Controlled Substances Quality Assurance Manual

Effective 12-31-2024

ATTENTION: If any portion(s) of the Controlled Substances Quality Assurance Manual or any of the Controlled Substances Policies is/are unclear to any analyst or if a circumstance arises outside the scope of these documents, it is the responsibility of each analyst to immediately notify the Technical Manager and the respective Supervisor to seek clarification/approval or obtain guidance on the issue BEFORE proceeding.

This manual is set out in several sections that deal with different areas relating to the quality of the work performed by the Criminalists in the controlled substance units.

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Note: Hyperlink and attachment maintenance (removal, addition, or correction of hyperlinks and attachments) shall not constitute a new document revision.

Objective

Throughout the Criminalistics Services Division of the OSBI, quality in all aspects of the work performed is sought. It is the goal of all Criminalists involved in the identification of controlled substances to provide the most accurate analyses possible. In order to ensure that this goal is being attained throughout the system of controlled substances identification units, this quality manual has been established. Some issues that specifically concern controlled substance analysis not covered in division policy will be addressed in this manual. The purpose of the Controlled Substances Quality Assurance Manual is to ensure consistency of practices among all of the controlled substance laboratories within the OSBI system and to ensure that the quality of casework is maintained.

Changes to the Controlled Substances Quality Manual:

Corrections, additions, or deletions to the Controlled Substances Quality Assurance Manual should be put forth to the Technical Manager in writing. This can be done by any analyst within any of the controlled substance identification units of the OSBI. If it is determined that a change is necessary then the current procedure QP3, Deviations, in the laboratory quality manual will be followed.

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1. Equipment Maintenance/Calibration

1.1 Purpose:

Equipment maintenance and maintenance documentation is essential for the smooth operation of a laboratory. By accurately documenting maintenance performed on laboratory equipment, a record of quality assurance is provided that can be referenced, if necessary, to troubleshoot future problems or to show that the highest level of integrity possible in casework results is being produced. It is the purpose of this protocol to establish a set of guidelines that are specific for the maintenance of equipment that will be utilized in the analysis of controlled substances.

1.2 Policy:

- A. Supervisors and analysts will be responsible for assuring that all maintenance on equipment involved in the identification of controlled substances is being performed and properly documented.
- B. All criminalists within the controlled substance discipline will be able to recognize when equipment maintenance is necessary and are charged with maintaining laboratory equipment and documenting all maintenance performed.

1.3 Definitions:

<u>Maintenance Log:</u> Documentation that is kept detailing maintenance that is performed on laboratory equipment.

In Routine Use: Equipment that is used and maintained on a regular basis.

<u>Not in Routine Use</u>: Refers to equipment that is in working order, but is not used routinely enough to have regular entries in its maintenance log. Some instruments not in routine use may require some maintenance performed prior to use.

<u>Out of Service</u>: Equipment that cannot be used for casework. These pieces of equipment may not be operational and may require servicing and/or calibration prior to being placed back into service.

1.4 Procedure:

- A. Maintenance logs will be kept on equipment that is used in the analysis of controlled substances.
 - 1. The maintenance log will contain the identifiers for the instrument including any name given to the instrument and its OSBI asset number.
 - 2. <u>All maintenance</u> that is performed will be documented in the maintenance log sheet for each piece of equipment.
 - 3. The log will include an explanation of why maintenance was performed, what maintenance was performed, the date maintenance was performed, and the initials of the analyst performing the maintenance. This includes documentation of any damage, malfunction, or repair to the equipment, example: replacing syringes on the GC due to malfunction.
 - 4. Any maintenance performed on the instruments or repaired equipment will be function tested by running a new QA/QC blank and the maintenance or repair documented in the maintenance log prior to being used for casework. "Repaired equipment" includes the

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- analyst changing parts (i.e., syringes or GC towers) due to malfunction.
- 5. Maintenance performed by someone outside of the unit (i.e., ASAP Analytical, Agilent Technologies, etc.) will also need to be documented on the maintenance log.
- 6. If parts of, or the entire instrument need to be sent away for repairs this will be noted in the maintenance log as well.

DRQM-1 is a General Maintenance Log; instrument maintenance logs can be found in the General Maintenance Logs folder.

- B. Maintenance that is performed on a regular basis such as monthly or when count limits are met (i.e., the changing of liners for the GC and GC/MS or hydrocarbon ladder on the GC/MS) needs to be noted in the maintenance log. No explanation for the action is necessary unless the maintenance is being performed for a reason other than routine maintenance (i.e., liner changed because of carryover). Counts for liner, septa, and gold seal changes should be documented in the maintenance log when changed. Liner/Septa changes are considered routine at a count of 225 or higher. *Changing only the glass wool and not changing the liner/septa is not permitted.* Gold seal changes are considered routine at 1200 for the GC and 1450 for the GC/MS and GC/IRD. Split vent line changes are considered routine at 4800 or higher. Split vent filter changes are considered routine at 2200 or higher for the GC/MS and 4800 or higher for the Agilent GC.
- C. Microscope lenses are cleaned during use as needed; avoid using abrasive materials for cleaning the lenses. There is no regularly scheduled maintenance for microscopes. Although any preventative maintenance, repairs, or changing of light bulbs will be documented in the instrument maintenance spreadsheet, located in the General Maintenance Logs folder.
- D. All pipettes used for DR-01 Attachment 1, that require measurement traceability, should be calibrated at least annually by an appropriately accredited calibration service supplier.

Verification checks are needed to maintain confidence in the calibration status of a pipette between calibrations. After pipettes have been externally calibrated and returned to the OSBI Controlled Substances Unit, an acceptable verification check must be completed before returning pipettes to service. If pipettes are calibrated by an external vendor on-site at the OSBI FSC, no verification check is needed since the pipettes remained in the custody of the laboratory. Approximately six months between external calibrations, an acceptable verification check will be completed before continuing use of each pipette.

The verification check will consist of evaluating each pipette to ensure that it is within tolerance. For adjustable volume pipettes, the same volumes used by the calibration company should be verified.

Pipette Verification using a Balance

Five measurements are required to confirm accuracy. One weigh boat may be used for multiple readings with a tare performed between each weight measurement. Multiple pipette calibration checks will require the boat to be emptied and a tare performed. The pipette precision must be within \pm 5% of the coefficient of variation (CV) and the accuracy must be within \pm 5% to be acceptable for use. For small volume pipettes (less than 20 μ L), pipettes must be within \pm 10%

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CV and \pm 10% accuracy to be acceptable for use. This will be performed gravimetrically with water and documented on a spreadsheet/pdf stored electronically at \\\VM-FSC-FILES\ContSub\Pipettes.

- E. Instruments and miscellaneous pieces of equipment, such as hydrogen generators, that have maintenance logs, should each have their own maintenance log. Each instrument/equipment maintenance log will have its own folder.
- F. If a piece of equipment requires maintenance that cannot be performed right away, then it should be labeled "Out of Service" and should not be used. This should also be documented in the maintenance log with a description of the issue and the steps taken to resolve the issue along with the date and initials of the analyst removing it from service. Once the proper maintenance has been performed and the instrument performs as expected, it can be returned to service and documented in the maintenance log along with any maintenance performed.
- G. If a piece of equipment is not in routine use it should be labeled as "Instrument not in Routine Use, Performance Checks Must Be Performed Prior to Laboratory Analysis." This should also be reflected in the maintenance log.
- H. Items that should have maintenance logs include:

Gas Chromatographs (DR30-1)
GC/IRD (DR75-1)
Hydrogen Generators (DRQM-1)
FTIR (DR60-1)
Ultrapure Water System (DROM-1)
Gas Chromatograph/Mass Spectrometers (DR70-1)
Hydrogen Generators (DRQM-1)
Air Compressors (if applicable) (DRQM-1)

Individual balances/scales will have forms (DR4-1, DR4-2, & DR4-3) for documentation of calibration checks and maintenance. Balances/scales and pipettes are the only equipment that requires a calibration, see protocols for calibration requirements.

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I. A schedule of routine maintenance and quality controls to be performed in the laboratory is as follows:

Maintenance:	When performed:	Protocol Reference:
Glass liners/septa changed	At or before <u>250</u> injections	DR-30, DR-70
		and DR-75
Gold seal changed	At or before $\underline{1250}$ injections for GC; at or before $\underline{1500}$ injections for	DR-30, DR-70
	GC/MS and GC/IRD. Clean the septum nut and metal insides of the	and DR-75
	injector when gold seal is changed on GC, GC/MS, and GC/IRD.	
Clean FID jets for each GC	When the gold seal is changed	Quality Manual 1.4-I
Standard ladder run	First five working days of the month, prior to use of a GC after a	DR-30
	new column is installed, or every time the column is cut.	
Hydrocarbon Ladder	First five working days of the month, prior to use of a new column	DR-70
	for the GC/MS, or every time the column is cut.	
Cocaine standard	Prior to the analysis of casework each day on both the GC and	DR-30, DR-70
	GC/MS. See DR-70 for <i>continuous</i> sequence exception.	and DR-75
Blanks	On the GC a solvent blank needs to be run every fifth sample (four	DR-30, DR-70
	samples then a blank). On the GC/MS and GC/IRD a blank made up	and DR-75
	of the solvent or extraction that is used for the samples in that case	
	needs to be run during the samples of each new case and at least	
	every sixth injection (five samples and a blank) within a case.	
ValPro System	First five working days of the month for the FTIR.	DR-60
Qualification		
Polystyrene Standard	Each day before casework is run on the FTIR.	DR-60
Balance calibration check	Daily (500g and 1g) and Monthly	DR-4
Deionizer bag replacement	When change water light comes on or every 6 months, whichever	Quality Manual 1.4-I
on hydrogen generators	comes first.	
Drain water for air	Unless equipped with an auto drain, at least monthly	Quality Manual 1.4-I
compressors		
Desiccant change for air	When visual inspection of desiccant indicates a change is necessary	Quality Manual 1.4-I
compressors		
Desiccant change for	When visual inspection of desiccant indicates a change is necessary	Quality Manual 1.4-I
hydrogen generators		
Split vent line for GC and	At or before 5000 injections	Quality Manual 1.4-I,
GC/MS changed		DR-30, DR-70
Split vent filter for GC/MS	At or before <u>2500</u> injections	Quality Manual 1.4-I,
changed		DR-70
Split vent filter for Agilent	At or before 5000 injections	Quality Manual 1.4-I,
GC changed		DR-30
Microscopes	Clean lenses as needed.	Quality Manual 1.4 C
Pipettes	As needed, the outside of the pipettes can be cleaned. Pipettes will	
	need to have a verification check 6 months after calibration.	Quality Manual 1.4 D

J. Refrigerators should have a Temperature Monitoring Form that is maintained. Refer to OSBI CSD QP 6.4 for form and a monitoring schedule.

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2. Reagents

2.1 Purpose:

The use of reagents in casework is a common practice throughout the controlled substance laboratory system of the OSBI. Most of these reagents are made by the Criminalists working in the controlled substance laboratories through the combination of the proper chemical components. The reagents used must be checked to ensure that they function as expected and documented to ensure quality and accountability.

2.2 Policy:

- A. All Criminalists in the controlled substance identification units will know how to properly prepare and QA/QC all reagents that are used in the identification of controlled substances.
- B. Supervisors and analysts will be responsible for verifying that historical reagent formulation sheets are properly archived, reagents are properly logged into ChemInventory, and that function verifications are being performed and documented.

2.3 Definitions:

Reagent: A substance used in a chemical reaction to detect, measure, examine, or produce other substances.

<u>Function Verification:</u> A test that is performed on a reagent to verify that it will function as expected.

2.4 Procedure:

- A. When reagents are made, the following will be documented in ChemInventory:
 - 1. Reagent Name
 - 2. Lot Number
 - 3. Expiration (if applicable)
 - 4. Components, including:
 - i. Quantity of each component
 - ii. Supplier of each component
 - iii. Lot Number of each component
 - iv. Expiration Date of each component (if applicable)
 - 5. Steps for preparation, including:
 - i. Analyst name preparing the reagent
 - ii. Date prepared
 - 6. Reagent function verification procedure, including:
 - i. If the Lot **DOES** function as expected, the analyst will log their name and date in the "QC by" and "QC date" fields in Chemical Inventory
 - ii. If the Lot **DOES NOT** function as expected, the analyst will document this in the "Notes" for the reagent in Chemical Inventory along with:
 - 1. Analyst name performing the verification procedure
 - 2. Date verification procedure performed

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After a reagent lot has been entered into ChemInventory, if the lot is moved to the Northeast Regional Laboratory (NERL), it does not need to be re-entered into ChemInventory. The custody and lab location needs to be updated to the correct location.

- B. Prepared reagents will be labeled with:
 - 1. The identity of the reagent
 - 2. The lot number. The lot number assigned will be the date the reagent was made; if more than one lot is made on the same day the additional lots will be designated by a dash and a sequential number (i.e., Lot# 103116-2)
 - 3. The initials of the analyst that prepared the reagent
 - 4. Storage requirements (as applicable)
 - 5. If the reagent is transferred into another container, the container will be labeled with the identity of the reagent, the lot number, the initials of the analyst transferring the reagent, and storage requirements (as applicable).
- C. Reagents such as the standard ladder and hydrocarbon ladder will be made in the FSC Laboratory and distributed to the NERL. If used, copies of the formulation sheets will be uploaded into ChemInventory, but do not need to be distributed with the reagent.
- D. All chemicals used to make reagents will have the name of the chemical, the manufacturer's name, lot number, date received, initials of the analyst that received the chemical, date opened, and initials of the analyst who opened the container, on the chemical container.
- E. The reagent must have a function verification completed before being used for casework. Reliability/verification may also occur concurrent with casework, as a part of the quality control system. The individual components of a reagent do not have to be verified with the exception of the standard ladder.
- F. All reagents routinely used in the course of casework will have the lot number recorded in the Reagent Information panel for each case within the BEAST. Reagents occasionally used in casework that are not currently listed in the Reagent Information panel shall have the lot numbers recorded in the analyst notes.

3. Solvents

3.1 Purpose:

Solvents play an essential part in the analysis of controlled substances throughout the system of controlled substance laboratories. They are used in a variety of ways that include dissolving casework samples and making reagents. The handling of solvents must ensure that they are kept free from contaminants to maintain quality in laboratory practices.

3.2 Policy:

A. Analysts will be responsible for verifying that solvents are free from contamination and will be able to recognize when possible contamination of a solvent exists. Analysts will also know what actions to take in the event of possible solvent contamination.

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B. Supervisors and analysts will be responsible for verifying that historical solvent logbooks are properly archived, solvents are properly logged into ChemInventory, and that quality verifications are being performed with proper documentation stored in ChemInventory.

3.3 Definitions:

Solvent: A substance that is intended to provide a solution.

3.4 Procedure:

- A. When a new solvent bottle is opened, the analyst opening the bottle will write their initials on the bottle and the date the bottle was opened.
- B. In most cases solvents should be ordered and shipped to the laboratory where they will be used. In some instances, it may be necessary to transport solvents between laboratories in the OSBI system. This can be done by either transporting the solvent in its original shipping container or by placing a solvent bottle in a bucket with a lid and filled with vermiculite. Great care should always be taken when transporting solvents.
- C. All solvents in their original containers will bear:
 - 1. Solvent name
 - 2. Lot number
 - 3. Manufacturer
 - 4. Date and initials of the analyst receiving the container
 - 5. Date and initials of the analyst opening the container.
 - 6. If the solvent is transferred into another container, the new container will be labeled with the name of the solvent, the lot number, and the initials of the person transferring the solvent.
- D. When solvents are received, the following will be documented in ChemInventory:
 - 1. Solvent name
 - 2. Lot number
 - 3. Manufacturer
 - 4. Date and initials of the analyst receiving the container
 - 5. Date and initials of the analyst opening the container for QA.
 - 6. Solvent function verification procedure, including
 - i. If the Lot **DOES** function as expected, the analyst will log their name and date in the "QC by" and "QC date" fields in Chemical Inventory
 - ii. If the Lot **DOES NOT** function as expected, the analyst will document this in the "Notes" for the reagent in Chemical Inventory along with:
 - 1. Analyst name performing the verification procedure
 - 2. Date verification procedure performed
- E. Before a new lot of a solvent can be used, it needs to be shown that it is free of contaminants. This can be done by taking a sample of the solvent and analyzing it on the GC/MS using a Blank10 or Drug10 method. The GC/MS scan will be archived in ChemInventory. If the GC/MS analysis shows no sign of contamination, the solvent lot can be used. If used, copies of the solvent log will

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be uploaded into ChemInventory, but do not need to be distributed with the solvent. If the solvent appears to be contaminated, the Supervisor and Technical Manager should be notified, and the solvent lot will not be used.

F. All solvents routinely used in the course of casework will have the lot number recorded in the Reagent Information panel for each case within the BEAST. Solvents occasionally used in casework that are not currently listed in the Reagent Information panel shall have the lot numbers recorded in the analyst notes.

4. Drug Reference Standards

- A. Drug reference standards are used throughout the system of controlled substance laboratories within the OSBI for a variety of purposes. They are used for comparison in casework, verification of proper instrument operation, method validation, and research. The handling of standards must ensure that they remain free from any contamination, and each standard must be verified to ensure its identity. The receipt and usage of all drug reference standards (controlled and non-controlled) will be documented using this procedure.
- B. Drug standards are considered reference materials.
- C. Each laboratory site of the OSBI will be properly permitted by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBNDDC), and by the Federal Drug Enforcement Administration (DEA) when controlled substances are stored at the site. It will be the responsibility of the NERL Criminalist Supervisor and the Criminalistics Division Director or designee at the Forensic Science Center, FSC, to ensure their permits remain current.
- D. All standards will be ordered, shipped, and logged into the FSC.
- E. All drug reference standards that are controlled under Title 63, O.S. Sections 2-204, 2-206, 2-208, 2-210, and 2-212 should be maintained in alphabetical order in an appropriated secure location. This location can include a safe, a locked drawer, a refrigerator that is maintained in a secure area, or any other area where access is limited to appropriate personnel. The Criminalist Supervisor(s) assigned to that particular laboratory or section will have the discretion to designate the Criminalist(s) that will have access to the drug standards.
- F. The receipt and usage of all drug standards will be accounted for on a Drug Reference Standard Receipt and Usage Log (DRQM-4). The log form will also be filled out completely unless a specific notation is made as to why information is being left out. Verification information may be left blank until the verification is performed. A separate reference standard log form will be used for each container except for DEA exempted analytical reference standards where one form can be used for multiple containers of the same lot number. If there is more than one container with the same lot number, each container will be numbered (1, 2, 3, etc.) and a separate log sheet made for each with the container number listed on the log form. If more than one log form is required to document the usage of a standard before it is expended, additional forms will be created as needed and the forms numbered. If a mistake is made on a log form, it is to be corrected by a single line strike out with initials and the correct information then written. Do not make obliterations and do not use whiteout on forms.

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- G. When the drug reference standard is opened, the initials of the analyst opening the container and the date opened will be documented on the container.
- H. Before a drug reference standard from a new lot can be used, its identity must be verified by a GC/MS, GC/IRD, or FTIR. This is done by simply analyzing the standard by GC/MS, GC/IRD, or FTIR and comparing the scan to a literary reference. The source of the literary reference can be a book, journal, previously established library entry such as GBI or NBS, or an independent analysis.
 - 1. If a drug reference standard cannot be verified by instrumental analysis, due to reasons other than a lack of reference data, then the Technical Manager must be notified. The supplier may be removed from the list of approved drug reference suppliers and the drug reference standard will not be used in casework.
 - will maintained 2. All scans be in the standard logbooks, or in the ContSub\Standard Verifications folder on the OSBI network, with the original log forms. The method of verification, source of the literary comparison, and the name and date of the analyst performing the verification will also be documented in the standard logbook or in the ContSub\Standard Verification folder.
 - 3. In some instances, standards will be labeled as the dextro, levo, or dextro/levo rotary isomer. If the compound is controlled under Title 63 of the Oklahoma State statutes with wording that would include both isomers to be controlled as the same substance (example: Methamphetamine), then it is not necessary verify the substance as dextro, levo, or dextro/levo rotary. If the substance is controlled as the dextro, levo, or dextro/levo rotary isomer (example: Levomethorphan), then it is necessary to verify the dextro, levo, or dextro/levo rotary isomer.
- I. A secondary standard is a solution with a known concentration prepared from a reference standard. When a secondary standard is made (i.e., 30 mg of methamphetamine diluted in methanol), a chemical formulation sheet is not required. The lot number reflected on the container will be the lot number of the standard. Along with the lot number, the container will be labeled with the standard name, the solvent system used, the lot number of the solvent, the initials of the analyst making the secondary standard, the approximate concentration, and the date made. If autosampler vials containing secondary standards are kept/stored, the vial must be labeled with ALL the information required on secondary standards.
- J. If a drug standard is to be taken to the NERL, it will be logged out under the NERL's DEA number and a photocopy made of the original form and all verification data for that standard. A note will be made on the original form documenting the standard has been transferred to the NERL and the person transferring it. The photocopied form and verification data will then be taken to the NERL and placed into a log book of current drug reference standards. The originals will always remain at the FSC. The amount taken will be entered as the total amount remaining on the copy taken to the NERL and the usage documented from that point. In these instances, all identifiers (drug name, lot number, manufacturer, etc.) are to be placed on the container utilized to transfer the drug to the region unless the entire original container is taken. If the entire container is to be transferred, a

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note will be made on the original log and placed with its forms of verification in the expended drug standards log book or in the ContSub\Expended_Standards folder on the OSBI network. If a standard is to be verified at the NERL after transfer from the FSC, then a notation will be made on the original that the verification will be done in the NERL.

- K. Drug standards that need to be destroyed are to be zeroed out and a note will be made indicating that the drug has been destroyed on the reference standard log form. The log form will then be placed in the expended drug standards notebook or scanned and stored in the ContSub\Expended_Standards folder on the OSBI network. A drug destruction inventory form will then be filled out and submitted to a Physical Evidence Technician Supervisor with the drug for destruction as required under Title 63, O.S. Section 2-315. A copy of the destruction form is to be maintained in a permanent file maintained by a Physical Evidence Technical Supervisor.
- L. Standard verification data and the initial drug log sheet will be kept in alphabetical order in a log book of current drug reference standards until expended, or will be stored in the ContSub\Standard_Verifications folder on the OSBI network.
- M. Drug log sheets with inventories pending will be kept in alphabetical order in a log book of current drug reference standards. This log book will be kept in the unit responsible for maintaining the standards.
- N. When a drug inventory is depleted, the log sheet will be zeroed out in the amount remaining column and the form maintained in alphabetical order in a log book of expended drug standards or scanned and stored in the ContSub\Expended_Standards folder on the OSBI network. This log book will be kept in the unit responsible for maintaining the standards.
- O. It is understood that the OSBI keeps a daily "working" inventory of drug standards. When secondary standards are created from primary standards, the secondary standard will be analyzed by the GC/MS, GC/IRD, or FTIR to ensure it has not been altered. If additional aliquots of secondary standard are created, the instrumental data will be kept with the log sheet. Once the primary standard has been expended, all additional instrumental data will be stored with the log sheet in the log book for expended standards or scanned and stored in the ContSub\Expended Standards folder on the OSBI network.
- P. Under no circumstances will standards be transferred out of the OSBI Criminalistics Laboratory System without the authorization of the designated Criminalistics Administrator and the DEA forms being completed.
- Q. It will be the responsibility of each authorized individual handling drug standards to ensure compliance with this policy. Violations of this policy may result in disciplinary action and possible criminal charges under the Uniform Controlled Dangerous Substances Act.

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5. Quick Reference Guide for Labeling Requirements in the Controlled Substances Laboratory

Below are the items that are to be labeled and the labeling that needs to appear on each item in the laboratory. Also included is the reference that directs such action.

Standards	Reference Standard containers will be labeled with: The initials of the analyst who received the standard and date received. The initials of the analyst who opened the container and date opened, manufacturer, name of standard, and lot number. All secondary standards will have: The name of the standard, lot number of the standard, initials of the analyst who made the secondary standard, date secondary standard was made, solvent, and solvent lot number.	CSD QP26; Controlled Substances Quality Manual 4.G & 4.I
Reagents	Upon receipt of all reagents, the initials of the analyst who received and the date received will be marked on the container. On commercially prepared reagents (Hydrogen Peroxide), the manufacturer's name, the initials of the analyst, and date opened will be marked on the container. All reagents will have the name of the reagent, lot number, identity of analyst preparing it, expiration date (if applicable) and storage requirements (as applicable)	CSD QP-08; Quality Manual 2.4-D
Solvents in original manufacturer's container	These solvent containers will bear the name of the solvent, lot number, manufacturer's name, date and initials of the analyst receiving the container, and the date and initials of the analyst opening the container.	Quality Manual 3.4-C
Solvents in other containers	These solvent containers will bear the name of the solvent, lot number, and the initials of analyst who transferred the solvent.	Quality Manual 3.4-C
All other chemicals without log sheets	The container should bear the name of the chemical, the manufacturer, lot number, date the container was received, initials of analyst opening the container, and date the container was opened.	Quality Manual 2.4-D

6. Weight Reference Standards

6.1 Purpose:

Weights are used monthly and daily to demonstrate that the scales and balances used to weigh case samples are working correctly. The proper storage, handling, and transportation of weights ensure that they are kept free from contamination or deterioration and protect their integrity.

6.2 Policy:

A. The certified reference standard weights used for balance/scale verification will be NIST Class F, ANSI/ASTM Class 6 or better, and will be calibrated and certified annually by an outside vendor that is accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed in the scope of accreditation. The calibration certificate should contain the uncertainty of measurement for the calibration. These weights are viewed as critical and the vendor weights are purchased from shall be evaluated.

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- B. The annual Certificate of Measurement Traceability, Certificate of Accreditation to ISO/IEC 17025, and Scope of Accreditation to ISO/IEC 17025 for the outside vendor will be maintained by the Controlled Substances Technical Manager.
- C. The certified reference standard weights will be kept in storage containers that will protect the weights from contamination and damage. The weights will be transported in the respective storage containers and not in buckets and/or boxes.
- D. The surrogate reference weights for the Quality Assurance Studies will be issued from FSC Controlled Substances Lab. The surrogate reference weights must be stored in a manner that ensures that they are kept free from contamination and damage. Any problems/issues with the surrogate weights will be reported to the Technical Manager and the weights shall not be modified or changed, without authorization from the Technical Manager.
- E. The reference standard weights will be used monthly to verify a scale is working correctly. If, at any time, a weight is outside of the acceptable 1% range on a scale, the weight will be weighed on a second scale to resolve that the issue is with the scale and not the weight. If it is determined the issue is with the weight, the weight will be sent to an outside vendor for re-calibration and recertification before it can be used again.
- F. Weight is a reported test result and requires traceability and uncertainty. Uncertainty is only reported for cases involving trafficking weights. Approximate volume is a description of evidence and does not require traceability or uncertainty.

7. Case Management and Analysis

7.1 Purpose:

It is necessary that casework and case files be handled similarly among all analysts. To ensure consistency throughout the system of controlled substances laboratories within the OSBI, this section will address issues regarding the analysis of casework samples and case reporting.

7.2 Policy:

- A. It is the responsibility of all analysts in the OSBI Controlled Substances Units to ensure that accuracy and quality are maintained and that the necessary work required to maintain the integrity of results is put forth in all cases. All appropriate analytical documentation will be completed in the BEAST.
- B. The technical manager, supervisors, or their designees are charged with reviewing the performance of analysts through case review, proficiency testing, or whatever measures are deemed necessary to ensure that consistency and quality throughout the laboratory system is maintained.
- C. There are no requirements for the facilities, necessary accommodations, and/or environmental conditions for evidence collection and handling that is performed within the OSBI Controlled Substances Units. There are no known factors that would impact testing results.

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7.3 Procedure:

A. The following is a list of examinations available in the drug identification units:

Confirmatory Tests (A)	Non-Confirmatory Tests (B)	<u>Presumptive Tests (C)</u>
GC/MS	TLC	Marquis
FTIR	GC	Cobalt Thiocyanate
GC/IRD	Literary References	Bates
	Visual/Microscopic examination	

For a conclusive analysis of a controlled dangerous substance (with the exception of marijuana), an analyst needs a positive presumptive or non-confirmatory test that agrees with a positive confirmatory test, or two confirmatory tests that agree.

- 1. Before using the GC/MS or GC/IRD, the sample must first be analyzed on the GC.
- 2. Marijuana requires a positive visual examination with a GC and GC/MS or GC/IRD, and TLC that is positive for Tetrahydrocannabinol.
- 3. Original observations must be recorded at the time they are made. If an analyst forgets to record an observation, the exam must be performed again. The results and new date must be recorded in the casefile.
- B. In the analysis of pharmaceuticals, a literary reference is sometimes sufficient to presumptively report results as outlined in DR-5 of the OSBI Controlled Substances Protocol Manual. If a literary reference is found that matches the logo on the pharmaceutical and the analyst proceeds to analyze the substance to confirm its identity, then the analyst should conclusively identify the substance. If a substance cannot be confirmed, it is not acceptable to simply report "No controlled substances identified." If it is not possible to confirm the substance due to a situation like a weak GC/MS or poor FTIR, then the report wording should indicate that instrumental analysis and literary reference indicate that a controlled substance is present, but was unable to be confirmed. Notes should also be made in the case file as to why the substance was not confirmed so that, when reviewed at a later date, the reviewer will understand why the substance was not confirmed.
- C. Analyzed tablets will be separated into different items by color, shape, and logo. Tablets that are not analyzed may be grouped together; the description needs to describe what is grouped together. For example:

One bag of tablets of various shapes, logos, and colors should be itemized as:

1A. Three blue round tablets with "Superman" logo

1B. Two blue round tablets with "PacMan" logo

1C. Two square blue tablets, no logo

1D. Six red round tablets with "Superman" logo

1E. Twelve tablets of various shapes, color, and logos

(analyzed item)

(analyzed item)

(analyzed item)

(not analyzed items)

- D. Tablets will be described using the following definitions/parameters:
 - 1. Whole tablets tablets with the entire imprinted logo; tablets with no logo must be intact.
 - 2. Partial tablets or tablet fragments pieces of tablets with a partial imprinted logo or pieces of tablets with no readable logo (numbers/letters).

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Whole tablets must be weighed and counted if there appears to be approximately 100 tablets or less. If there are more than 100 tablets they can be weighed only. Partial tablets or tablet fragments can be weighed and include a descriptor such as "several," "multiple," or grouped with a powder, for example: "...tablet fragments and powder..." Whole, partial, and tablet fragments can be weighed together, but the whole tablets must be counted if there appears to be approximately 100 tablets or less.

- E. Reports relating to the analysis of tablets and capsules will reflect the number of tablets, tablet fragments or capsules analyzed and confirmed.
 - 1. If a case contains multiple items of tablets, tablet fragments, or capsules and one tablet, tablet fragments, or capsule was analyzed for each item, one statement at the bottom of the result section will be acceptable for this requirement.
 - 2. If an item(s) contains tablets, tablet fragments, or capsules and more than one is analyzed, results will be reported as follows:

Item #: Controlled substance, Schedule XX (five tablets analyzed and confirmed)

or

Item #: Controlled substance, Schedule XX (five tablets analyzed, one tablet confirmed)

01

Item #: No Controlled Dangerous Substances Identified (five tablets analyzed)

3. If the case has single tablet item(s) and tablet(s) is/are tested, then it is up to the analyst to decide if they want to remove the statement from the report.

All tablet/capsule samples should consist of a maximum of ½ of the tablet, tablet fragment, or capsule being sampled. If multiple tablets, tablet fragments, or capsules are tested, then only ½ of each tablet/capsule should be sampled and analyzed individually, the halves/fragments cannot be combined. The remaining tablet/tablet fragment/capsule halves should be marked and returned to evidence.

- F. For each item containing tablets/tablet fragments/capsules, it is necessary to label each item and what was analyzed, by either wrapping the item in tape or placing the item in an individual plastic bag and labeling. When ½ of a tablet is used for sampling, the other half should be labeled. It is important that all items are labeled clearly. For example, if one container contains four types of tablets, one of each type of tablet should be labeled with the item number, lab number, date, and initials of the analyst. If a container only contains one type of tablet, then it is acceptable to label the container with the item number, lab number, date, and initials of the analyst and wrap the tested tablet with tape and initial the tape.
- G. When analyzing blotter squares/gelatin squares/candy/individual or multiple dosage units, it is necessary to clearly indicate what was analyzed. This is accomplished with item labeling of the evidence, documentation in case file notes, and notations on the report. The following uses "sheets" as the descriptor, but it may apply to evidence in forms other than sheets, i.e., pieces of candy.

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Labeling:

If you have multiple similar sheets of evidence with dosage units, you may inventory them by the following methods:

- 1. Separate one sheet as one item and analyze it and report results. All other sheets are a different item with no analysis.
- 2. Label the sheets with different item numbers and take samples from different sheets, analyze them separately and report the individual results.

You may not label all sheets as one item, take multiple samples from different sheets and combine them into one sample for analysis.

If you have multiple single dosage units, you may inventory them by the following methods:

- 1. Make one dosage unit its own item and analyze ½ of it. All remaining dosage units are a different item with no analysis.
- 2. Make multiple dosage units into one item, take ½ of one square, analyze it, and apply results to all dosage units (since they are considered one item).

Sampling of dosage units:

If you have a piece of evidence with individual dosage units, i.e., may be separated with perforations, you may:

- 1. Take ½ of one dosage unit for analysis
- 2. Take ½ of many connected dosage units for analysis (2 or more)

Whichever labeling and sampling methods are chosen, it must be documented in the item notes how many dosage units were analyzed. The report must also specify the number analyzed and confirmed in the same manner as tablets and capsules. *If two or more connected halves are analyzed, report "X dosage units were combined, analyzed, and confirmed."*

If an analyst needs to combine samples from <u>individual</u> dosage units to obtain a conclusive identification, authorization must be obtained from the Technical Manager or designee, prior to the combination of samples. The authorization must be documented in the case file.

- H. Any sample(s) of evidence, i.e., sample vials of liquids or bags with samples taken from bundles, provided by the submitting agency, that were not collected by OSBI Controlled Substances Criminalists, shall have a statement in the report regarding that the results of analysis only apply to the sample(s) received.
- I. When performing GC/MS analysis with a sodium hydroxide/hexanes extraction, and there is not a controlled substance that can be identified, a second extraction has to be performed on the item. The analyst may perform the second extraction using methanol or sodium hydroxide/chloroform.
- J. If an item is analyzed using a methanol extraction and the chromatography is poor, i.e., peak fronting, no base-line separation, peak tailing, or no sharp peak formation, then a second extraction is required. The second extraction can be a methanol/sodium hydroxide/chloroform extraction of the original sample, or a second sample can be taken and extracted using sodium

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hydroxide/chloroform or sodium hydroxide/hexanes.

K. If an item is analyzed/extracted and the results are negative or unexpected *and* the decision is made to take a second sample or third or fourth and the results *differ*, then the report must specify the number of samples analyzed and confirmed for that particular item.

If a sample is extracted with methanol and then it is decided that better results/chromatography could be obtained with a different extraction and the analyst: 1. takes another sample or 2. extracts the methanol with sodium hydroxide and chloroform/hexanes, an additional statement regarding analyzed/confirmed is not necessary.

If a sample is extracted and it evaporates, and a second sample is taken from the item, an additional statement regarding analyzed/confirmed is not necessary.

- L. If a case contains multiple items in one container, the item(s) tested must be given separate item numbers, different from the item(s) not tested. Internal packaging/containers do not have to have an item number or be on the items tab, but do need to be in the notes in the matrix. Examples:
 - 1. One plastic bag containing three spoons, and only one of the spoons is tested. The spoon tested would be labeled "Item 1A" and the remaining two spoons, not tested, would be labeled "Item 1B".
 - 2. One plastic bag containing multiple filter papers with residues, and only one of the filter papers is tested. Physically separate the filter paper(s) tested from filter papers not tested, by placing in separate appropriately labeled plastic bags.

"One plastic bag containing:

- 1A: One tightly wrapped bundle of filter paper containing white powder.
- 1B: Four tightly wrapped bundles of filter paper."
- 3. One plastic bag containing a loose green leafy substance and three pipes. Physically separate the green leafy substance (to be tested) from other items, tested or not tested, and label all appropriately.

"One plastic bag containing:

- 1A: A loose green leafy substance.
- 1B: One smoking device containing a residue.
- 1C: Two smoking devices, each containing residues.

Results:

- 1A: Cannabis....Schedule I.
- 1B: Tetrahydrocannabinols, Schedule III.
- 1C: No analysis."

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If a case contains multiple items in one container and more than one item is going to be tested, the items may not be tested together or grouped into one extraction. Each item must be given separate item numbers. They must be extracted and tested separately. It is not acceptable to combine two or more items into only one analysis. For example: One plastic tube containing 4 syringes. The syringes could be labeled as described with results as follows:

"One plastic tube containing:

1A: One syringe with a residue.

1B: One syringe with a residue.

1C: Two syringes.

Results:

1A: Controlled substance1, Schedule XX.

1B: Controlled substance2, Schedule XX.

1C: No analysis."

If a case contains a container that has been physically altered to compartmentalize its contents, the individualized contents/items may not be tested together or grouped into one extraction. Each compartmentalized item must be given separate item numbers. And they must be extracted and tested separately. It is not acceptable to combine two or more compartmentalized items into only one analysis. For example: a glove that has samples in each of the "fingers" that have knots separating the "fingers" into individual compartments. The glove could be labeled as follows:

"One glove with individual "fingers" that are each knotted and contain:

1A: A crystal-like substance, net weight: 0.25 gram

1B: A crystal-like substance, net weight: 0.32 gram

1C: A crystal-like substance, net weight: 0.27 gram"

If the container, i.e., glove, has one knot and the contents of the fingers are not compartmentalized, the container and contents can be considered one item.

This does not apply to tablets and capsules; refer to sections B, C, and D regarding tablet labeling, testing, and reporting.

- M. If a case contains items that are not analyzed, and the items are considered "containers," the items and/or contents need to be distinctly described. Be clear in the description so the reader understands what are contents and which are separate items.
 - i. Good Description example:

"One evidence envelope containing:

1A: One empty metal container on a ring and four plastic bags each containing residues

Results:

1A: No Analysis"

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ii. <u>Bad Description</u> example:

"One evidence envelope containing:

1A: Four plastic bags each containing residues and one empty metal container on a ring

Results:

1A: No Analysis"

If the containers are empty, then describe them as such.

If a box/container is not going to be opened/none of the items within the container are going to analyzed, the analyst may use the officer's description to report the contents. It must be clear on the report that the box was not opened and the officer's description is being used.

- N. If items are "sealed" by the manufacturer or wrapped in such a manner (i.e., bundle/kilo wrapped in tape/cellophane/etc.) that the contents cannot be seen by the analyst. The analyst may:
 - 1. Open the item and describe contents.
 - 2. Not open the item, and if available, use the officer's description, making sure to note on the report that it is the "officer's description" and that the item was not opened.

 (i.e., Item 1: One wrapped bundle, officer's description "containing a powder." Not opened.)
 - 3. Not open the item and document on the report that the container was not opened. (i.e., Item 1: One wrapped bundle, not opened.) *This option should only be used for trafficking cases or safety purposes, i.e., suspected fentanyl. *
- O. Field Test Kits (FTK) submitted with evidence are NOT to be thrown away/disposed of. If received in the evidence container, the field test kit needs to be placed in a heat-sealed bag to render it safe. The kit does not require an item number and should be included in the analysts notes and report or it can be combined with other non-analyzed items. Examples:

One evidence envelope containing Items 1A through 1B:

- 1A One plastic bag containing a green leafy substance...
- 1B One used marijuana field test kit and one package of papers

Or

One evidence envelope containing one field test kit and:

- 1A One plastic bag containing a green leafy substance...
- 1B One plastic bag containing a crystal-like substance...
- P. If, after analysis, a sample vial is kept with the evidence and placed in the container, the vial must be added to the "Items" tab in the BEAST as a sub-item. The sample vial does not have to be included on the report. The sample vial is considered a work product that can be used for future testing.

Items Tab Example: 1A One syringe with residue; 1A1 Sample vial

Q. When evidence is received, any abnormalities regarding the packaging or condition of evidence will be recorded. If there is doubt whether the item is suitable for testing or if the item does not match the description provided, the stakeholder will be consulted for clarification and the

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conversation recorded using the "Narrative" button on the "Case Info" tab in the LIMS before proceeding.

If testing the items is possible, and the stakeholder agrees to continue with testing the item, the report shall include a disclaimer indicating which results may be affected by the abnormality. *The wording for the disclaimer will vary with different scenarios*.

Example: The marijuana plants were submitted in a plastic bag and molded.

Disclaimer: Due to the nature of the plant material being moldy, results may be affected.

- R. If evidence needs to be stored or maintained under specific environmental conditions (i.e., refrigerated), document in the item notes where the item was stored or scan the item to that location so it is reflected on the chain of custody.
- S. If a residue is analyzed, the analyst will document the sampling method in the Matrix (i.e., swabbed, scraped, sampled, etc.).
 - 1. "Sampled" means there was enough powder/sample to dump out of the container for analysis, but not enough to register as a weight on the scale.
 - 2. "Swabbing" can include a "dry" swab or a "wet with solvent" swab; documentation of wet or dry is not required.
- T. The description of the evidence on the report must include, at a minimum, the inner most packaging and its contents. If all layers of packaging are not listed on the report, they must be included in the notes section for that item in the BEAST. Examples:

One sealed evidence envelope containing one plastic bag containing one plastic bag containing one plastic bag containing a green leafy substance.

Report: One sealed evidence envelope containing:

1A: One plastic bag containing a green leafy substance

Notes in matrix: one pbc one pbc 1A

7.4 Starting and Ending Date of Analysis:

The start date for analysis is the date the analyst assigns the case to themselves in the BEAST. The ending date of analysis is the date the analyst routes the report for technical review in the BEAST.

Unless otherwise indicated in the case notes, the date of sample weighing and sample extraction will be the date the analyst assigns the case to themselves in the BEAST. Also, unless noted, the assigned analyst will be the analyst performing the weighing and extractions.

The date(s) for instrumental analysis will be reflected on the instrument printout(s); the date(s) for reviewing data/results will range from the date of instrument analysis until the analyst routes the report for technical review. Unless noted in the casefile, the analyst reviewing data/results will be the analyst noted on the instrument printout(s). By signing the case, the analyst is documenting that a review of the technical records was performed.

The analyst performing the technical review will be indicated by the analyst signature on the technical review form; the date(s) of review will range from the initial date of routing for technical review until the

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case has been approved by the reviewer.

8. Abbreviation List

The following is a list of approved abbreviations for OSBI Controlled Substance Laboratory analysts' notes and within the chemistry matrix panel.

	through	gsd	glass smoking device
<u>-</u> →	containing		glass vial
~	approximately	gv	gross weight
		gw h hov	hexanes
apb	analyst provided bag	h, hex	
anw	approximate net weight	hr	hand rolled
app	approximate	hrc	hand rolled cigarette
blr	burnt leafy residue	hrcs	hand rolled cigarettes
bls	burnt leafy substance	hspb	heat sealed plastic bag
br	burnt residue	1	labeled
bps	brown paper sack	lg	large
cap	capsule	liq	liquid
cbd	cannabidiol	lit ref	literary reference
cbg	cannabigerol	m	marked
cds	controlled dangerous substance	me	manila envelope
cfp	coffee filter papers	meoh	methanol
cig	cigarette	misc	miscible
cigs	cigarettes	ml	milliliter
clr	clear	mls	milliliters
cls	crystal-like substance	mnc, m-n-c, or m/n/c	methanol/sodium
			hydroxide/chloroform
con, cont	containing	msd	metal smoking device
cpb	clear plastic bag	na	no analysis
cpzb	clear plastic zip lock bag	nc, n-c, or n/c	sodium hydroxide/chloroform
cs	crystalline substance	net vol	net volume
cw	cellophane wrapper	nw	net weight
czb	clear zip lock bag	obn	Oklahoma Bureau of Narcotics
d	diameter	ofw or ow	off-white
ea	each	pb	plastic bag
ee	evidence envelope	pbc	plastic bag containing
env	envelope	peb	plastic "EVIDENCE" bag
ext	extraction	pre	prescription bottle containing
fib mat	fibrous material	ps	powdery substance
FTIR	Fourier transform infrared	psc	plastic sharps container
GC	gas chromatograph	psv	plastic sample vial
GCMS,	gas chromatograph/mass	pwb	plastic wrapped bundle
	spectrometer	•	
GC/MS,	speciforneter		II
· ·	spectrometer		
GC/MS, GC-MS g, gm	gram	pzb	plastic zip lock bag

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glr	green leafy residue	r	radius
gls	green leafy substance	res	residue
gpcr	glass pipe containing a residue	rls	rock-like substance
sm	small	v, vol	volume
sj	sample jar	wbr	with a burned residue
stu	safety tube	we	white envelope
tab	tablet	wht	white
tlc	thin-layer chromatography	wp	white powder
tll	two-layer liquid	wkst	worksheet
tp	tan powder	wps	white powdery substance
twb	tape wrapped bundle	w/	with
uom or	uncertainty of measurement	zpb	zip lock plastic bag
UoM			

9. Standard Forms for Documentation

The following is a list of forms that should be utilized for the maintenance documentation and recording Drug Reference Standards. DRQM forms are attachments to this document; the other forms are linked/embedded within the Drug Protocols document.

Documentation Forms

Maintenance Log Sheets for:	<u>Other</u>
GC (DR30-1)	Drug Reference Standard Receipt and Usage Log (DRQM-4)
GC/MS (DR70-1)	
GC/MS/IRD (DR75-1)	
FTIR (DR60-1)	
Hydrogen Generator (DRQM-1)	
Air Compressors (DRQM-1)	
Ultrapure Water System (DRQM-1)	

10. Documentation for the Training Manual

Included in the training manual are topics and checklists that should be used when training a new employee. Copies of the checklists that document an employee's training will be kept in the employee's training manual that is maintained by the employee's supervisor or the employee. Employees that have prior experience in drug chemistry may receive a modified training plan. The most recent training manual will be modified for such purposes; all modifications must be approved by the Controlled Substances Technical Manager. The most recent training manual is available in the Quality Management System (QMS).

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11. Examination Documentation

- A. OSBI controlled substance analysts must store examination documentation within the image vault in the BEAST.
- B. Copies of the data/documentation may also be kept on the analyst's OSBI computer. The goal is to keep required documentation in the BEAST, without using excessive storage. If an analyst wants to keep multiple pages from a sample/shot, they may keep a copy on their OSBI computer and only upload the required documentation.
- C. Instrument documentation (GC, GC/MS, GC/IRD, or FTIR) that support the identification of substances must be kept in the image vault in the BEAST.
- D. **Rejected data:** Data that cannot be used to reach a conclusion because of quality issues or because it does not meet requirements of policy. Additional or alternative testing must be performed, if possible. Examples include but are not limited to: RI/RT not within the 2% window, standard information not on the scan, cocaine standard peak is not integrated, autotune was not run prior to casework, carryover in a sample, or contamination of a blank.
- E. Rejected data <u>must</u> be entered on the rejected data panel in the BEAST matrix. The analyst must identify the data that is rejected (Instrument/Test and Validation Code if available), document the date of the rejection, and the reason for the rejection. Rejected data may be included in the final data uploaded to the image file, but each page must be marked "Rejected" and must still be listed on the rejected data panel.

For example:

- 1. If a GC is rejected due to QA/QC issues, the analyst would add the "Rejected Data Panel" to the matrix for the case and log the Instrument, item number, validation code, date, and reason.
- 2. If a GC/MS is rejected due to QA/QC issues, the analyst would add the "Rejected Data Panel" to the matrix for the case, log the Instrument, item numbers affected, validation code of the blank, date, and reason for rejection.

Example:

Case Methanol Blank has 58 in it and there were 3 tablets (items 1A, 1B and 1C) that followed. Analyst would enter Instrument, Items 1A-1C, the validation code of the blank which has the 58 ion present, date, and the reason on the "Rejected Data Panel."

- 3. If a GC/MS is rejected because it is outside the 2% retention index window, the analyst would add the "Rejected Data Panel" to the matrix for the case, log the instrument, item number, validation code for the scan and the blank (if the blank is not already included in the uploaded data file), date, and reason for rejection.
- 4. If a TLC plate is run with three items from one case along with one item from a second case, and the entire plate changes color when the visualizing agent is applied, then the data should be rejected due to a quality issue (contamination of the solvent). The analyst would

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add the "Rejected Data Panel" to the matrix for both cases and log the test, item numbers affected, date, and reason.

F. Samples/shots that are <u>not used in the identification</u>, but <u>not rejected</u>, will be uploaded into the image vault of the BEAST. The analyst must keep at least one page from each sample/shot.

Examples include but are not limited to:

- 1. A sample must be re-run to increase/decrease concentration on GC/MS because there are not enough ions, too many ions, or the ratio of the ions are off (but the retention index is within 2%). For example: Drug100 is too weak, reshoot using Drug50. Analyst would keep both the Drug100 and the Drug50 scans in the uploaded data file.
- 2. An extraction needs to be performed because chromatography is poor. For example: Extract initially into methanol, but chromatography is poor, so extract into MeOH/NaOH/CHCl3. Analyst would keep both scans in the uploaded data file
- 3. FTIR scan indicates a mixture
- G. Autotunes and hydrocarbon ladder data from the GC/MS do not have to be uploaded into the case file. Copies of instrumental data, QA/QC (autotunes, ladders, blanks & cocaine) and PDFs are kept on each instrument computer and are backed up routinely.
- H. For cases in which weights are included in the results section of the examination report, a PDF document or Excel spreadsheet with calculations for the total weight and uncertainty is to be included in the case file. This is only required for cases in which two or more items are involved in the calculations. The items, weights, units, and uncertainty must be labeled and the totals identifiable. The OSBI Lab number, analyst name, and date (of calculation) must also be documented on the document.
- I. A complete step by step detailed description of the PDF procedure is available in DR-50. This procedure should be followed by all controlled substance analysts when using PDF exam documentation.
- J. Examination documentation maintained in the BEAST image vault is not required to have page numbers. Any examination documentation printed and maintained as a permanent record in the case file are required to follow all requirements listed in the Criminalistics Services Division Laboratory Quality Manual.

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12. Case Reviews

QP31 requires that all OSBI case files be reviewed by an individual other than the reporting analyst prior to being released to an outside agency. Administrative and Technical Reviews will meet all requirements set forth by QP31 and will include a thorough review of the entire case file and Criminalistics Examination Report by a qualified reviewer. The specific procedure followed by the controlled substances laboratories will be as follows:

- A. Once the analyst has signed the case in the BEAST, the case will be distributed for review utilizing the routing function in the BEAST. Analysts will rotate reviews through all approved Controlled Substances analysts before sending another review to the same analyst. Exceptions to this can be made for rush cases or if the next reviewing analyst has notified Controlled Substances analysts of vacation or extended leave.
- B. If any changes or corrections are required, QP31 requires the case to be routed for correction. The reviewer must include an explanation in the comments field of the routing box describing what must be corrected. Once corrections have been made, the case will be routed back, with corrections/changes documented in the comments field, to the original reviewing analyst for additional review.
 - 1. If the correction involves multiple cases, the analyst must notify the Technical Manager, or designee, of all cases that were reviewed for necessary correction and cases in which corrections were required and made.
 - 2. If the two analysts are unable to come to an agreement, the Controlled Substances Technical Manager should be consulted and the case routed to the Technical Manager, or designee, using the "Route to Technical Manager" code. The Technical Manager, or designee, will then route the case back with their decision; the Technical Review will be completed by the original reviewer.
 - 3. The reviewing analyst is considered a "designee" approved by the Technical Manager for approving Class II nonconforming work. At any time during the review process, if the reviewing analyst has a question as regarding the correction, they need to contact the Technical Manager for clarification. The Technical Manager receives a daily report of all routings and will document any relevant corrections on the Nonconforming Work Log. The Technical Manager maintains authority to override decisions of the reviewing analyst.
- C. By answering "yes" to the statement on the Technical Review form the reviewer agrees to the following statements.

For all cases:

- 1. Tests conform with the appropriate Controlled Substances Unit protocols and methods, the Controlled Substances Quality Assurance Manual and CSD policies and procedures.
- 2. Results, opinions, and interpretations are accurate, properly qualified and supported by the technical records.
- 3. Spectra, data, images, observations, etc. that support findings, are included in the file.
- 4. Conclusions reported are in accordance with conclusions listed in the analytical notes.
- 5. Result reporting is consistent with protocol recommended reporting.
- 6. QA/QC documentation is included (blanks, standards, etc.).
- 7. Handwritten notes, calculations, analyst notations in PDFs, and the naming of PDFs have been reviewed and compared to documentation in the BEAST Matrix.

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For cases in which instrumentation was used:

8. The initials/name of the analyst performing the analysis shall be on each page of their notes. The case number shall be on all pages of the instrument data except for standards.

For cases in which GC and GC/MS were used:

- 9. GC retention time differences are 2% or less from the standard.
- 10. GC/MS retention index differences are 2% or less from the standard.

For cases in which FTIR was used:

- 11. The spectra of a polystyrene standard obtained, on the day of casework.
- 12. FTIR background is performed before each sample.

For cases in which weights are included in the results:

- 13. PDF document/page or Excel spreadsheet, with calculations of weight and uncertainty, is included in the case file for cases in which the total weight consists of two or more items.
- 14. Totals/calculations are correct.
- 15. Uncertainty used for calculations is the current/correct uncertainty for the reporting laboratory.
- 16. The coverage probability statement is on the report.
- D. Approving the report will be documentation that an administrative review was completed by the approving analyst. Once a technical/administrative review is complete, the reviewing analyst will notify the requesting analyst that the review has been completed. This is accomplished by routing route for approval (RFA) in the BEAST. If reports must be mailed, they should be sent from the originating laboratory.

13. Attachments

OSBI DRQM 1, Rev. 0, General Maintenance Log

OSBI DRQM 4, Rev. 1, Drug Reference Standard Receipt and Usage Log or QMS

OSBI DRQM 6, Rev. 0, Oklahoma Trafficking Levels or QMS

Approval

Technical Manager:	Michella Carter	Date:	12-18-24
OSBI CSD Quality M	anager: Dilber Co	Date:	12/18/24
OSBI CSD Director:	Xamure	Date:	12/18/2024

Controlled Substances Quality Assurance Manual Revision Number: 27 Effective Date: 12-31-2024

History

Rev.#	Issue Date	History	
27	12-31-2024	Changed "regional laboratories" to NERL and "customers" to	
		"stakeholders" throughout the QM.	
		Section 1.4.A: Removed "are incorporated into the Controlled Substances	
		Protocol Manual" and added a link to where the maintenance logs are	
		stored.	
		Section 1.4.B: Added GC/IRD.	
		Section 1.4.C: Add maintenance for microscopes. Updated the bullet	
		lettering for the sections following C.	
		Section 1.4.D: Added calibration requirements and verification checks for	
		pipettes.	
		Section 1.4.E: Removed "It is not necessary to keep the maintenance log	
		for each piece of equipment needing to be maintained in a separate	
		book" and updated it to "Each instrument/equipment maintenance log	
		will have its own folder.	
		Section 1.4.I: Added "Clean the septum nut and injector when the gold	
		seal is changed" to the gold seal changed section. It was in the protocol	
		but not in the QM. Updated protocol references. Removed Ultrapure	
		Water System because neither lab has one. Added Microscopes. Added	
		Pipettes.	
		Section 4.C: Added "or designee" after Criminalistics Division Director.	
		Section 4.K: Updated "Admin. Program Officer for Physical Evidence"	
		to "Physical Evidence Technician Supervisor."	
		Section 4.N: Updated the link.	
		Section 4.Q/4.O: Moved this section to 4.O because 4.N and 4.Q were	
		discussing expending standards and made since to be together. Updated	
		the bullet lettering for the sections following C.	
		Section 4.Q: Removed "#5" because it referred to the next section which	
		is a brief outline. We need to be familiar with the entire section on	
		standards.	
		Section 5: Updated the protocol references.	
		Section 6.2.A: Add "The calibration certificate should contain the	
		uncertainty of measurement for the calibration."	
		Section 7.3.A: Removed Ehrlich's (LSD). It was removed from the	
		protocol during the last revision.	
		Section 7.3.D: Updated to require counting tablets if there appears to be	
		100 or less whole tablets.	
		Section 7.3.G: Removed Labeling 1 that allowed all sheets to be grouped	
		together and only one tested.	
		Section 13: Added links and that they can be found on QMS.	