

3.3 Conduct Validation Experiments

The following experiments are listed alphabetically and not necessarily in procedural order. Discipline-specific documents and/or the validation plan will contain details with regards to the required number of replicates, number of runs, pre-defined acceptable limits, etc.

3.3.1 Accuracy

Accuracy (also referred to as bias) is the closeness of a measured value to the known, or "true" value and is typically reported as a percent difference. The accuracy of an analytical method can be estimated by measuring materials of known concentration or amount and comparing the result(s) with the known value(s). Matrix-matched reference materials are preferred for estimating accuracy. When practicable, these samples are obtained from an independent source rather than produced by the same person performing the validation.

$$Accuracy = \left[\frac{Measured\ Value - Known\ Value}{Known\ Value}\right] \cdot 100$$

3.3.2 Calibration Model

The calibration model is the mathematical model used to describe the relationship between signal response and analyte concentration. When possible, matrix-matched, spiked calibrator samples are analyzed to establish the calibration model.

The most often used calibration model is the least squares model for linear regression, although it should be noted that this model is only applicable when there is constant variance over the concentration range. When there is a significant difference between variances at the lowest and highest concentration levels, an appropriate non-linear model (e.g., weighted least squares) should be applied. Ultimately, the simplest calibration model that adequately describes the concentration-response relationship should be used.

Once established, the calibration model will not be changed unless additional validation studies have been conducted to evaluate and justify the change.

3.3.3 Carryover

Carryover is the appearance of an analyte signal in samples after the analysis of a positive sample. Carryover will be evaluated during method development and its source investigated. This can be accomplished by running matrix blank samples immediately after a high concentration sample or calibration standard. If possible, the analytical procedure will be modified to remove any carryover. In cases when it is not possible to eliminate the carryover, the technical procedure and/or a guidelines document must address how carryover will be assessed (e.g., the signal in a case sample must be ten times greater than the signal in a blank sample immediately preceding the case sample).

3.3.4 Ionization Suppression/Ionization Enhancement

The enhancement or suppression of analyte ionization resulting from the presence of co-eluting matrix components is a phenomenon commonly encountered in liquid chromatography/mass spectrometry (LC/MS). Ionization suppression/enhancement experiments may be performed during the method development phase to ensure extraction and instrumental conditions are optimized. It can be further evaluated during the validation phase using either of the following approaches.

3.3.4.1 Post-Column Infusion

Post-column infusion provides information on retention times where ionization suppression/enhancement occurs. A solution of the analyte is constantly infused with a syringe pump into the mobile phase from the column via a post-column tee-connection and a constant, baseline signal for the analyte of interest is collected. Extracted matrix blanks are injected into the LC/MS. If there is any considerable suppression or enhancement (>25%) of the infused analyte signal at the retention time of the analyte, then modification of the chromatographic system or the sample preparation may be required to minimize the ionization suppression/enhancement.

3.3.4.2 Post-Extraction Addition

Post-extraction addition yields a quantitative estimation of ionization suppression/enhancement. Two different sets of samples are prepared, and the analyte peak areas are compared between sets to evaluate the ionization suppression/enhancement. The first set consists of the neat standards at both low and high concentrations.

Set two consists of samples extracted from different matrix sources. The extracts are then fortified with the neat standard at either the low or high concentrations.

The average area of each set ($\bar{X}$) is used to estimate the ionization suppression/enhancement effect at each concentration as follows:

$$Effect = \left[\frac{\bar{X}(extracted)}{\bar{X}(neat)} - 1\right] \cdot 100$$

A negative value is indicative of ionization suppression, while a positive value is indicative of ionization enhancement. In instances when it is not possible to eliminate ionization suppression/enhancement during method development, the technical procedure should address how it will be managed.

3.3.5 Limit of Detection (LOD)

The LOD is an estimate of the lowest concentration (or amount) of an analyte that can be reliably differentiated from the analyte-free matrix and/or the background noise. In some instances, it may not be necessary to establish the absolute LOD provided it is shown to be less than the lowest concentration required by the method. Because a method's LOD incorporates the instrumental performance as well as the sample matrix and inherent procedural limitations, it may be important to assess LOD over multiple days. The LOD may be estimated by one or more of the following approaches.

3.3.5.1 Estimating LOD for Screening Methods

This approach is used for non-instrumental screening methods (e.g., chemical color tests). Blank matrix sources are fortified with decreasing concentrations of the specified analyte. The matrix-matched samples are then analyzed. Multiple analysts should be involved in assessing the results if there is subjectivity involved in the screening method. The lowest concentration of analyte that yields a positive result on all runs and confirmed by all participating analysts is considered the LOD.

3.3.5.2 Estimating LOD Using Background Noise

The following approaches may be used for determining the LOD of methods that demonstrate equipment-related background noise.

3.3.5.2.1 Estimating LOD Using Reference Materials

Matrix-matched reference materials at known concentrations are analyzed. The LOD is defined as the lowest concentration (or amount) of an analyte that reproducibly yields a signal greater than or equal to 3.3 times the noise level of the background signal.

3.3.5.2.2 Estimating LOD Using Statistics

The LOD may also be determined by statistically comparing results obtained from blank matrix samples and matrix-matched reference materials at known concentrations. The average and standard deviation for the signal of the blank samples are calculated. Likewise, matrix-matched reference materials at decreasing concentrations are analyzed, however the signals are evaluated independently (not averaged). The LOD is considered as the lowest concentration of a reference material that consistently yields a signal greater than the average signal of the blank matrix samples plus 3.3 times the standard deviation of the blank matrix samples.

3.3.5.3 Estimating LOD Using Calibration Curves

3.3.5.3.1 Concentration of Lowest Non-Zero Calibrator

In some instances, it may be sufficient to define the LOD as the value of the lowest acceptable non-zero calibrator. It is acceptable to use the replicates generated to establish the calibration model (see section 3.3.2).

3.3.5.3.2 Linear Calibration Curve

A linear calibration model is useful for estimating the LOD for quantitative procedures. The LOD is estimated from the standard deviation of the y-intercept (s_y) and the average slope of the best-fit lines (m_{avg}) as:

$$LOD = \frac{3.3 \cdot s_y}{m_{avg}}$$

3.3.6 Limit of Quantitation

The limit of quantitation (LOQ) is an estimate of the lowest concentration or smallest amount of an analyte that can be reliably differentiated and quantitated from an analyte-free matrix. In some instances, it may not be necessary to establish the absolute LOQ, provided it is shown to be at least that of the lowest non-zero calibrator. Because a method's LOQ incorporates the instrumental performance as well as the sample matrix and inherent procedural limitations it may be important to assess LOQ over multiple days. The LOQ may be estimated by one or more of the following approaches.

3.3.6.1 Estimating LOQ Using Concentration of Lowest Non-Zero Calibrator

In some instances, it may be sufficient to define the LOQ as the value of the lowest acceptable non-zero calibrator. It is acceptable to use the same replicates that were analyzed to establish the calibration model (see section 3.3.2).

3.3.6.2 Estimating LOQ Using Reference Materials

Matrix-matched reference materials are analyzed, and the concentrations are calculated from a calibration curve constructed over the entire working range. The lowest concentration that is capable of achieving an acceptable accuracy (see section 3.3.1) and precision (see section 3.3.7) is considered the LOQ.

3.3.7 Precision

Precision is a measure of the repeatability of a series of measurements of the same sample. It is expressed as the coefficient of variation (%CV) and two different types of precision studies will be assessed during method validation: within-run precision and intermediate precision.

Matrix-matched reference materials are preferred for estimating precision. When practicable, these samples are obtained from an independent source rather than produced by the same person performing the validation.

3.3.7.1 Within-Run Precision Calculations

Within-run precision may be calculated at each concentration level using the average and standard deviation of the replicates within a sequence:

$$Within\ Run\ CV(\%) = \frac{standard\ deviation\ (single\ run\ of\ samples)}{\bar{X}\ (single\ run\ of\ samples)} \cdot 100$$

3.3.7.2 Intermediate Precision Calculations

Intermediate precision may be calculated at each concentration level using the combined data from all replicates as:

$$Intermediate\ CV(\%) = \frac{standard\ deviation\ (all\ samples)}{\bar{X}(all\ samples)} \cdot 100$$

3.3.7.3 One-way ANOVA Approach to Calculating Within-Run and Intermediate Precision

Both within-run precision and intermediate precision may be calculated using the one-way ANOVA approach with the varied factor (run number) as the grouping variable. Using this approach, within-run precisions may be calculated at each concentration level as:

$$Within\ Run\ CV(\%) = \left[\frac{\sqrt{MS_{wg}}}{\bar{X}(all\ samples)}\right] \cdot 100$$

where MS_{wg} is the mean square within groups obtained from the ANOVA table.

Likewise, intermediate precisions may be calculated as:

$$Intermediate\ CV(\%) = \left[\frac{\sqrt{\frac{MS_{bg} + (n-1) \cdot MS_{wg}}{n}}}{\bar{X}(all\ samples)}\right] \cdot 100$$

where MS_{bg} is the mean square between groups obtained from the ANOVA table and n is the number of observations in each group (e.g., n=3 when doing triplicate analyses).

3.3.8 <u>Processed Sample Stability</u>

Circumstances may arise in which samples that have undergone routine preparation cannot be immediately analyzed. In these instances, it is important to evaluate the length of time a prepared sample can be maintained before it undergoes changes, which may prevent reliable detection and/or quantitation.

Matrix-matched reference materials are processed and used for stability determinations. It is important to ensure that sufficient quantity is prepared to complete this evaluation, keeping in mind that it may be necessary to split the sample into multiple portions. For example, samples in different autosampler vials may be analyzed every 8 hours up to 72 hours. The average responses for analytes of interest and any internal standards are used to evaluate any significant changes over the duration of the study.

3.3.9 Interference Studies

Interference studies are used to assess the selectivity of a method. Selectivity is the extent to which an analytical procedure is free from interferences arising from non-analytes, including matrix components which may be expected to be present. Selectivity can often be improved by modifying sample preparation or instrumental parameters (e.g., using a different column in chromatography).

The use of an alternate analytical procedure for verification of analytical findings is an additional assessment of selectivity. Whenever possible, orthogonal analytical techniques will be employed to respond to different properties of a particular analyte. For example, Fourier Transform Infrared Spectroscopy (FTIR) and mass spectrometry are orthogonal to each other, while FTIR and Raman spectroscopy are complementary, but non-orthogonal.

3.3.9.1 Matrix Interferences

Matrix interferences are usually sample specific and will be addressed on a matrix-by-matrix basis. When applicable, analyze matrix blanks from different sources to demonstrate the absence of interferences in the matrix.

3.3.9.2 Other Interferences

In certain instances, it is necessary to check for possible interferences from other analytes which may be expected to be present in authentic samples. For example, a method for analyzing blood samples for cocaine must be evaluated for interferences caused by the blood matrix, but also evaluated for common drugs of abuse (e.g., opiates, cannabinoids, amphetamines). This is accomplished by analyzing a negative matrix spiked with the potential interference(s) at appropriate concentration(s). Alternatively, neat standards of potentially interfering compounds can also be injected for this evaluation.

3.3.9.3 Stable-Isotope Internal Standard Interferences

In methods using stable-isotope labeled analogs, the isotopically labeled compounds may contain the non-labeled compound as an impurity. Additionally, the mass spectra of the labeled analogs may contain fragment ions with the same mass-to-charge ratios as the significant ions of the target analyte. In both instances, the peak area(s) of the analyte could be overestimated.

Internal standard interferences are assessed by analyzing a blank sample spiked with the internal standard and monitoring the signal(s) of the analyte(s) of interest. Likewise, a blank sample spiked with the analyte(s) at the upper limit of the calibration range is analyzed without internal standard, to evaluate if the unlabeled analyte ions appear as isotopically labeled compound fragments.

3.4 Modifications of Validated Procedures

Modifications to a validated procedure require verification that the changes do not have an adverse effect. The decision regarding which performance characteristics require additional validation will be based on logical consideration of the specific parameters likely to be affected by the change(s). These changes may include, but are not limited to:

- Analytical conditions
- Equipment
- Sample processing
- Data software

For example, changes of extraction solvent or a buffer may affect linearity, selectivity, LOQ, precision, and accuracy. A change of the analytical column or mobile phase may affect linearity and selectivity. Further, consideration should be given to conducting parallel studies with known samples utilizing both the previously validated procedure and the modified procedure in order to evaluate the effects of the changes.

3.5 Validation Summary

A *Validation Summary* form (CHEM-012) will be completed for each CU validation study that results in a new technical procedure. The individual that led the validation study will complete the form and provide it to the applicable TL. If the TL is the "Lead Scientist" for the study, then another SME will review and approve the validation summary. The summary will briefly describe the performance characteristics that were evaluated to include the values that were obtained for the performance characteristics, if applicable. Other details may be included in the summary. An abstract for a scientific article is a basic model that may be considered when composing the summary.

3.6 Technical Review of Validation Records

The technical review(s) will be recorded on the cover page of the validation records.

3.7 Records

The data generated during method validation studies must be retained. Validation records must include a summary of the studies conducted, who conducted the studies, and the results. The records will include the following:

- Validation Plan (i.e., CHEM-009, CHEM-010, or CHEM-011)
- Validation Summary (CHEM-012)
- Description of performance characteristics that were evaluated. If any of the required performance characteristics were not evaluated, then the reason will be stated.
- Sample preparation steps to include concentrations and matrices
- Data printouts or reference to where the raw data may be found
- Results and calculations
- Conclusions
- References

3.8 Minor Deviations to Previously Validated Procedures

3.8.1 Minor Deviation Records

All minor deviations to technical procedures will be recorded by the applicable TL in a centralized location. The format of the records is left to the discretion of the TL. In addition to the required information in LAB-100, the records will include the following if applicable:

- FBI Laboratory number(s) or batch code(s) [linked to the FBI Laboratory number(s)] associated with the minor deviation
- Reference to additional validation records

4 MEASUREMENT UNCERTAINTY

4.1 Scope

These requirements apply to CU personnel recording and/or reporting measurement results that require an estimation of measurement uncertainty. Measurement uncertainty will be estimated for all reported quantitative results and when the measurement uncertainty is relevant to the validity and/or interpretation of the examination results.

4.2 Estimating Measurement Uncertainty

The eight steps listed below are used to estimate measurement uncertainty:

- Step 1: Specify the measurement process
- Step 2: Identify uncertainty components
- Step 3: Quantify uncertainty components
- Step 4: Convert quantities to standard uncertainties
- Step 5: Calculate combined standard uncertainty
- Step 6: Expand the combined standard uncertainty by coverage factor (k)
- Step 7: Evaluate the expanded uncertainty
- Step 8: Report the uncertainty

The CU utilizes uncertainty budgets for performing estimation of measurement uncertainty calculations.

4.2.1 Step 1: Specify the Measurement Process

In the first step, the measurand is defined. The measurand is the quantity intended to be measured. It is important to be as specific as possible when defining the measurand. The measurand will likely be determined by a combination of measurement processes. If necessary, include a reference to a specific technical procedure, instrument, etc., in the statement defining the measurand to distinguish one measurement process from another.

4.2.2 Step 2: Identify Uncertainty Components

Possible uncertainty components associated with the measurement process should be assembled into a reasonably comprehensive list. This list must include all uncertainty

components considered, and which uncertainty components were deemed to be significant. An uncertainty component is considered significant if a change in the uncertainty component corresponds to a change in the significant figures of the stated value or uncertainty of the measurement result. Several uncertainty components that may be considered in this process are provided below. The specific measuring device or instrument used will be evaluated in the estimation of measurement uncertainty for the associated technical procedure.

- Sampling (homogeneity, physical state, environment, etc.)
- Sample preparation (homogenizing, dissolving, extracting, diluting, concentrating, derivatizing, etc.)
- Reference materials (purity, ability to matrix match, etc.)
- Uncertainty of a calibration (pipettes, balances, etc.)
- Calibration curves (uncertainty of calibrators, matrix matching of calibrators, etc.)
- Analysis (systematic errors, random errors, environment, matrix interferences, run-to-run precision, etc.)

4.2.2.1 Reconciliation of Uncertainty Components

Reconciliation simplifies the uncertainty budget. In this step, a review is conducted to determine whether a listed uncertainty component is adequately accounted for by existing data (usually repeatability data) or small experiments are planned to account for the uncertainty component. The basis for this step lies in the fundamental assumption that if an uncertainty component is representatively varied during the course of a series of observations, then the uncertainty associated with that component is adequately accounted for in the repeatability of those observations. Of course, it is important that those uncertainty components that are reconciled in this step are truly represented through the existing data or planned experiments.

4.2.3 Step 3: Quantify Uncertainty Components

Once the uncertainty components have been identified and reconciled, the standard deviation of each will be determined. The approach to calculating the standard deviation is dependent on whether the uncertainty component is classified as a *Type A* or *Type B*.

4.2.3.1 Type A Uncertainty

Type A uncertainty is evaluated by the statistical analysis of data from a series of measurements, assuming a normal distribution. The CU relies on the use of "historical" data (e.g., method validation data, positive control data) to establish a historical standard deviation for the measurement process. The historical standard deviation is the value assigned to the *Type A* uncertainty associated with the measurement process and the equation for calculating the historical standard deviation (s_{hist}) is shown below.

$$s_{hist} = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}},$$

where $\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$ (i.e., $\bar{x}$ is the average measurement result),
and $n =$ the number of measurements

There may be instances where the standard deviation for a measurement process is calculated to be extremely small or even zero due to the standard deviation being less than the resolution of the measuring device. In these instances, the estimated standard deviation (s_p) will be calculated from the below equation, where *d* = the measuring device resolution. The estimated standard deviation will be compared to the historical standard deviation and the larger value will be used.

$$s_p = \frac{d}{\sqrt{3}}$$

4.2.3.1.1 Measurement Assurance and Updating the Historical Standard Deviation

At least one positive control sample is analyzed with each measurement process. A range of acceptable values for positive control samples is defined in the associated technical procedure. If a value that does not fall within the acceptable range is observed, then the result will be investigated. If the value cannot be explained (e.g., human error, instrument malfunction) then an appropriate statistical analysis will be performed to determine if the value is an outlier. An outlier value will be rejected and not used to update the historical standard deviation. Otherwise, the value will be included in the updated standard deviation calculation.

The schedule to review and update the repeatability component (i.e., historical standard deviation) used in uncertainty calculations will be defined within the applicable technical procedure.

4.2.3.1.2 Adjustments to the Historical Standard Deviation when Reporting the Average of Multiple Measurements of a Case Specimen (Standard Deviation of the Mean)

It is common for multiple measurements of a case specimen to be made and the average of the multiple measurements to be reported. These repeat measurements provide more information and more confidence in the reported result. In these instances, the standard deviation of the mean (s_{mean}) will be calculated as follows, where s_{hist}= the historical standard deviation, and n = the number of measurements used to calculate the average value of the case specimen:

$$s_{mean} = \frac{s_{hist}}{\sqrt{n}}$$

The standard deviation of the mean is then used as the *Type A* uncertainty value.

As an example, if a historical standard deviation for a procedure was equal to 4.3_8% and a case specimen measurement result was based on an average of 5 measurements, then the standard deviation of the mean would be calculated as [$(4.3_8\%) / \sqrt{5}$] = 1.9_6%. This value of 1.9_6% would then be used as the *Type A* uncertainty value in the estimation of measurement uncertainty calculations (note- in this example three significant figures are carried forward as indicated by the subscript in the hundredths place, with the intention of rounding up to two significant figures at the conclusion of the uncertainty calculations).

4.2.3.2 Type B Uncertainty

Type B uncertainty is evaluated by means other than the statistical analysis of data from a series of observations. No single approach is applicable for evaluating and quantifying these uncertainty components. Examples of *Type B* uncertainty components include uncertainty of a calibration (i.e., external calibration services), uncertainty of a reference material, and uncertainty of volumetric glassware.

Some *Type B* uncertainty values can be derived from sources of information that are readily available. These sources include:

- Calibration certificates
- Manufacturer's specifications
- Reference data

When information sources such as those listed above are not available for deriving *Type B* uncertainty values, but the upper and lower limits of the equipment are known, then the uncertainty value will be estimated using the Rectangular Distribution or Triangular Distribution approaches described below. When in doubt, use the Rectangular Distribution approach as it is the more conservative approach.

4.2.3.2.1 *Type B* Uncertainty- Rectangular Distribution

A Rectangular Distribution approach can be used to estimate a *Type B* uncertainty component if the following criteria are met: the upper and lower limits of the equipment are known, the probability that a value lies outside of these limits is zero, and one value is just as likely as another value between the limits (equal probability). For a Rectangular Distribution, the upper limit = +a, the lower limit = -a, and the possible range of values = 2a. The calculation to estimate the equivalent of one standard deviation is defined as:

$$s = \frac{a}{\sqrt{3}}$$

For example, if a 100 mL volumetric flask has a tolerance of ±0.2 mL, then the upper limit = +0.2 mL, the lower limit = -0.2 mL, and the range of the outer limits = 0.4 mL. The estimated standard deviation is calculated as:

$$s = \frac{0.2\ mL}{\sqrt{3}} = 0.1_2\ mL$$

4.2.3.2.2 *Type B* Uncertainty- Triangular Distribution

A Triangular Distribution approach can be used to estimate a *Type B* uncertainty component if the following criteria are met: the upper and lower limits of the equipment are known and a value near the center is more likely than one at the upper or lower limit. For a Triangular Distribution, the upper limit is still equal to +a, and the lower limit is still equal to -a. The calculation to estimate the equivalent of one standard deviation is defined as:

$$s = \frac{a}{\sqrt{6}}$$

4.2.4 *Step 4: Convert Quantities to Standard Uncertainties*

Standard uncertainty is simply the measurement uncertainty expressed as a standard deviation. All statistically calculated uncertainty components (*Type A*, *Type B*- Rectangular Distribution, and *Type B*- Triangular Distribution) should already be expressed as one standard deviation.

The information source (e.g., calibration certificate) for any other *Type B* component must be carefully reviewed in order to arrive at the standard uncertainty. For example, calibration certificates generated by NIST are typically calculated assuming a normal distribution and reported at a 95% confidence level (k = 2). In this case, the reported uncertainty on the certificate will be divided by the coverage factor, 2, to arrive at the standard uncertainty.

In preparation for the next step, all standard uncertainties must be expressed in the same measurement unit. If the same measurement unit is not associated with each standard uncertainty, then convert each standard uncertainty into a percentage (i.e., relative standard uncertainty).

4.2.5 *Step 5: Calculate Combined Standard Uncertainty*

In this step, all of the individual standard uncertainties are combined to calculate a standard uncertainty of the measurement process, which is an estimated standard deviation. This combined standard uncertainty [$u_c\ (y)$] is calculated as the square root of the sum of the variance of each of the combined uncertainty components:

$$u_c(y) = \sqrt{s_p^2 + u_0^2 + u_1^2 + u_2^2 + \ldots\ldots + u_i^2}\ ,$$

where s_p is the *Type A* calculated standard uncertainty for the measurement process and u_i are the *Type B* calculated standard uncertainties.

4.2.6 *Step 6: Expand the Combined Standard Uncertainty by Coverage Factor (k)*

The combined standard uncertainty calculated in the previous step is an estimated standard deviation with a confidence level of ~68.27% (k = 1). The combined standard uncertainty will be expanded by an appropriate coverage factor (k) to yield a confidence level of ≥ 95%. The specific value for the coverage factor is based on the amount of data that is available for the measurement process (i.e., *Type A* data). For example, Table 1 provides the coverage factor (k) to apply for a confidence level of 99.7% based on the degrees of freedom (*n-1*), where *n* is equal to the number of *Type A* data points. Coverage factors other than those shown in Table 1 can be calculated using Redacted The combined standard uncertainty [$u_c\ (y)$] is simply multiplied by the coverage factor to yield the expanded uncertainty (U) as shown below:

$$U = k * u_c(y)$$

Table 1: Coverage factor, *k*, at a 99.73% confidence level

Redacted **reported as "99.7% confidence level").**

Degrees of Freedom	Probability (1-CL)	k-value (99.73% CL)
10	0.0027	3.9569
11		3.8499
12		3.7642
13		3.6941
14		3.6358
15		3.5864
16		3.5441
17		3.5075
18		3.4754
19		3.4472
20		3.4221
25		3.3296
30		3.2703
35		3.2291
40		3.1987
60		3.1299
80		3.0965
100		3.0767
500		3.0150

4.2.7 Step 7: Evaluate the Expanded Uncertainty

In this step the expanded uncertainty (U) is evaluated to determine if it makes sense and is reasonable. This evaluation may identify calculation errors that can be corrected. Additionally, if pre-determined acceptable limits were defined for measurement uncertainty, then the expanded uncertainty should be evaluated against the acceptable limits. If the measurement uncertainty is deemed to be unacceptable, areas of method improvement can be identified and evaluated for their impact on the estimation of measurement uncertainty using the information available from Steps 3 and 4.

4.2.8 Step 8: Report the Uncertainty

Expanded uncertainty will be rounded up and reported with two or less significant figures. This rounding up should only be done at the end of the measurement uncertainty calculation, to prevent cumulative effects from rounding up each standard uncertainty value. The reported measurement result will be truncated to the same level of significance that the rounded expanded uncertainty is reported. For example, if the measurement uncertainty of methamphetamine concentration in blood is 29 ng/mL (99.7% confidence level), and the

measurement result for the case specimen is 498.23 ng/mL, then the measurement result will be truncated and reported as 498 ng/mL.

When reporting quantitative values in a *Laboratory Report*, the CU will include the measurement result with the associated expanded uncertainty and the confidence level. For example, "Item 1 weighed 506.5 milligrams ± 1.2 milligrams (99.7% confidence level)."

4.3 Records

Supporting records related to the estimation of measurement uncertainty may be maintained in multiple locations to include: technical procedures, validation binders, measurement uncertainty records (to include electronic files, e.g., Redacted), and case files. Refer to LAB-100 for the specific information that needs to be recorded.

5 MEASUREMENT TRACEABILITY

Measurement traceability is required for all measurements where measurement uncertainty is estimated. Measurement traceability can be characterized by the following essential elements:

- Documented unbroken chain of calibrations
- Documented measurement uncertainty (including specification of the measurand and evaluation of each step in the traceability chain)
- Documented measurement procedure
- Technical competence
- Realization of the International System of Units (SI Units)
- Documented calibration intervals
- Measurement assurance

5.1 Establishing Measurement Traceability

5.1.1 Establishing Measurement Traceability Through the Calibration of Equipment Used

5.1.1.1 Equipment List

The following CU equipment requires calibration when the measurement accuracy or measurement uncertainty of the equipment affects the validity of the examination and/or the calibration is required to establish metrological traceability of the examination. However, equipment of the type listed below that is used in CU for qualitative purposes only is not required to be calibrated.

- Balances
- Weight sets
- Pipettes
- Rockwell Hardness tester (HRB and HRC scales)
- Microhardness tester (Knoop and Vickers scales)
- Micrometers
- Calipers
- Gauge blocks
- Load cells

- Extensometers
- SmartScope
- Volumetric glassware

5.1.1.2 Specifications for Suppliers of External Calibration Services

See LAB-100.

5.1.1.3 Specified Requirements for Calibrations

Suppliers of external calibration services will be considered to meet CU requirements when a calibration certificate is supplied that provides the calibration status, the specified property, its associated measurement uncertainty, and a statement of metrological traceability. Reviews of calibration certificates for accuracy and conformance are recorded in the LIMS.

5.1.1.4 Interval of Calibration

CU equipment that requires calibration is calibrated on an annual basis. The calibration due date is maintained in the LIMS and is indicated on (or near) the equipment.

5.1.2 Establishing Measurement Traceability Through Reference Materials

5.1.2.1 Calibrators

CRMs with valid measurement traceability will be used as the source of calibrators when calibrators are used in conjunction with a measuring system to establish measurement traceability. If the CRM is changed in a way that alters the traceable measurement value (e.g., dilution) then calibrated equipment will be used to alter the CRM (e.g., pipette, volumetric glassware) and will be considered part of the traceability chain.

Specific information related to preparation and evaluation of calibrators can be found in the applicable CU technical procedures.

5.2 Measurement Assurance

Applicable CU technical procedures contain information on the performance checks utilized to maintain confidence in the calibration status of the equipment and CRMs used for measurements.

5.3 Records

Measurement traceability relies upon a variety of records. Applicable TLs will ensure the necessary records are compiled into a measurement traceability file, which may consist of paper and/or electronic records. At a minimum, this measurement traceability file will contain:

- A list of uncertainty components deemed to be significant to the measurement and how traceability of each of the uncertainty components is established (i.e., through calibration of equipment or through CRMs).
- Supporting documentation that demonstrates a supplier of external calibration services meets requirements.
- Supporting documentation that demonstrates a CRM provider meets requirements.

- Supporting data and/or calculations that demonstrate calibration of particular equipment is not significant to the measurement result and associated measurement uncertainty (where applicable).

6 PROFICIENCY TESTING/INTRALABORATORY COMPARISON

Each CU examiner and analyst must complete one annual open proficiency test in each "Test Description" listed in Table 2 in which they routinely perform casework. Note- the "Metallurgy (Trace Metal Comparison)" test is an intralaboratory comparison.

Table 2- CU Proficiency Test/Intralaboratory Comparison Summary

Discipline	Test Description	Frequency
Seized Drugs	Drug Analysis	1/year/individual
Toxicology	Whole Blood Alcohol/Volatiles (Survey AL1)	1/year/individual
	Forensic Toxicology (Survey FTC)	3 team tests/year
	Drug Facilitated Crime (Survey DFC)	2 team tests/year
Fire Debris and Explosives	Ignitable Liquid Identification	1/year/individual
Materials (Trace)	Chemical Unknown	1/year/individual
	Paint	1/year/individual
	Tape	1/year/individual
	Metallurgy (Trace Metal Comparison)	1/year/individual
	Metallurgy (Steel Quantitation)	1/year/individual

6.1 Distribution

Prior to distribution of any proficiency test, the "Participant & Test Info" and "Test Preparation" sections of the *CU Open Proficiency Test Preparation and Evaluation Form* (CHEM-006) will be completed by the CU proficiency test representative (CU PTR). The CU PTR will ensure the proficiency test and associated paperwork is delivered to the test participant. The test participant will sign and date the applicable memo as an acknowledgment of receipt of the proficiency test and due date. This memo will be retained in the proficiency test file.

6.2 Analysis Approach

Each examiner will complete their proficiency test independently. The only exceptions are the Forensic Toxicology and Drug Facilitated Crime tests.

6.3 Metallurgy Intralaboratory Comparison (Trace Metal Comparison)

6.3.1 Preparation

The Trace Metal Comparison test will be prepared as needed by the CU PTR and/or an examiner/analyst that is authorized in the applicable discipline/subdiscipline. Any other

personnel participating in sample preparation will need prior approval from the applicable TL. This approval will be recorded on the *CU Open Proficiency Test Preparation and Evaluation Form* (CHEM-006) or attached records. Sample and test preparation records will be retained permanently in the intralaboratory comparison file.

6.3.2 Test Design

The intralaboratory comparison will consist of either a positive or negative association based on the composition of the material. All samples provided to the participant will come from a source that has an established composition. The sources include NIST-traceable reference materials or other metal samples of known provenance. The samples should be chosen to be homogeneous for the purposes of analysis and should be of sufficient size to allow all necessary analyses to be performed. The individual samples will be placed in appropriate, separate packaging and given unique identifiers. The sample(s) and test preparation information will be provided to the CU PTR. The CU PTR will distribute the test sample(s) to the participant.

6.3.2.1 Positive Test

The positive test will consist of a minimum of three splits of samples provided to each participant. At least two of the splits will be from the same source.

6.3.2.2 Negative Test

The negative test will consist of a minimum of three splits of samples provided to each participant. All of the splits will be from different sources.

6.4 Proficiency Tests

The CU PTR will ensure proficiency tests are procured for CU. Proficiency tests are administered as directed by the provider. Additional information is provided below.

6.4.1 Toxicology

Each qualified examiner and analyst will take at least one Whole Blood Alcohol/Volatiles (Survey AL1) proficiency test per year. Each examiner and analyst may assist in the analysis of the Forensic Toxicology (Survey FTC) and Drug Facilitated Crime (Survey DFC) tests, but this will not count as an individual proficiency test.

6.4.1.1 Whole Blood Alcohol/Volatiles (Survey AL1)

A subscription to Survey AL1 provides three tests per year that are shipped at different times. All samples contained within a single Survey AL1 must be analyzed by the test participant. Since the Toxicology team does not routinely perform ethylene glycol testing, this section of the Survey AL1 results form will be left blank.

6.4.1.2 Forensic Toxicology (Survey FTC)

A subscription to Survey FTC provides three tests per year that are shipped at different times. All samples within the Survey FTC will be analyzed by the Toxicology team in order for the survey to be considered complete. Each test will be assigned to one examiner who will coordinate the analysis of the samples, collect all data, and assemble the final results.

6.4.1.3 Drug Facilitated Crime (Survey DFC)

A subscription to the Survey DFC provides two tests per year that are shipped at different times. All samples within the Survey DFC will be analyzed by the Toxicology team in order for the survey to be considered complete. Each test will be assigned to one examiner who will coordinate the analysis of the samples, collect all data, and assemble the final results.

6.4.2 Tape Analysis

In the event that the test sample(s) received consist of a type of tape not routinely analyzed by CU (e.g., office tape, masking tape), the CU PTR will coordinate the preparation of an intralaboratory comparison using retained proficiency tests. The sample(s) and test numbers will be changed so they cannot be correlated to published test results.

6.4.3 Metallurgy (Steel Quantitation)

Measurement uncertainty will not be estimated nor reported for this test since it does not influence the interpretation of the results of examinations and the test provider (ASTM) does not allow it to be reported.

6.5 Reporting and Evaluation

Proficiency test and intralaboratory comparison results will be reported and reviewed similar to casework. The requirements for marking case records are the same as for casework, with the exception that the CU Test ID # (analogous to the FBI Laboratory number in casework) only needs to be on the first page of bound examination records.

6.5.1 Division of Labor

For a proficiency test/intralaboratory comparison assigned to an analyst, the analyst will provide all notes and analytical data to an examiner authorized in the applicable discipline/subdiscipline. For an intralaboratory comparison, the analyst and examiner will complete their respective portions of the *CU Internal Proficiency Test Results Form* (CHEM-004). For proficiency tests, the examiner will complete the provider's data sheet(s).

6.6 Completed Intralaboratory Comparison/Proficiency Test Samples

Upon completion of a proficiency test/intralaboratory comparison, all remaining samples will be returned to the CU PTR.

6.7 Evaluation

The "Evaluation" section of the *CU Internal Proficiency Test Results Form* (CHEM-004) will be completed by the CU PTR for each proficiency test/intralaboratory comparison administered, with the exception of his or her own proficiency test/intralaboratory comparison which will be evaluated by the UC or applicable TL. The Evaluator, UC, and Participant will then sign and date the form after reviewing the proficiency test/intralaboratory comparison and summary report(s).

6.8 Records

The CU PTR will ensure that the relevant records associated with a completed proficiency test/intralaboratory comparison are maintained permanently. The following records will be maintained in CU, electronically, and/or in the LIMS:

- *CU Open Proficiency Test Preparation and Evaluation Form* (CHEM-006)
- Examination records
- Results of test and sample validations (for intralaboratory comparisons)
- Memo from the CU PTR to the test participant that accompanies the proficiency test/intralaboratory comparison
- *CU Internal Proficiency Test Results Form* (CHEM-004)
- Results and evaluation notices from proficiency test providers
- All notices to and from the Laboratory Division Proficiency Test Program Manager (PTPM) concerning a particular test
- Completed provider data sheets

7 EVIDENCE HANDLING AND EXAMINATION PROCESS

Appendix A contains a list of abbreviations that are specific to CU. Any other CU-specific abbreviations will be defined upon first use within each case file.

7.1 Evidence Handling

7.1.1 Evidence Storage

Other than the below exceptions, evidence will be stored in an Redacted at the end of each day. When evidence is stored in a location other than an individually assigned locker within an ESR, each transfer to-and-from the storage location (e.g., cage, refrigerator, shelf) will be recorded.

Evidence that is not transferred to an ESR at the end of the day will be secured by placing an "Evidence Do Not Disturb" sign (or similar) on top or in front of the evidence and locking the door to the room (where possible). This practice is limited to evidence that is too large and/or bulky to transfer, or evidence that is being processed in a manner that prohibits transfer. Transfer of the evidence to the non-ESR storage location will be recorded at the end of each day it was examined.

7.1.2 Evidence Seal

7.1.2.1 Boxes with Zip Tie Closures

Boxes with zip tie closures (also referred to as "blue bins") will be considered properly sealed when zip ties are applied to both ends of the box and each zip tie is initialed by the individual sealing the box.

7.1.2.2 Exception- Toxicology Racks

Routine toxicology evidence (i.e., blood, vitreous humor, urine and other biological specimens) may be stored in its collection tube/specimen container without a proper seal. The

tubes/containers will be individually labeled with the FBI Laboratory number and item identifier and will be stored in racks or trays within the CU evidence refrigerators in Redacted [Exception to LAB-200, Section 1.2.1- A., C. 1. and C. 2.]

7.1.3 Repackaging Drug Evidence Following CU Exams

Prior to returning evidence and where practicable, any item(s) that require additional examinations (e.g., latent prints) will be separated from bulk drug evidence and repackaged. An *FBI Laboratory Drug Evidence* label (7-248) is not required if the item(s) can be handled as general evidence within the FBI Laboratory (see LAB-200, *Drug/Valuable Evidence Flow Chart*).

7.2 Evidence Inventory

After a submission is assigned and the evidence is delivered to the CU, the evidence container(s) and/or packaging will be opened and the contents inventoried. The *CU Evidence Check-In Sheet* (CHEM-003) form or the *FBI Laboratory Evidence Check-In Notes* (generated in the LIMS) will be used for recording the inventory.

A *CU Evidence Check-In Sheet* (CHEM-003) is not required when the evidence management personnel's *FBI Laboratory Evidence Check-In Notes* adequately describe the details of the received evidence, so long as the applicable examiner or analyst records this review.

7.3 Examination Process

7.3.1 Secondary Evidence

Secondary evidence is material derived from an examination process on an item of evidence (e.g., prepared microscope slides, pill boxes containing debris, vials containing extracts). If sufficient original evidence remains after the examination process such that the process could readily be repeated, then the material is not required to be retained as secondary evidence.

Secondary evidence is recorded on the *CU Secondary Evidence Log* (CHEM-008). The item description will include "Secondary Evidence" along with the unit, discipline, number, and type of evidence. For example:

- Item 2 Secondary Evidence, Chemistry-General (2 vials)

7.3.2 Autosampler Verification

When an autosampler is used, a sequence log containing the file name, autosampler position, and sample identification will be printed, or otherwise retained. For instruments that do not have the ability to print a sequence log, or in other situations when a sequence log cannot be obtained, the *CU Autosampler Verification Log* (CHEM-000) will be completed and retained. The sequence log or *CU Autosampler Verification Log* (CHEM-000) will be completed by the instrument operator and will be acknowledged by the operator (e.g., initialed, electronic entry, communication log entry) to indicate that the sequence was checked against the sample position(s) to ensure the two are in agreement.

8 CASE RECORD AND REVIEW

8.1 Contemporaneous Changes to Physical Records

If a handwritten change is made contemporaneously to a physical record, this will be indicated with an asterisk (*) along with an initialed single strike-out and the change entered alongside.

8.2 Case Record Review

The review of CU case records encompasses three forms of review: verification of identifications and associations, technical review, and administrative review. Each review process must be completed and recorded prior to issuing a *Laboratory Report* to a contributor.

An association, as defined by the CU, exists between two or more items if they possess one or more characteristics that indicate they could have originated from a common source. The strength of the association can vary and depends on the characteristics observed. Details on the nature and relative strength of an association between evidentiary items and/or evidentiary item(s) and known materials will be provided in the *Laboratory Report*.

8.2.1 Technical Reviews and Verifications of Identifications and Associations

The technical review and verification of identifications and associations are combined into a single review process. This technical review will include a check of manual calculations, data transcriptions, and data reductions relevant to the examinations.

8.2.1.1 Packets

An examiner may perform a technical review on a case record that contains a "packet(s)" of examination records they authored/co-authored, provided that the packet(s) has been technically reviewed by another authorized individual in the discipline that did not co-author the packet(s) in question. The technical review of the packet(s) will be recorded on the first page of the packet(s) with the reviewing examiner's initials and/or signature (handwritten or secure electronic equivalent), the date, and a statement indicating that the packet(s) has been technically reviewed.

8.2.2 Administrative Reviews

8.2.2.1 Reviewers

Authorized CU administrative reviewers are documented in an Electronic Communication (EC) uploaded to Sentinel.

8.2.2.2 Packets

A reviewer may perform an administrative review on a case record that contains a "packet(s)" of examination records they authored/co-authored, provided that the packet(s) has been administratively reviewed by another reviewer that did not co-author the packet(s) in question. The administrative review of the packet(s) will be recorded on the first page of the packet(s) with the reviewer's initials and/or signature (handwritten or secure electronic equivalent), the date, and a statement indicating that the packet(s) has been administratively reviewed.

8.3 Expedited Results

Expedited or partial results of an examination(s) will be technically reviewed prior to dissemination. The technical review will be recorded in the examination records.

8.4 Recording Nonconformities

Nonconformities will be recorded within a logbook that is maintained by the UC.

9 REVISION HISTORY

Revision	Issue Date	Changes
00	01/28/2022	Drafted new manual to replace previous Chemistry Unit Quality Assurance Manual documents.

APPENDIX A- CU ABBREVIATIONS

Abbreviations

ABS	acrylonitrile-butadiene-styrene co-polymer
BC	basecoat
BOPP	biaxially-oriented polypropylene
bpt	black plastic tape
cap	capsule
CC	clear coat
CD, c.d.	cross direction
CT	culture tube
gms	glass microscope slide
GSV	gray stoppered vial
gws	glass well slide
GWt	gross weight
HDPE	high-density polyethylene
HS	heat-sealed
HSB	heat-sealed bag
HSE	heat-sealed envelope
HSEE	heat-sealed evidence envelope
IS, ISTD	internal standard
LDPE	low-density polyethylene
LSV	lavender stoppered vial
MD, m.d.	machine direction
MMA	methyl methacrylate
MMY	make/model/year
MOPP	monoaxially-oriented polypropylene
NC	negative control
NCB	negative control blood
NCS	negative control serum
NCU	negative control urine
ND, n.d.	not detected
N/R	no reaction
NR, n.r.	not reporting
PB	plastic bag
PBX	pill box
PC	positive control
PCB	positive control blood
PCH	positive control high
PCL	positive control low
PCS	positive control serum
PCU	positive control urine
PE	polyethylene
PP	polypropylene
PS	polystyrene
RSV	red stoppered vial
SBR	styrene butadiene rubber
SIS	styrene-isoprene co-polymer
Tab	tablet
TM	testmix
tt	test tube
TWt	tare weight
VCF	vacuum collection filter
w/f	warp/fill
ZPB, ZPLB	ziplock/zippered plastic bag