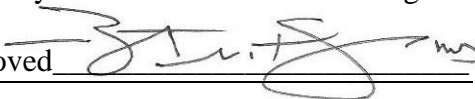


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TITLE: QUALITY ASSURANCE AND CONTROL PROGRAM

- Policy:** OCME QUALITY ASSURANCE AND CONTROL PROGRAM
Each OCME Divisional Unit is to establish a QA/QC program specific to their professional discipline as prescribed in this policy.
- Purpose:** The purpose of the Quality Assurance and Control Program of the D.C. Office of the Chief Medical Examiner (OCME) is to ensure that: 1) the professional activities of the OCME staff are in compliance with the standards of the National Association of Medical Examiners (NAME) and the College of American Pathologists (CAP); and 2) policies and procedures comply with District law, as well as with their key performance indicators.
- Scope:** The OCME Quality Control Officer is responsible for ensuring that all units within the OCME are in compliance with the quality assurance and control program. The Quality Control Officer will also be responsible for assessing quality control measures in other jurisdictions and obtaining information on the best practices in other medical examiner offices throughout the region. The officer shall make recommendations on quality control issues within the agency as it relates to the overall death investigation and certification process, acceptance and release processes, case filing and retention and mortuary services. Toxicology will only be reviewed and commented on from a laymen's perspective.
- Definitions:** Provide definitions of terms and actions that will aid with monitoring and control

QUALITY ASSURANCE PROGRAM

Each division is required to identify all the elements of their QA program in a list and/or summary format

ORGANIZATION AND MANAGEMENT

Provide – at a high level - the structure of your unit to include all required or obtained credentials that qualify the staff and management to perform the work you do.

PERSONNEL

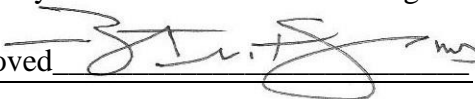
Describe the staff requirements and how those requirements are confirmed.

As an example, Tox indicates the following:

“Laboratory personnel shall have the education, training and experience necessary to meet or excel the minimum requirements for accreditation as Post-Mortem Forensic Toxicology Laboratory.”

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The laboratory shall:

- Have a written job description
- Have documented training program for qualifying all technical laboratory personnel etc.

FACILITIES

Each division is required to describe the location and the security requirements of their unit and/or office areas and whether or not this office space is secure and adequate for the work performed.

EVIDENCE CONTROL

Where applicable, describe how evidence is handled by your unit and what controls are in place to ensure the integrity of physical evidence.

ANALYTICAL PROCEDURES

Provide as required

EQUIPMENT CALIBRATION AND MAINTENANCE

Document all equipment that is used within your unit and provide information as to how, when and by whom equipment is calibrated, serviced and maintained. Include maintenance schedule (where applicable or required).

REPORTS

Provide documentation regarding official reports that your unit is required to provide for the official case file. Provide mandatory elements of the reports. For example, Case number, Decedent Name, Decedent Age, Informant, etc.

REVIEW

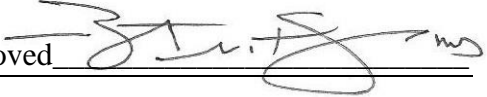
Describe how work is peer reviewed for quality and accuracy, which should include how often the reviews occur, weekly, monthly or daily – in a meeting setting or as an assigned task.

CORRECTIVE ACTIONS

Identify corrective actions as outlined in the Quality Corrective Action SOP document. For matters that escalate to or are related to personnel corrective actions, please reference the DPM Chapter 16 for non-conformance of standards, procedures or regulation, to include gross neglect of duties as related to work performed. However, each unit shall establish a corrective action process that addresses each element defined below:

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Each OCME Divisional Unit shall establish a policy and procedures that identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

Selection and Implementation of Corrective Actions: When a corrective action is necessary the unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

Monitoring of Corrective Actions: The unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective action(s) taken are effective. An internal audit process should be developed to track and record effectiveness.

Documentation: The unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the Quality Program Manager. Such documentation shall be retained in accordance with applicable federal or state law.

PREVENTATIVE ACTIONS

The OCME Divisional Units shall identify needed improvements and potential sources of nonconformities, either technical or within the management system. When improvement opportunities are identified or where a preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

AUDITS

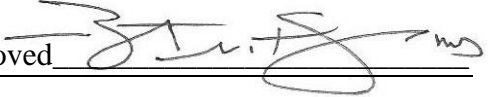
Each OCME Divisional Unit shall establish an audit program appropriate to the operations and requirements of that unit. Each unit shall describe the audit process to include how often audits are conducted and what they include for what purpose – where applicable.

SAFETY

Describe your unit's health and safety program to include PPE's that are required for specified work conditions. (Where applicable)

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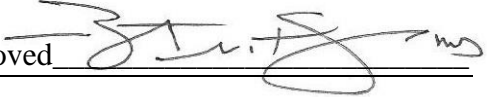
OCME QUALITY ASSURANCE PROGRAM

UNIT PROGRAMS

1. **Medical Examiner**
2. **Investigations**
3. **Toxicology Laboratory**
4. **Records Management**
5. **Anthropology/Identification**
6. **Mortuary**
5. **Photography**

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**OCME QUALITY ASSURANCE AND CONTROL PROGRAM
MEDICAL EXAMINER/PHYSICIAN UNIT**

Purpose: The purpose of this program is to establish a quality assurance system appropriate for the physicians of the DC OCME

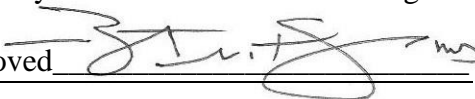
Scope: The Forensic Pathology Unit is responsible for:

1. Accept or decline jurisdiction of a case.
2. Determine appropriate type of examination.
3. Perform and document external and internal (autopsy) examinations.
4. Enter cause and manner of death into the Forensic Automated Case Tracking System (FACTS), primarily for the purpose of certifying the death and completing the death certificate.
5. Approve/decline all cremations, anatomic donations, and burials at sea.
6. Sign death certificates and checklist for release, in order to meet Key Result Measure for percent of positively identified bodies ready for release within 48 hours.
7. Review decedent medical records to establish medical history and determine if it was the cause or contributable to the death (when applicable).
8. Review microscopic specimens (when applicable).
9. Request expert consultations (when required or applicable)
10. Produce autopsy reports
11. Produce external examination reports when applicable.

Provide expert testimony, depositions and witness conferences for civil and criminal cases.

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QUALITY ASSURANCE PROGRAM

- 1.1 **Daily Conferences:** The Medical Examiners and the Medico-legal Investigators meet daily to discuss all cases examined. The daily case census is reviewed. Scene photographs, if applicable, are reviewed and examination type determined. There is review of findings, including photographs, of previous day's cases. Also, Investigation and Autopsy Services are periodically evaluated (see Mortuary Unit QA program for details).
- 1.2 **Weekly and Bi-weekly Conferences:**
 - 1.2.1 Consensus Case Conference: This case conference combines the review of difficult cases that require pathology consensus with the Histology reviews. This meeting will be conducted weekly, and appropriately logged.
 - 1.2.2 Toxicology Case Conference: This meeting occurs weekly and includes a Toxicologist for the review of pending cases that need further consultation/peer-review.
- 1.3 **Monthly and Bi-monthly Conferences:**
 - 1.3.1 60-Day Conference: This conference is to review cases
 - 1.3.2 Quality Assurance: This meeting occurs bi-monthly, for the purpose of reviewing current, revised or new procedures to ensure proper training, dissemination and compliance; to review process concerns across units; to identify non-conformities or gross neglect of duties; to determine root cause and identify and record a corrective action.

ORGANIZATION AND MANAGEMENT

The Chief Medical Examiner (CME) in accordance with DC Code §5-1404 is responsible for all administrative, operational and medical functions formerly performed by the coroner in the District of Columbia. The CME and such other medical examiners as may be appointed may administer oaths and affirmations and take affidavits in connection with the performance of their duties. The CME, other medical examiners, medicolegal investigators and toxicologists as the CME may appoint, may be authorized by the CME to teach medical and law school classes, to conduct special classes for law enforcement personnel and to engage in other activities related to their work

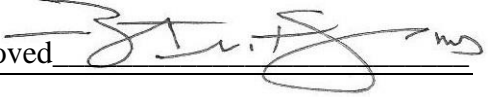
PERSONNEL

The Chief Medical Examiner (CME), the Deputy CME, and any medical examiners shall be physicians licensed to practice medicine in the District of Columbia. The CME, the Deputy CME, and any medical examiners appointed after October 19, 2000, shall be certified in forensic pathology by the American Board of Pathology or be eligible for such certification as mandated in DC Code §5-1402. The Medical Examiner/Pathologist positions held are:

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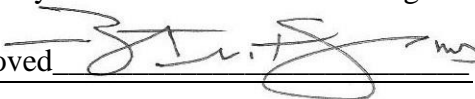
1. Chief Medical Examiner (1)
2. Deputy Chief Medical Examiner (1)
3. Deputy Medical Examiners (5)

FACILITIES

- The Pathology Unit is located within the Office of The Chief Medical on the 5th floor.
- Postmortem examinations are performed in the autopsy suites located on the 5th floor.

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EVIDENCE CONTROL

The pathology and mortuary unit shall have and follow a documented evidence handling system to ensure the integrity of physical evidence. This system shall ensure that:

- Evidence is uniquely identified with an OCME Case number for identification.
- Chain of custody for all evidence is maintained. (See Chain of Custody SOP)
- The pathology and mortuary unit follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence.
- The autopsy suite has secure areas for evidence storage.
- The pathology and mortuary units shall have procedures requiring that evidence sample/specimen(s) are stored and handled in a manner that minimizes degradation

ANALYTICAL PROCEDURES

Autopsy Process: Because each body in the custody of the DC OCME is to be treated as evidence, all autopsy findings are documented in written form and photographically by OCME staff, and when appropriate by law enforcement entities from appropriate jurisdictions. In addition, in Homicide cases the bodies are x-rayed and the x-rays are stored – as are all other records, photo's, and specimens related to the case - for a period that complies with the Millicent Allewelt Amendment Act of 2004 (65 years for open homicide cases). Autopsies are not performed in seclusion, which enables fellow colleagues and the Chief Medical Examiner to review controversial or difficult cases during the time of the procedure. Morning meetings provide a forum for the Medical Examiners to peer-review cases and obtain input from the investigators, as well as review scene photographs. Different opinions, additional information, and perspectives are expressed in order to determine an appropriate type of examination.

EQUIPMENT CALIBRATION AND MAINTENANCE

The Pathology unit shall establish and provide a calibration and maintenance program for the agency microscopes.

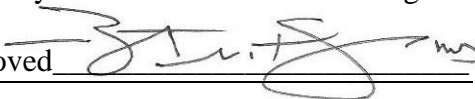
REPORTS

In order to ensure that autopsy reports are completed whether or not the medical examiner that performed the autopsy examination is still employed with the agency, standardized autopsy reporting is utilized along with standards for recording the initial data. The autopsy report format and body templates have been standardized and are available electronically, which enables the Medical Examiner to produce a first draft of the report immediately after the autopsy examination. This process not only enables a medical examiner to complete another medical examiner's report more easily, but it also expedites the report process of each medical examiner with minimal corrections.

In addition to the above standardized processes a set timeframe in which autopsy findings - which may or may not include the cause and manner of death - must be ready for transcription has been established as

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well. Each medical examiner is required to produce a draft report within five days of the autopsy. Medical examiners can then provide the draft report of their findings to the medical transcription unit for completion. This ensures that a draft of the autopsy report is produced and documented within five days.

REVIEW

A formal review of the Autopsy Reports using the NAME review standards is conducted. The findings are reported out at the meeting for resolution where required and provided to the Quality Program Manager for analysis and filing. Also, when necessary OCME obtains consults with Neuropathologists, Cardio-pathologists, Radiologists, Anthropologists and other consultants as appropriate.

CORRECTIVE ACTIONS

The Pathology unit shall establish a policy and procedures, to identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

Selection and Implementation of Corrective Actions: When a corrective action is necessary the unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

Monitoring of Corrective Actions: The pathology unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective actions taken have been effective. An internal audit process should be developed to track and record effectiveness.

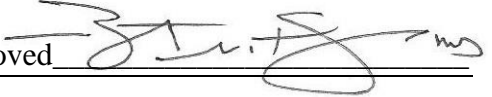
Documentation: The Pathology unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the OCME Quality Program Manager. Such documentation shall be retained in accordance with applicable Federal or state law.

PREVENTATIVE ACTIONS

The Pathology unit shall identify needed improvements and potential sources of nonconformities, either technical or within the management system. When improvement opportunities are identified or where a preventive actions is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

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Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

AUDITS

Internal Audits: 100% peer-review audits are conducted on Homicide, Undermined, and Sudden infant death cases by the Medical Examiner Staff.

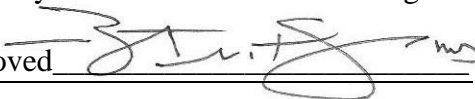
External Audits: The OCME participates in microscopic audits and testing, which are conducted through the College of American Pathologists (CAP).

SAFETY

- The Pathology Unit performs autopsies and may be exposed to biohazard materials. Universal precautions are followed when handling biohazard materials.
- Proper PPE donning and doffing is trained and reviewed quarterly
- Fit Testing for N95 Respiratory Mask is conducted per Occupational Safety Health Standards (OSHA) requirement

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**OCME QUALITY ASSURANCE AND CONTROL PROGRAM
INVESTIGATIONS UNIT**

OCME QUALITY ASSURANCE AND CONTROL PROGRAM

Purpose: To assure that all death investigations by the Office of the Chief Medical Examiner are carried out in accordance with District Law Code (Chapter 14 §5-1405b). The QA Program will serve as module and measuring tool which will assure that death investigations are complete and independent. It will serve as a check and balance system confirming that all required information is captured and accurately recorded in Forensic Automated Case Management System (FACTS) for the purposes of reporting.

Scope: The Investigation Unit is responsible for evidence gathering, medical interpretation and provision of information to aid in the determination of the cause and manner of death.

Peer Review of products produced by the Investigation Unit

- Data entry in FACTS
- Process and procurement of evidence (DC Code Chapter 14 §5-1408a,b),
- Review of cremation request in the District of Columbia (DC Code §5-1405c)
- Process of request for storage of unclaimed remains (DC Code §5-1411c)
- Collection of reference specimen from relatives of persons who are not visually identifiable to possibly establish by means of DNA analysis and comparison

QUALITY ASSURANCE PROGRAM:

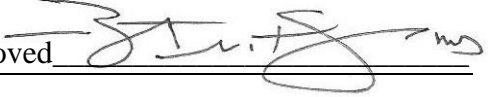
The Investigations unit shall establish a documented quality assurance program that is appropriate to the activities of Medico-legal Death Investigation. Random auditing of cases with various statuses will be done by the review of critical data entry in the Forensic Automated Case Management System specific to Investigations.

Documentation of the presence or absence of critical data will be collected in a usable format Deficiencies will be noted, corrected and documented as such.

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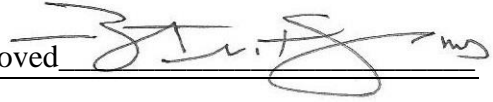
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It is critical to confirm that the data accurately reflects the original information, for purposes of reporting. Data entries must be consistent, numbers and values entered correctly, and spell check utilized.

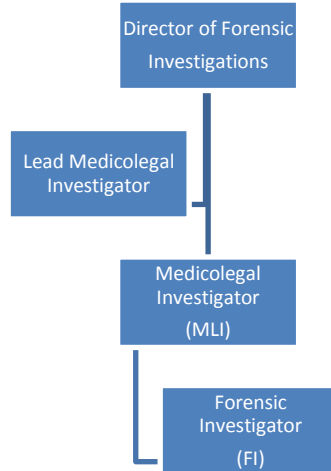
QA of death investigation data is essential to ensure accuracy in computer-generated office documents and data used for research and public health purposes.

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ORGANIZATION AND MANAGEMENT

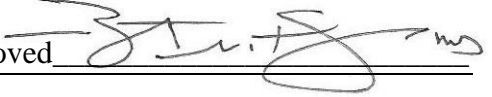


PERSONNEL

- Director of Forensic Investigations
 - Physician Assistant or Advanced Practice Registered Nurse with 2-4 years clinical experience.
 - Licensed in the District of Columbia
 - Knowledge of District and Federal Laws and regulations governing the work of the OCME
 - Certification on Diplomat level with the American Board of Medico-legal Death Investigators is recommended
 - Highly skilled in oral and written communications
- Lead Medico-legal Investigator
 - Physician Assistant or Advanced Practice Registered Nurse with 2-4 years clinical experience.
 - Licensed in the District of Columbia
 - Knowledge of District and Federal Laws and regulations governing the work of the OCME
 - Certification on Diplomat level with the American Board of Medico-legal Death Investigators is recommended
 - Highly skilled in oral and written communications
- Medico-legal Investigators
 - Physician Assistant or Advanced Practice Registered Nurse with 2-4 years clinical experience.
 - Licensed in the District of Columbia
 - Certification on Diplomat level with the American Board of Medico-legal Death Investigators is recommended

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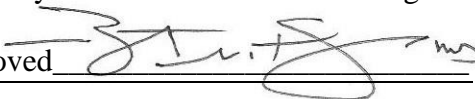
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- Knowledge of District and Federal Laws and regulations governing the work of the OCME
 - Highly skilled in oral and written communications

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- Forensic Investigator
 - Masters in Forensics Science (MFS)
 - Certification on Diplomat level with the American Board of Medicolegal Death Investigators is recommended
 - Knowledge of District and Federal Laws and regulations governing the work of the OCME
 - Highly skilled in oral and written communications

FACILITIES

- The Investigation Unit is a secured, controlled unit within the Office of The Chief Medical Examiner in Room 5081. Access to the unit is limited to investigators, medical examiners and the mortuary staff.
- A designated changing rooms (Room 5194 for females and Room 5182 for males) and decontamination area (Room 5201) are available for Investigations
- All investigators utilize a secured password to gain entry into the Forensic Automated Case Management System

EVIDENCE CONTROL

Controlled prescription medications are counted and documented on scene by the investigator in consort with law enforcement present at the scene. The medications are then placed in an evidence bag, labeled, securely sealed and transported back to OCME. The controlled prescription information is entered in FACTS, the sealed controlled medication is deposited in a dedicated Toxicology safe in the autopsy suite and the appropriate entries made into the assigned log book.

Syringes removed from scenes, are placed in a transport container specifically for sharps, labeled with the case number, date, decedent name and initials of the collecting investigator. Upon return to the office that evidence is placed in the toxicology safe in the autopsy suite and the appropriate entries made into the assigned log book.

Other evidence important to the death investigation is appropriately packaged, labeled, secured and then transported back to OCME and placed in the appropriate safe- personal property, evidence or toxicology.

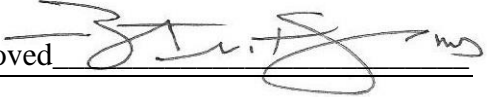
REPORTS

Investigators are required at a minimum to complete the initial Investigative report and the Scene report prior to the daily morning report/meeting. Additional information that is obtained after the initial death report should be documented in supplemental reports until the investigation is determined to be complete and no other information is required. All contact information is to be documented, including the date/time contact is made, name of individual providing the information, relationship to the decedent and contact telephone number(s), the name of the investigator creating the report and the hard copy with an actual signature. Should the report be done by an intern/student under the supervision of an investigator, that investigator must co-sign all intern/student reports and is responsible for their work.

REVIEW

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- Accepted cases are reviewed on a daily basis by the Director of Investigations and the Medical Examiner assigned to the case for completeness.
- Declined cases are reviewed by the pathologist on call
- Storage cases that transition to Public Disposition are reviewed by the ID Unit

CORRECTIVE ACTIONS

The Investigations unit shall establish a policy and procedures, to identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

Selection and Implementation of Corrective Actions: When a corrective action is necessary the Investigations unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

Monitoring of Corrective Actions: The investigations unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective actions taken have been effective. An internal audit process should be developed to track and record effectiveness.

Documentation: The Investigations unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the OCME Quality Program Manager. Such documentation shall be retained in accordance with applicable Federal or state law.

PREVENTATIVE ACTIONS

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Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

AUDITS

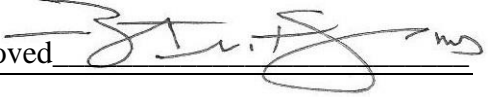
No written audit program has been established for the Investigations unit at this time. However, investigation reports are reviewed daily at morning meeting.

SAFETY

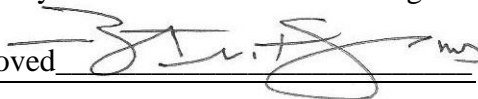
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- Universal Precautions are followed when handling biohazard materials and on all scene investigations
 - Proper PPE donning and doffing is trained and reviewed quarterly
 - FIT Testing for N95 Respiratory Mask is conducted per Occupational Safety Health Standards (OSHA) requirements



OCME QUALITY ASSURANCE AND CONTROL PROGRAM TOXICOLOGY LABORATORY

Purpose: The purpose of this program is to establish and maintain a documented quality assurance system that is appropriate for Post-Mortem and Human Performance Forensic Toxicology testing activities at the OCME.

Scope: This SOP describes the quality assurance requirements that the OCME Forensic Toxicology should follow to ensure the quality and integrity of the data and competency of the laboratory. This SOP does not preclude the participation of the laboratory, by itself or in collaboration with others, in research and development, and on procedures that have not yet been validated.

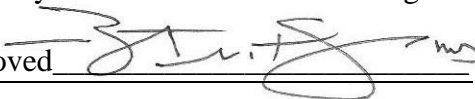
2. DEFINITIONS

As used in this SOP, the following terms shall have the meanings specified:

- (a) Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and completeness for editorial correctness.
- (b) Analytical procedure is an orderly step by step procedure designed to get a result, while ensuring operational uniformity.
- (c) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.
- (d) Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.
- (e) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:
 - (1) Internal proficiency test is one prepared and administered by the laboratory.
 - (2) External proficiency test, which may be open or blind, is one which is obtained from a second agency.
- (f) Quantifying test measures proficiency in both technical skills and knowledge.
- (g) Quality assurance includes the systematic actions necessary to demonstrate that a service meets specified requirements for quality.

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(h) Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate, calibrators or other documentation which is issued by a certifying body.

(i) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

(j) Secure area is a locked space (for example, cabinet, vault or room) with access restricted to authorized personnel.

(k) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes: accuracy, reproducibility, and limitations.

3. QUALITY ASSURANCE PROGRAM

3.1 The laboratory shall establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1 The quality manual shall address at a minimum:

- (a) Organization and management
- (b) Personnel Qualifications and Training
- (c) Facilities
- (d) Evidence control
- (e) Validation
- (f) Analytical procedures
- (g) Calibration and maintenance
- (h) Proficiency testing
- (i) Corrective action
- (j) Reports
- (k) Review
- (l) Safety
- (m) Audits

4. ORGANIZATION AND MANAGEMENT

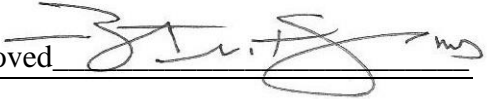
4.1 The laboratory shall:

(a) have a lab director with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.

(b) specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the Forensic Toxicology analysis.

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5. PERSONNEL

5.1 Laboratory personnel shall have the education, training and experience necessary to meet or exceed the minimum requirements for accreditation as a Post-Mortem Forensic Toxicology laboratory.

The laboratory shall:

5.1.1 have a written job description for personnel to include responsibilities, duties and skills.

5.1.2 have a documented training program for qualifying all technical laboratory personnel.

5.1.3 have a documented program to ensure technical qualifications are maintained through continuing education.

5.1.3.1 Continuing education - the technical manager or leader and examiner/analyst(s) must stay abreast of developments within the field of Post- Mortem Forensic Toxicology by reading current scientific literature and by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas.

5.1.4 maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

6. FACILITIES

6.1 The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that:

6.1.1 Access to the laboratory is controlled and limited.

6.1.2 The laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.

7. EVIDENCE CONTROL

7.1 The laboratory shall have and follow a documented evidence handling system to ensure the integrity of physical evidence. This system shall ensure that:

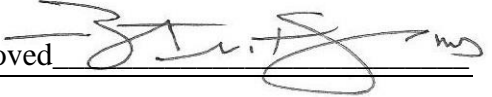
7.1.1 Evidence is marked for identification.

7.1.2 Chain of custody for all evidence is maintained.

7.1.3 The laboratory follows documented procedures that minimize loss, contamination, and/or deleterious change of evidence.

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7.1.4 The laboratory has secure areas for evidence storage.

7.2. The laboratory shall have a procedure requiring that evidence sample/extract(s) are stored and handled in a manner that minimizes degradation.

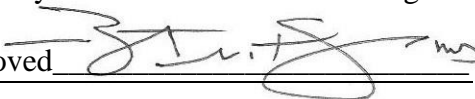
8. VALIDATION

8.1 The laboratory shall use validated methods and procedures for forensic casework analyses.

8.1.2 Before the introduction of a procedure into forensic casework, the analyst shall successfully complete training.

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9. ANALYTICAL PROCEDURES

9.1 The laboratory shall have and follow written analytical procedures approved by the laboratory Chief Toxicologist.

9.1.1 The laboratory shall have a standard operating protocol for each analytical technique used.

9.2. The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

10.1 The laboratory shall have a documented procedure for calibration of instruments and equipment.

10.2. Where available and appropriate, standards traceable to National Institute of Standards and Technology (NIST) shall be used for the calibration of all instrumentation.

10.2.1 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results.

10.2.2 The frequency of the calibration shall be documented for each instrument requiring calibration. Such documentation shall be retained as long as the Chief Toxicologist deems necessary.

10.3 The laboratory shall have and follow a documented program to ensure that instruments and equipment are properly maintained.

10.3.1 New instruments and equipment, or instruments and equipment that have undergone repair or maintenance, shall be calibrated before being used in casework analysis.

10.3.2 Written records or logs shall be maintained for maintenance service performed on instruments and equipment. Such documentation shall be retained as long as the Chief Toxicologist deems necessary.

11. REPORTS

11.1 The laboratory shall have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports.

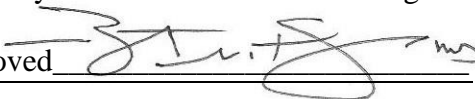
11.1.1 The laboratory shall maintain, in a case record, all documentation generated by examiners related to case analyses.

11.1.2 Reports shall include:

- (a) Case identifier
- (b) Description of evidence examined

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- (c) A description of the methodology
 - (d) Results and/or conclusions
 - (e) An interpretative statement (either quantitative or qualitative)
 - (f) Date issued
 - (g) Disposition of evidence
 - (h) A signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report.

11.1.3 The laboratory shall have written procedures for the release of case report information.

12. REVIEW

12.1 The laboratory shall conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

12.1.1 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewer(s).

12.2 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each examiner.

13. PROFICIENCY TESTING

13.1 Laboratory personnel shall undergo, at regular intervals of not to exceed 180 days, external proficiency testing in accordance with these standards.

13.1.1 The laboratory shall maintain the following records for proficiency tests:

- (a) Identity of the examiner.
- (b) Date of analysis and completion.
- (c) Copies of all data and notes supporting the conclusions.
- (d) The proficiency test results.
- (e) Any discrepancies noted.
- (f) Corrective actions taken.

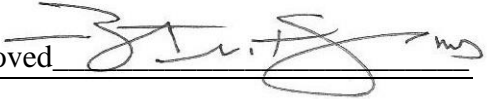
Such documentation shall be retained as long as the Chief Toxicologist deems necessary.

13.1.2 The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

- (a) All discrepancies/errors and subsequent corrective actions must be documented.
- (b) All final reports are graded as satisfactory or unsatisfactory by the Chief Toxicologist.
- (c) All proficiency test participants shall be informed of the final test results.

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14. CORRECTIVE ACTION

14.1 The laboratory shall establish and follow procedures for corrective action whenever proficiency testing discrepancies and/or casework errors are detected, such as filling out a corrective action form and putting it into the case file.

14.1.1 The laboratory shall maintain documentation for the corrective action. Such documentation shall be retained in accordance with applicable Federal or state law.

15. AUDITS

15.1 The laboratory shall conduct audits annually in accordance with the standards outlined herein.

15.1.1 Audit procedures shall address at a minimum:

- (a) Quality assurance program
- (b) Organization and management
- (c) Personnel
- (d) Facilities
- (e) Evidence control
- (f) Validation
- (g) Analytical procedures
- (h) Calibration and maintenance
- (I) Proficiency testing
- (j) Corrective action
- (k) Reports
- (l) Review
- (m) Safety
- (n) Previous audits

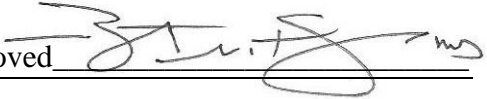
15.1.2 The laboratory shall retain all documentation pertaining to audits in accordance with relevant legal and agency requirements.

16. SAFETY

16.1 The laboratory shall have and follow a documented environmental health and safety program. This program shall be reviewed annually.

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**OCME INTERNAL AUDIT PROGRAM
TOXICOLOGY PROGRAM**

1. PURPOSE

The purpose of this program is to establish and maintain a documented internal audit program that is appropriate for Post-Mortem and Human Performance Forensic Toxicology testing activities at the OCME.

2. SCOPE

This Standard Operating Procedure (SOP) describes the internal audit requirements that the OCME Forensic Toxicology should follow to ensure the quality and integrity of the data being reported and competency of the laboratory.

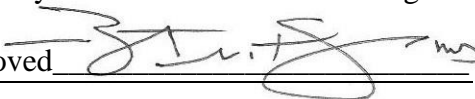
3. DEFINITIONS

As used in this SOP, the following terms shall have the meanings specified:

- (a) Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and completeness for editorial correctness.
- (b) Analytical procedure is an orderly step by step procedure designed to obtain a result, while ensuring operational uniformity.
- (c) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.
- (d) Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

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(e) Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

- (1) Internal proficiency test is one prepared and administered by the laboratory.
- (2) External proficiency test, which may be open or blind, is one which is obtained from a second agency.

(f) Quality assurance includes the systematic actions necessary to demonstrate that a service meets specified requirements for quality.

(g) Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

(h) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes: accuracy, reproducibility, and limitations.

4. INTERNAL AUDIT OVERVIEW

4.1 The laboratory shall establish and maintain a documented internal audit system that is appropriate to its testing activities.

4.2 The laboratory shall conduct audits on a monthly basis, in accordance with the standards outlined herein.

4.3 The laboratory shall aim to review ten (10) cases per month. This will result in 120 reviewed cases per year, representing approximately 10% of the caseload (as of January 2006).

4.4 Participants in the internal audit shall be forensic toxicologists at a Grade 13 level or higher. A minimum of four (4) forensic toxicologists are required for each audit.

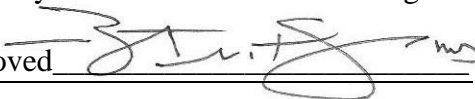
4.5 Overall internal audit procedures shall address at a minimum:

- (a) Quality assurance program
- (b) Personnel
- (c) Evidence control
- (d) Validation
- (e) Analytical procedures
- (f) Quality control
- (g) Calibration and maintenance
- (h) Proficiency testing
- (i) Corrective action
- (j) Written reports
- (k) Administrative review, and
- (l) Previous audits

4.6 Any errors and/or inconsistencies revealed as part of the audit shall be discussed and documented.

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4.7 Any resulting corrective action(s) shall be implemented prior to the next month's audit.

4.8 Corrective action(s) implemented from the previous audit shall be reviewed each month for appropriateness.

5. INTERNAL AUDIT PROCEDURES

5.1 Internal audits will be held on or near the 15th day of each month.

5.2 The Chief Toxicologist and/or the Toxicology Quality Control Official shall randomly select ten (10) cases from those signed out during the previous month.

5.3 Random selection will continue until these cases include at least one (1) negative case, one (1) positive case and one (1) case submitted from an outside agency.

5.4 Each case review shall address at a minimum:

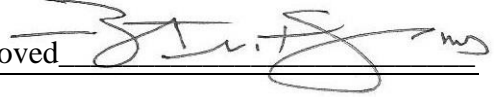
- (a) Submission of evidence
- (b) Receipt of evidence
- (c) Accessioning of evidence
- (d) Database entry
- (e) Routine assay assignment
- (f) Additional assay assignment
- (g) Overall workflow
- (h) All individual analyses
- (i) All corresponding technical reviews
- (j) Chromatography and/or validity of analytical data
- (k) Corresponding data packages
- (l) Overall chain-of-custody
- (m) Any corrective action(s) taken
- (n) Disposition of evidence
- (o) Final administrative review
- (p) Written reports, and
- (q) Final cause and manner of death as assigned by Medical Examiner, where applicable.

5.5 Individual toxicology reports (to include preliminary, final, supplemental and/or amended reports) shall include:

- (a) Submitting agency
- (b) Case identifier(s)
- (c) Description of evidence examined
- (d) Description of the methodology used
- (e) Results and/or conclusions
- (f) Date issued, and
- (g) Signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report.

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5.6 Individual case files shall contain appropriate and sufficient documentation to support the results and/or conclusions drawn in any corresponding report.

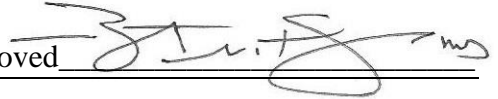
Receipt of OCME Tox, Int Audit

The following personnel have read the preceding SOP, and agree to abide by its terms and not to modify any part without the prior approval of the Chief Toxicologist.

Name (print)	Signature	Date
_____	_____	_____
_____	_____	_____
_____	_____	_____

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**OCME QUALITY ASSURANCE AND CONTROL PROGRAM
RECORDS MANAGEMENT UNIT**

Purpose: The purpose of the Records Management quality assurance program is to ensure the decedent case files are accurate, complete and error free. The program should also ensure the security of the case files that requests are fulfilled in a timely manner and the authenticity of the records released to the public, law enforcement and other governmental officials is ensured.

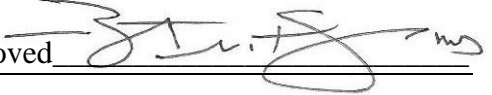
Scope: Records management staff and interns that serve within the unit to adhere to the guidelines established within the quality assurance and control program for the Records Management unit to ensure the quality of the Medical Examiner case files.

QUALITY ASSURANCE PROGRAM

1. Ensure all documents and materials – identified on checklist - of the Medical Examiner case file are present and correctly filed when received from ID Unit. Which requires staff to:
 - a. Analyze ALL documents for accuracy and completeness, which includes dates, times, signatures and proper name and case file number.
 - b. Review autopsy report for accuracy and completeness primarily for minor inaccuracies such as typographical errors (i.e. name and case number).
 - c. Review toxicology and other ancillary reports for typographical errors (i.e. name and case number) and file in record.
 - d. Review Death Certificate for accuracy and completeness
 - e. Review all Transport, property, and release forms for accuracy and completeness
 - f. Review all Investigative Reports for dates and signatures
2. Ensure proper completion of case files into the Forensic Analysis Case Tracking System (FACTS) by case file type and then by “Exam” type.
3. Ensure accuracy of Delayed Report of Diagnosis before delivery to the Department of Health, Division of Vital Records.
4. Maintain Medical Examiner case file tracking logs for: 1) Amendments; and 2) Case File check-out/check-in.
5. Ensure timely rotation and archival of case files on an annual basis, which includes compliance with the Millicent Allewelt Amendment Act of 2004
6. Respond to and process all communication – whether e-mail, US mail or via telephone - within a timeframe as mandated by the Mayoral guidelines. Which includes:

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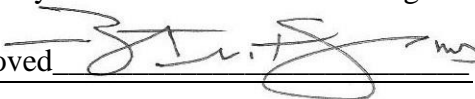
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-
- a. Process subpoenas for access to, or disclosure of, case file information, and record in appropriate database.
 - b. Establish kinship for proper and accurate response to written requests.

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ORGANIZATION AND MANAGEMENT

Records management staff is responsible for authenticating and certifying documents for public and judicial use; therefore the records management staff must be expert in records management and processing of records. Records management staff must also be versed and understand the laws and agency policies that govern the management and release of these confidential Medical Examiner records.

PERSONELL

1. Records Manager – Must possess a Bachelor’s or Master’s degree from an accredited university in Information Technology or related field and possess experiences in data analysis/management, or the management of information systems is preferred.
2. Records Management Specialist – Must possess a High School diploma and have experience in the management of health records
3. Staff Assistant – Must possess a High School diploma and have secretarial experience.

FACILITIES

The Medical Examiner Case files are kept in a secured location, so that the confidentiality of the records can be ensured. More specifically the current rotation of Medical Examiner Case file records are house on the 6th floor in secured File room 6076 within suite 6070. The file room area is only accessible by RMU Staff and selected Executive management. There is selected historical record information located in a secure storage room on the 5th floor, which also has access limited to the RMU Staff, and selected Executive management.

EVIDENCE CONTROL

The Medical Examiner case file is the only evidence maintained within the Records Management Unit. These case files are located in an access controlled environment and are only reviewed by those authorized to review Medical Examiner case files. In addition a stringent check-in/check-out process for case files is followed, which document the date, case file number and the recipient’s name.

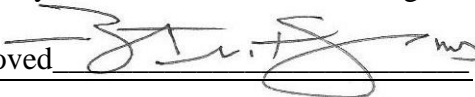
ANALYTICAL PROCEDURES

Under consideration

EQUIPMENT CALIBRATION AND MAINTENANCE

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n/a

REPORTS

The Office of the Chief Medical Examiner (OCME) report is published annually, which documents and reports on all case related statistical data as mandated by law and required by the National Association of Medical Examiners. The records management department produces monthly reports to identify workload activities for the purpose of improving and streamlining processes as well as develop new quality checks where appropriate.

REVIEW

An annual Administrative Case file review is conducted on 10% of all Medical Examiner case files.

CORRECTIVE ACTIONS

The Records Management Unit shall establish a policy and procedures, to identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

Selection and Implementation of Corrective Actions: When a corrective action is necessary the Records Management unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

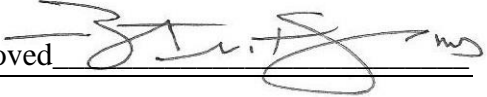
Monitoring of Corrective Actions: The Records Management Unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective actions taken have been effective. An internal audit process should be developed to track and record effectiveness.

Documentation: The Records Management Unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the OCME Quality Program Manager. Such documentation shall be retained in accordance with applicable Federal or state law.

PREVENTATIVE ACTIONS

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The Records Management unit shall identify needed improvements and potential sources of nonconformities, either technical or within the management system. When improvement opportunities are identified or where a preventive actions is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

AUDITS

Auditing of the above activities is done on a daily, weekly and monthly basis by all of the Records Management staff. In addition, case files are reviewed on a regular basis for content, accuracy, completeness and timeliness. Review is accomplished by the following methods:

Audit and Reviews

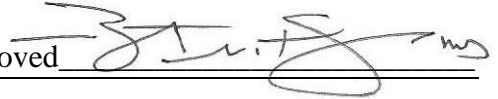
1. Daily review of new case files processed, including review of the ID units checklist.
2. Daily review of correspondence to ensure requestor's has proper and legitimate interest.
3. Weekly review of electronic log to determine extensive out times of case files
4. Weekly review of all Delayed Report of Diagnosis prior to delivery to Vital Records to ensure accuracy of the data entered.
5. Monthly reviews of the following:
 - c. Case file numbers to ensure a sequential numeric filing system for medical examiner case files. Where gaps occur determine cause, for example determine if the case was voided, misfiled or misplaced
 - a. Review all requests to ensure legitimate interest as defined by law.

SAFETY

The Records Management unit complies with the agency-wide Health and Safety program - specifically related to office safety.

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**OCME QUALITY ASSURANCE AND CONTROL PROGRAM
ANTHROPOLOGY/IDENTIFICATION UNIT**

OCME QUALITY ASSURANCE AND CONTROL PROGRAM

Purpose: The purpose of the Anthropology/Identification Unit quality assurance program is reduce work produce and procedural error, monitor quality and timeliness of work product, and to define and implement preventative actions to reduce potential error.

Scope: The Anthropologist, ID Unit Staff, Customer Service Representative, students and interns are required to follow the quality assurance program while operating within the responsibilities of the Anthropology/ID Unit.

Definitions: Provide definitions of terms and actions that will aid with monitoring and control

QUALITY ASSURANCE PROGRAM

Identify all the elements of your QA program in a list format

- Peer review of all products produced by the ID Unit
 - Death Certificates
 - Cremation permits
 - Visual Identification forms
- Peer review by an external anthropologist 10% of trauma reports.

ORGANIZATION AND MANAGEMENT

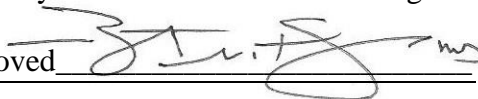
- ID Unit staff – high school diploma or the equivalent
- Anthropologist – Doctorate with a concentration in forensic anthropology or the equivalent, three years of work experience in a medical examiner setting, two years of supervisory experience, and certification by the American Board of Forensic Anthropology (ABFA).

PERSONNEL

ID Unit staff shall be proficient in data entry into FACTS and EDRS and triaging telephone calls using the Cisco telephone. ID unit staff shall be trained and remain proficient in the visual identification procedures. They must be well versed in the Medical Examiner law specifically as it relates to releasing information.

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The anthropology staff must maintain certification by the ABFA. They must receive annual continuing education credits as dictated by the ABFA recertification guidelines.

FACILITIES

Records are securely maintained in the ID Unit office (rm 5040), file room (rm 5041) and Visual Identification Office. Access to the ID Unit office and file room is limited to OCME staff. The public has access to the Visual Identification Office after passing through DFS security. An ID Unit staff member remains in the Visual Identification Office during normal business hours.

Anthropology records and evidence are securely maintained in the Anthropology Laboratory, Anthropology Incubator, Anthropology Storage Room and Anthropology Office. Access to the Anthropology Laboratory and Anthropology Incubator are controlled by key card readers. Only individuals with essential duties in the mortuary areas have access to the Anthropology Laboratory or Incubator. Access to the Anthropology Storage Room and Anthropology Office are controlled by standard key locks. Only the Forensic Anthropologist and Chief Medical Examiner have access to the key.

EVIDENCE CONTROL

Evidence control is detailed in SOP ANT 01.002

ANALYTICAL PROCEDURES

Analytical processes are detailed in SOP ANT 01.001

EQUIPMENT CALIBRATION AND MAINTENANCE

This SOP is under development.

REPORTS

The Anthropology Report of Consultation is detailed in ANT 01.001, sections 8.9, 9.5, and 11.4.

REVIEW

ID Unit peer review process is detailed in SOP IDU 01.006 Peer Review.

Anthropology peer review process is detailed in ANT 01.001, Section 14.

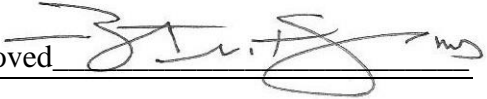
CORRECTIVE ACTIONS

The ID unit shall establish a policy and procedures, to identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

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Selection and Implementation of Corrective Actions: When a corrective action is necessary the ID unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

Monitoring of Corrective Actions: The ID unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective actions taken have been effective. An internal audit process should be developed to track and record effectiveness.

Documentation: The ID unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the OCME Quality Program Manager. Such documentation shall be retained in accordance with applicable Federal or state law.

PREVENTATIVE ACTIONS

The ID unit shall identify needed improvements and potential sources of nonconformities, either technical or within the management system. When improvement opportunities are identified or where a preventive actions is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

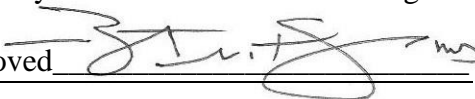
AUDITS

No audit program has been established yet.

SAFETY

The Anthropology Unit participates in autopsy and analysis of biohazard materials. Universal precautions are followed when handling biohazard materials.

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OCME QUALITY ASSURANCE AND CONTROL PROGRAM MORTUARY UNIT-Autopsy and Transport

OCME QUALITY ASSURANCE AND CONTROL PROGRAM

Purpose: The purpose of the quality assurance and control program within the mortuary unit is to ensure that continuous operations are performed with improved integrity and efficiency. These practices identify the guidelines and requirements to optimize the work product and minimize nonconformities relating to decedent and evidence handling, autopsy services, and identification procedures.

Scope: Quality assurance and control shall be implemented for mortuary unit procedures that involve the acquisition, custody, integrity, and release/transfer of remains, evidence, personal property, and specimens. These practices will involve peer review applications and process mapping checkpoints performed by OCME staff as well as external partners to meet the compliance standard.

Definitions: For purposes of this document, the following terms shall have the designated meanings:

CFL: Consolidated Forensic Laboratory

FACTS: Forensic Automated Case Tracking System

METT: Medical Examiner Transport Team

ME: Medical Examiner

OCME: Office of the Chief Medical Examiner

PACS: Picture Archiving and Communication System

PPE: Personal Protective Equipment

QUALITY ASSURANCE PROGRAM

ACTIVITIES OF AUTOPSY/MORTUARY:

1. Decedent Handling Procedures:

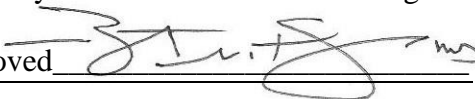
The following activities are completed to perform decedent transport, intake, storage, and release processes:

A. Decedent Transport from the Following Locations:

- Public view;
- Private Home/Residence;

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- Hospital Facility;
- Nursing Home Facility; and
- Funeral Home, etc.

B. Intake of Remains Process:

- Documentation of Date/Time of Decedent Transport and Arrival to OCME;
- Documentation of Decedent Demographics (Name, Age, Race, Weight, Height);
- Documentation of Removal Location/Address; and
- Documentation of Personal Belongings and Data Entry into FACTS.

C. In-House Decedent Inventory and Storage:

- Documentation of Decedent Custody in the Human Remains Storage Log;
- Placement of Decedents In-Storage and Documentation of Storage Location on the Box/Cart Sheet; and
- Verification of Decedent and Location In-Storage on the Daily Census Log.

D. Decedent Release:

- Decedents are released to family via funeral home representative;
- Decedents are released for public disposition via funeral home representative;
- Decedents are released for anatomical donation via funeral home representative; and
- Release of Personal Property to Funeral Home Representative.

2. Decedent Identification Procedures:

The following activities are completed to perform identification processes:

A. Radiographic Imaging for Case Examination Diagnostic Review and Antemortem Comparison for Identification

- Full Body Radiographs (Head, Chest, Abdomen, Pelvis, and Extremities); and
- Dental Radiographs (Full Mouth, and Bite Wings, etc.)

B. Fingerprinting Techniques

- Digital Technique for Non-Decomposed Cases; and
- Ink Technique for Rehydration of Tissue for Remains in State of Advanced Decomposition

C. DNA Sampling

- Blood Stained Card for DNA analysis; and
- Bone/Teeth for DNA analysis

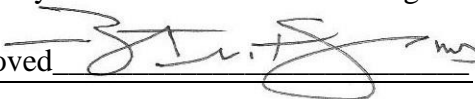
3. Examination Procedures:

The following activities are completed to assist with examination procedures:

A. Full Service Assistance with External and Autopsy (partial and full) Examinations

- Removal of Clothing and Medical Therapy for External Examinations; and
- Evisceration of the Body Cavity for Autopsy Examinations.

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4. Specimen Handling:

The following activities are completed to assist with specimen handling procedures:

A. Procurement and Collection of Wet Tissue/Toxicological/Mircobiological/Viral Specimens from:

- External and Autopsy Examinations; and
- Hospital Facilities/Laboratories; and
- Tissue Harvesting Affiliate

B. Storage and Packaging of Specimens for Internal Testing and External Reference Laboratory Review:

- Refrigerator
- Shelving
- Incubator

5. Evidence Handling:

The following activities are completed to assist with evidence handling procedures:

A. Collection of Evidence to include:

- Fingerprints
- Sexual Assault Kits
- DNA Blood Cards
- Fingernail Clippings
- Hair Samples
- Swabs
- Trace
- Ballistics
- Photographs, etc.

B. Transfer of Evidence to the following:

- Records Management
- Law Enforcement/Crime Scene Representative

6. Administrative Tasks

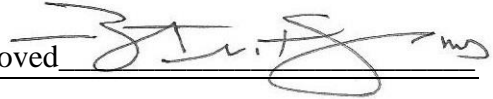
- Supply Ordering/Inventory
- Individual Performance Reporting
- Completion of Requisition/Chain of Custody/Release forms
- Documentation files for QA/QC tracking (Radiographs, Release, Transport, and FACTS) and Reference Laboratory Reporting (Report Distribution)
- Documentation files for Specimen Tracking/Report Distribution

7. Maintenance Programs:

A. Maintenance of Equipment:

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- Preventative Maintenance;
- Ad hoc Repair Services; and
- Documentation of Maintenance Logs

B. Maintenance of Vehicles:

- Preventative Maintenance;
- Ad hoc Repair Services; and
- Documentation of Maintenance Logs
- Daily and Quarterly Interior/Exterior Cleaning
- Stocking

8. Mortuary Unit Maintenance

- **Organization, cleaning, disinfecting of the autopsy suite/mortuary unit areas, paperwork, instruments, and equipment**

9. Photography Assistance As Needed

10. Escort Service of Vendors/Visitors

DECEDENT TRANSPORT AND REMOVAL QA PROCESS

The identity of the decedent remains shall be verified at the transport location prior to removal [See Reference Body Handling SOP Section 5.3, 6.4, 6.7, and 6.8] for 100% of the cases. Transport Checklist will be in future development as a reference for the METT to ensure compliance of procedures for decedent identification and transport and associated evidence and personal property. The following are controls to ensure efficient labeling and identity of decedent remains prior to transport:

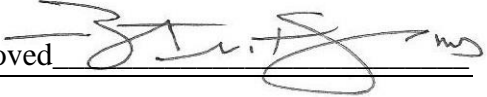
A. Hospital/Facility Removal

1. Decedents removed from hospital or nursing facilities shall be verified for presence of the labeled hospital band and toe tag to confirm decedent identity. The hospital band and toe tag must include:

- Decedents demographics (Name, Age, Sex, and Race); and
- Decedents medical record/patient identification number.
- Decedents without hospital toe tag and band shall not be removed from facility so that identification can be verified by facility staff prior to transport.

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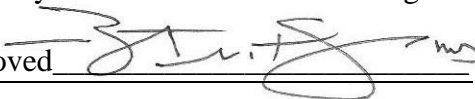
2. Decedent identification and hospital medical record/patient identification number must be cross-referenced checked with decedent demographics and medical record number generated on OCME labels and Transport Notification Form to ensure decedent identity.
3. Decedents identification and medical record/patient identification number on hospital toe tag and hospital band shall be cross-referenced to the decedents demographics in the facilities release log, as well as on the OCME labels.
4. The releasing official at facility will review and sign the OCME Transport Notification Form and cross reference with decedent demographics and medical record number on the hospital toe tag and band to acknowledge and confirm decedent identity.
5. Decedents shall be immediately tagged prior to transport with OCME labeled toe tag and band to ensure a unique identifier is present.
6. Body bag shall be secured with lock to include OCME case number; decedent demographics; dated and initialed by METT to ensure integrity of decedent and corresponding evidence and personal effects.

B. Scene/Residence Removal

1. Decedents removed from scenes or residences shall be verified for presence of OCME labeled toe tag and band prior to transport to confirm decedent identity. [See Reference Body Handling SOP Section 5.3]
 - In the absence of OCME investigator at scene/residence location, the METT must verify the decedent identity by requesting that the nursing representative or designated point of contact on scene place a label on the decedent to include:
 - Decedents demographics (Name, Age, Sex, and Race); and
 - Decedents medical record/patient identification number (if applicable)
 - METT must cross reference the decedents identification provided by nursing representative or designated point of contact on scene with the OCME labels and Transport Notification Form.
2. Body bag shall be secured with lock to include OCME case number; decedent demographics; dated and initialed by METT to ensure integrity of decedent and corresponding evidence and personal effects. [See Reference Body Handling SOP Section 5.4]

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INTAKE QA PROCESS

The intake of decedent remains and personal belongings shall be reviewed for integrity and compliance with chain of custody procedures for 100% of the cases. [See Intake SOP Section]. Intake of Remains Checklist will be in future development as a reference for the mortuary staff to ensure compliance of procedures for intake of remains. The Intake of Remains Checklist shall be reviewed by mortuary staff prior to receiving custody of decedent remains. The following are controls to ensure accuracy in labeling, documentation, and storage of decedent remains and corresponding personal property:

After arrival to OCME:

1) The following shall be verified and immediately documented on decedent body bag to ensure proper labeling and identification:

- Decedents Demographics (Name, Sex, Race, Age); and
- OCME Case Number; and
- Decedent Weight

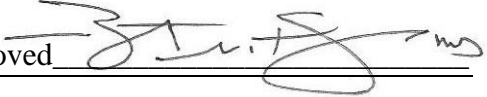
2) The OCME Intake Log Book shall be updated to maintain documentation archives. This documentation is cross referenced into the Forensic Automated Case Tracking System (FACTS) to ensure information and data integrity:

- Decedents Demographics (Name, Sex, Race, Age); and
- OCME Case Number; and
- Decedent Weight; and
- Transport Location; and
- Date/Time of Transport; and
- METT representative whom transported decedent

3) The Decedent Storage Log Book and Human Remains Inventory must be immediately updated and cross referenced to ensure accurate documentation of the timeframe for transfer of custody of decedent remains to refrigerated storage.

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4) OCME Intake Log Book, FACTS, Decedent Storage Log Book, and Human Remains Inventory Census must be checked daily to ensure compliance with custody documentation.

- Human Remains Inventory Census must be cross referenced daily prior to morning meeting with the following:

OCME case number on decedent toe tag

Decedent demographics on decedent toe tag

Decedent location in refrigerated storage

5) The OCME Transport Notification, Personal Property, and Vehicle Utilization Forms shall be reviewed daily prior to morning meeting to ensure proper signatures, times, and accuracy of custody. Documentation on the forms should be cross referenced with the OCME Intake Log Book, FACTS, Decedent Storage Log Book, and Human Remains Inventory Census.

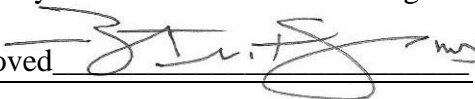
PERSONAL PROPERTY HANDLING QA PROCESS

The personal property and clothing handling process shall be reviewed for integrity and compliance with chain of custody procedures for 100% of the cases. Collection, securing, and transfer of personal property should be thoroughly completed for a single case at a time. The following are controls to ensure accuracy in labeling, documentation, and storage of personal property and clothing transported with decedent remains:

- 1) Inventory of personal effects and clothing in the decedent body bag shall be verified immediately after lock is removed at examination and cross referenced to the Personal Property Intake List updated in FACTS during the Intake Process to ensure integrity regarding the custody of the documented items.
- 2) Personal property and clothing returned to the body bag should be cross referenced with the Personal Property Intake List completed after case examinations and decedent toe tag to verify accurate placement of belongings.
- 3) Inventory verification of personal effects and clothing returned to body bag shall be documented by mortuary staff on the Daily Case Census Document [See Appendix] to acknowledge compliance in chain of custody procedures.

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4) Submission of personal property to the safe shall be verified and completed by mortuary staff and a witness to enhance visibility in transfer of custody process and eradicate errors in documentation.

- Mortuary staff and witness shall verify the following prior to transferring personal property to the safe:

Label on bag to include decedent demographics (Name, Age, Race, Gender)

Label on bag to include OCME Case Number

Completed Personal Property form which corresponds to label, contents in the bag, signature of submitter, and date and time of submission.

Bag containing personal property is sealed with date and initial of submitter.

- Mortuary staff and witness shall complete Personal Property Log Book to include:

Verification of OCME Case Number

Verification of Date and Time of Submission to Safe

Verification of Mortuary Staff and Witness Initials

EVIDENCE AND SPECIMEN HANDLING QA PROCESS

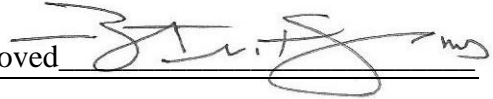
All evidence and specimens for transfer to internal units (e.g. toxicology, ID, etc.), external reference laboratories, and law enforcement shall be reviewed for 100% of the cases to ensure integrity and compliance with chain of custody procedures. Collection, securing, and transfer of evidence and specimens should be thoroughly completed for a single case at a time. [For example, See DNA Collection SOP Section]. The following are controls to ensure accuracy in labeling, documentation, storage, and disposition of evidence and specimens:

1) Evidence and specimens shall be collected in an isolated area, at a single grossing station for a single case and shall be verified with assigned Medical Examiner (ME) prior to packaging to eradicate errors in collection, labeling, and documentation processes.

- The evidence and specimen collection methods should be verified and cross referenced by mortuary staff with the Evidence Handling SOP [Reference Sect] to ensure compliance in acquisition procedures.
- Evidence and specimens shall be labeled immediately after collection as follows:

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Decedent demographics (Name, Age, Race, Gender)

OCME Case Number

Site/Source of Specimen

Date of Collection

Initials of Collector

- Evidence and specimen collection shall be documented by mortuary staff on the Daily Case Census Document [See Appendix] to acknowledge acquisition of evidence and specimens and compliance of chain of custody procedures.

2) Evidence and specimens shall be verified to ensure samples are packaged and retained in the appropriate storage location. The packaging and storage location should be verified and cross referenced by mortuary staff with the Evidence Handling SOP [Reference Sect].

- Packaged evidence and specimens should be visually reviewed by mortuary staff to ensure integrity of the seal for presence of date and initial of collector.
- Retention of evidence and specimens should be verified by mortuary staff to ensure secured storage by cross referencing the documentation in the Evidence and Specimen Log Books to include:

OCME Case Number

Purpose for Transfer to/Removal from Storage Location

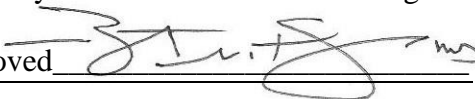
Date of Submission to /Removal from Storage Location

Initials of Mortuary Staff and Witness Handling Submission to and Removal from Storage Location

3) Documentation corresponding to the transfer of evidence and specimens (e.g. Chain/Transfer of Custody, Release, and Requisition Forms. See Appendix) shall be cross referenced with the evidence and specimen samples by Mortuary staff and ME prior to submission to internal units (e.g. toxicology, ID, etc.), external reference laboratories, and law enforcement to ensure efficient labeling and item descriptions.

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- Documentation of evidence and specimens should be cross referenced with the documentation on the Chain/Transfer of Custody, Release, and Requisition Forms and in FACTS to include:

Verification of the decedent demographics (Name, Age, Race, Gender)

Verification of the OCME Case Number

Verification of the Site/Source of Evidence/Specimen

Verification of the Quantity of Specimen/Evidentiary Items to be Transferred

Verification of Date/Time of Collection and Submission

Verification of Signature for Collector/Submitter

4) Transfer of evidence and specimens shall be verified by mortuary staff with the receiving representative to ensure efficient documentation and chain of custody compliance, to include:

- Verification of the labels on the evidence and specimens
- Verification of the Quantity of Specimen/Evidentiary Items to be Transferred
- Cross reference of evidence and specimens with the documentation forms (e.g. Chain/Transfer of Custody, Release, and Requisition Forms).
- Completion of the Release forms with date, time, and signatures of submitting representative and receiving representative.
- Completion of the Evidence and Specimen Log Book with OCME Case Number, Purpose for Transfer, Date/Time of Transfer, and Initials of the receiving representative.

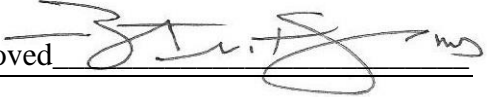
5) Disposition of Evidence and Specimens shall be in accordance with the OCME retention policy [See SOP Records and Retention SOP Section]

- Evidence and specimens for disposal shall only be approved by the assigned ME to ensure that items are confirmed for disposition.
- Evidence and specimens shall be visually confirmed and verified with the ME for disposal to include:

Verification of the Decedent Demographics (Name, Age, Race, Gender)

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Verification of OCME Case Number

Verification of Site/Source of Specimen

- Documentation of the evidence and specimens for disposal should be cross referenced with the documentation on the Biohazardous Discard Form [See Appendix] and in FACTS to ensure compliance in chain of custody procedures to include:

Verification of the decedent demographics (Name, Age, Race, Gender)

Verification of the OCME Case Number

Verification of the Site/Source of Evidence/Specimen

Verification of the Quantity of Specimen/Evidentiary Items to be Disposed

Verification of Date/Time of Disposal

Verification of Signature for Disposing representative and assigned ME

RADIOGRAPH QA PROCESS

Radiographs obtained for identification purposes and diagnostic review of the case examinations shall be reviewed for quality assurance [see Radiology QA/QC Program Policy Sect], integrity of labeling, and body position for 100% of the cases. The Radiograph Checklist will be in future development as a reference for the mortuary staff to ensure accuracy in quality and labeling of digital images. The radiograph checklist shall be reviewed and verified prior to obtaining images. The following are controls to ensure accuracy in acquisition, labeling, documentation, and storage of radiographs:

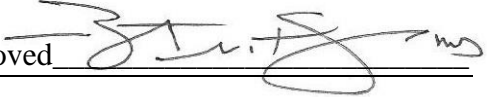
1) Criteria for obtaining full body radiographs shall be evaluated for every case daily prior to the morning meeting by review of the circumstances provided in the Daily Case Census to ensure images are acquisitioned in accordance with standard operating procedures [See Pathology/Post Mortem Examination SOP Sect].

- Completion of radiographs shall be verified by mortuary staff on the Daily Case Census Document to acknowledge acquisition of images.

2) Decedent positioning shall be visually verified in radiographs daily prior to morning meeting by mortuary staff or forensic anthropologist to ensure correct anatomical position.

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- Radiographs shall be visually verified by forensic anthropologist to ensure the presence of full dentition to include the root and gums, if edentulous.
- 3) Established techniques (e.g. kV and MAs settings) for varying body states, age, and size shall verified by mortuary staff and forensic anthropologist and cross referenced with national standards to ensure that overexposure of radiographic images is eradicated.
- Quality of technique exposure shall be visually reviewed for radiographs completed prior to morning meeting for case examination by mortuary staff and forensic anthropologist for identification purposes.
- 4) Anatomical markers (Right or Left) shall be visually verified in the body radiographs by mortuary staff to ensure accurate review of images in accordance with national standards [Reference NAME Checklist].
- 5) Archived storage of the completed radiographs shall be visually verified by mortuary staff prior to the morning meeting to ensure adequate export on the images to the digital repository (PACS) for long term storage.
- 6) Documentation and review of decedent positioning, placement of anatomical markers, quality of radiographic image, and export to PACS shall be completed daily for cases prior to morning meeting and cross referenced with the Radiograph Checklist, and in FACTS to ensure compliance with the Radiology SOP.

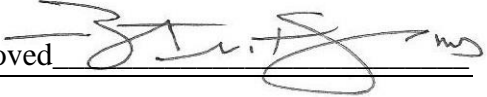
FINGERPRINT QA PROCESS

Review of fingerprints shall be verified during the acquisition process [See SOP Section] and reviewed for quality and compliance with chain of custody procedures for 100% of the cases. Fingerprint Checklist will be in future development as a reference for the mortuary staff to ensure compliance of procedures. The Fingerprint Checklist shall be reviewed and verified prior to collecting fingerprints. The following are controls to ensure accuracy in labeling, acquisition, documentation, and storage of fingerprints:

- 1) Fingerprint cards shall be verified by mortuary staff prior to completing the fingerprints to ensure appropriate documentation of decedent identification to include:
- Decedent Demographics (Name, Age, Race, Gender)
 - OCME Case Number

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- OCME Staff whom will Obtain Fingerprints
 - Deceased Disposition Status

2) OCME labeled fingerprint envelopes shall be cross referenced by the mortuary staff with the fingerprint card prior to ensure the appropriate storage of the fingerprints to include:

- Decedent Demographics (Name, Age, Race, Gender)
- OCME Case Number
- Initials of Mortuary Staff Collecting Fingerprints
- Date Fingerprints Collected

3) Collection of fingerprints (Digital or Ink) shall be verified by mortuary staff by cross referencing the cases on the daily case census and in the OCME Intake Log Book to ensure that all decedents are printed daily prior to release.

- The mortuary staff must initially verify the decedent to be fingerprinted by cross referencing the decedent demographics and OCME Case Number on the completed fingerprint print cards with the decedent toe tag to ensure decedent identity.
- Fingerprints shall be immediately affixed to fingerprint card following case examination and verified by mortuary staff to eradicate documentation and identity errors.

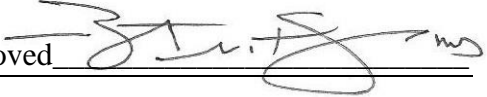
4) Fingerprint card placement in envelope and storage in drawer should be verified and cross referenced with the Daily Case Census by the mortuary staff following case examination to ensure security and integrity of custody procedures.

- The mortuary staff must cross reference decedent demographics and OCME case number on the fingerprint card with affixed fingerprints with the labeled envelope.
- The mortuary staff shall verify and acknowledge the acquisition and storage of fingerprints completed on the Daily Case Census Document [See Appendix].

6) The quality of fingerprints collected receives a layman's review daily following case examination to determine the need to obtain additional fingerprints prior to decedent release.

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Documentation completed on the fingerprint card and fingerprint envelope shall be cross referenced with FACTS.

- Future consideration shall be made support the certification or training of mortuary staff to ensure compliance of quality review of fingerprint collection in accordance with national standards.

7) Requests for fingerprints from decedents that require tissue rehydration due to decomposed body condition shall be forwarded to the mortuary staff via the ID or Investigation unit staff.

- Disarticulation may be required for tissue rehydration. The following quality procedures are outlined to include:

Decedent demographics and OCME Case Number must be verified and cross referenced with decedent toe tag to ensure correct identification of remains prior to disarticulation.

Location and labeling of disarticulated tissue must be verified by mortuary staff for placement in one container for a single case, label of container with decedent Name and OCME case number. Special Fingerprint Procedures form [See Appendix] shall be cross referenced with completed date and signature of mortuary staff following tissue disarticulation.

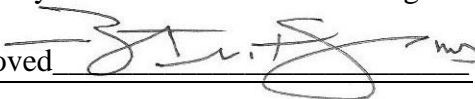
Decedent body bag shall be locked during the tissue rehydration process to ensure that the remains aren't released prior to return of tissue and identification process completed. Notification must be placed on decedent body bag. Secured body bag and notification must be verified by mortuary staff to ensure staff visibility of identification status.

After collection of fingerprints, the tissue shall be returned to decedent body bag and verified by witness to ensure integrity of chain of custody procedures. Special Fingerprint Procedures form shall be completed with date and signature of mortuary staff following the return of the tissue. Body bag shall be relocked to maintain custody control of the disarticulated tissue until the release process.

Documentation of collection and quality of fingerprints shall be verified and cross referenced by mortuary staff and witness after completion with

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Fingerprint Card, Fingerprint Envelope, Special Procedures Form, and in
FACTS.

RELEASE QA PROCESS

The release of decedent remains and personal belongings shall be verified during the disposition process [See Reference Release SOP Section] and reviewed for integrity and compliance with chain of custody procedures for 100% of the cases. Release Checklist will be in future development as a reference for the mortuary staff to ensure compliance of procedures for release of remains to funeral home representatives. The release checklist shall be reviewed and verified prior to releasing decedent remains. The following are controls to ensure accuracy in decedent remains release procedures:

1) The Release process requires the following staff to verify procedures:

- Mortuary Staff
- Witness
- Funeral Home Representative
- For decedent release for public disposition and anatomical donation the mortuary supervisor or designee must oversee the release process to ensure compliance with chain of custody procedures.

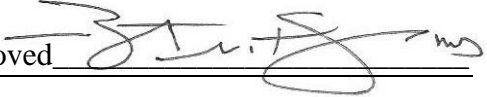
2) The storage location of decedents to be released shall be verified and cross referenced with the Human Remains Inventory Log [See Appendix] to ensure correct decedent identification to include:

- Decedent Demographics (Name)
- OCME Case Number
- Location in Refrigerated Storage.

3) Funeral home representatives must present valid funeral director, funeral apprentice, and courtesy card license to mortuary staff for confirmation that decedent remains are being released to authorized agent.

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4) Funeral home representatives will be required to verbally verify the decedent to be released with mortuary staff and witness prior to initiating the transfer of decedent to acknowledge correct remains to be released.

5) Mortuary staff must receive a copy of the Release Authorization form from the funeral home representative to cross reference to the Release Authorization form provided by the ID unit staff

- Release Authorization Forms shall document the following:

Release Authorization Approval

Decedent Demographics (Name, Age, Race, Gender)

Signatures of deceased family

- Mortuary staff and funeral home representative must acknowledge verbal verification of decedent to be released on the Release Authorization Form [See Appendix]

6) Funeral home representative shall be required to visually confirm the decedent to be released and verify identity of remains on the decedent toe tag.

- Mortuary staff, witness, and funeral home representative will verify toe tag to cross reference:

Decedent Demographics (Name, Age, Race, Gender)

OCME Case Number

- Mortuary staff, witness, and funeral home representative will initial decedent toe tag to verify remains
- For decedent release for public disposition and anatomical donation, the anthropologist and mortuary supervisor or designee must do the following prior to initiating the release process with the funeral home representative to ensure correct identity:

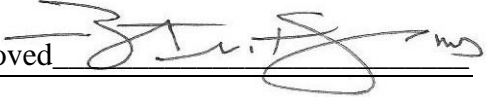
Visually confirm the decedent to be released

Verify the decedent demographics and OCME case number on the decedent toe tag and initial the toe tag

Verify personal property and clothing in decedent body bag

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- For decedent release for public disposition and anatomical donation, the mortuary staff, witness, and funeral home representative must verify and initial the decedent toe tag after initial review by anthropologist and mortuary supervisor or designee.

7) Documentation and verification of the disposition of decedent remains shall be completed by mortuary staff, witness, and funeral home representative by cross referencing the following during the release process:

- Decedent Demographics on Toe Tag
- OCME Case Number on Toe Tag
- Completed Receipt of Remains Forms
- Completed Release Log Book
- FACTS
- Completed Personal Property Released to Funeral Home Forms

8) Documentation and review of personal property and clothing to be released to the funeral home representative must be verified in the decedent body bag with the funeral home representative and witness; and cross referenced on the Property Released to Funeral Home Form with the Property list in FACTS during the release process to ensure that the appropriate belongings are provided to the family.

9) Documentation on Receipt of Remains and Personal Property Released to Funeral Home forms, copy of initialed toe tag, FACTS, Release Log Book, and Autopsy Photographs will be verified daily to review chain of custody compliance.

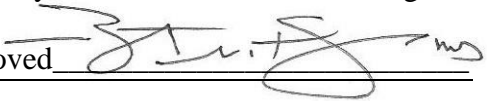
ORGANIZATION AND MANAGEMENT

The mortuary unit is comprised of the following areas:

- Management to include oversight of mortuary unit operations: Forensic Pathology Support, Forensic METT, and Forensic Photography Services.
- Forensic Pathology Support Services to include assistance to the MEs for case examination, evidence and specimen handling, and identification procedures.
- Forensic METT Support Services to include assistance in decedent livery, mass fatality preparedness and continuity of operations, and decedent release processes.

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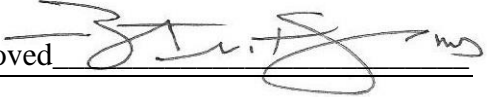
- Forensic Photography Support Services to include assistance in forensic imaging of the case examinations, digital evidence processing, and digital media archiving.

PERSONNEL

- Forensic Autopsy Assistants –Must possess an intermediate knowledge of chain of custody protocols, body handling, and/or autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science. Incumbent must have knowledge and skill in the use and maintenance of equipment, instruments, and vehicles. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator’s permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education requirement is a high school diploma or the equivalent; Associates degree and 2 years work experience in related field preferred.
- Lead Forensic Autopsy Assistant- Must possess in-depth knowledge of chain of custody protocols, body handling, technical autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science; and use of surgical instruments. Incumbent must have knowledge of specimen collection procedures for toxicological, bacteriological, and histological analyses for special studies; and digital gross photography. Incumbent must lead and train the team of entry-level staff in daily autopsy and mortuary unit operational procedures. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator’s permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education requirement is a high school diploma or the equivalent; Associates degree and 2 years work experience in related field preferred.
- Forensic Pathology Assistants – Must possess in-depth knowledge of chain of custody protocols, body handling, technical autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science; and use of surgical instruments. Incumbent must have knowledge of specimen collection procedures for toxicological, bacteriological, and histological analyses for special studies; and digital gross photography. Incumbent provides support in histology services and assists in executing quality assurance/quality control and peer review programs for unit operations. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator’s permit during the duration of employment in this position. This position has been declared as ESSENTIAL.

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Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field.

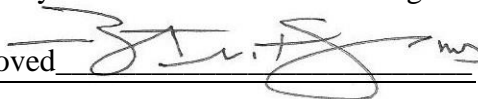
- Forensic Photographers- Must possess in-depth knowledge of the capabilities and limitations of digital photography, imaging equipment, digital editing software, and technical advances in the field of forensic photography. Incumbent must have basic knowledge of anatomy and medical terminology related to the field of Forensic Pathology or Forensic Science, sterile techniques, and safety precautions required during autopsy, and necessary precautions needed to handle specimens. Incumbent supports the development and modification of forensic imaging operating procedures. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field. Must possess a valid motor vehicle operator's permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field.
- Forensic Supervisory Pathologist Assistant- Must possess in-depth knowledge of chain of custody protocols, body handling, technical autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science; and use of surgical instruments. Incumbent must have knowledge of specimen collection procedures for toxicological, bacteriological, and histological analyses for special studies; and digital gross photography. Must manage staff and coordinate daily unit responsibilities, supervise staff performance, and coordinate training, consultation, and maintenance schedules for unit operations. Incumbent provides support in histology services and develops standard operating procedures, quality assurance/quality control, and peer review programs for unit operations. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator's permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field.

FACILITIES

The OCME facility has autopsy rooms, evidence, specimen, and decedent storage areas within the mortuary unit which require authorized security access by staff. Each of the entrances into these areas is secured by card key or door lock access. Specifically the decedent storage refrigerators, evidence/specimen storage, and decedent transport elevators are isolated from the general public and designated to conduct only official OCME business to maintain quality control and integrity of custody. Security cameras have been installed for future implementation for daily surveillance in the mortuary unit areas for safety and chain of custody compliance. In addition, all visitors entering the mortuary unit areas must be escorted at all times and must sign the OCME visitors log book on the 5th floor waiting area and Visitors Log Book located in the mortuary unit. The Consolidated Forensic Laboratory (CFL) policy

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also ensures that staff working in the facility must possess a security clearance, and visitors entering the CFL facility must undergo an ID verification and check-in process.

EVIDENCE CONTROL

Evidence control is detailed in the Evidence Handling SOP [Reference Section] and in the aforementioned section of this QA/QC program [Section Evidence and Specimen Handling QA Process].

ANALYTICAL PROCEDURES

Analytical processes are under development.

EQUIPMENT CALIBRATION AND MAINTENANCE

Equipment calibration and maintenance procedures are under development.

REPORTS

The mortuary unit produces monthly reports to identify workflow activities for the purpose of identifying improvement of processes and to develop quality assurance processes when appropriate.

REVIEW

Mortuary peer review program is under development. The peer review SOP and corresponding checklists shall be drafted in FY2016 for aforementioned areas. The mortuary unit is currently performing 100% review of all the transport and release processes and corresponding documentation.

CORRECTIVE ACTIONS

The Mortuary unit shall establish a policy and procedures, to identify when non-conforming work or departures from policies and procedures in the management system or technical operations have been identified.

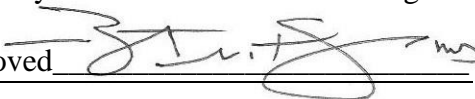
Cause Analysis: The procedures for corrective action shall begin with an investigation to determine the root cause(s) of the problem

Selection and Implementation of Corrective Actions: When a corrective action is necessary the Mortuary unit shall identify potential corrective actions, and it shall select and implement the actions most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to the degree appropriate to the magnitude and the risk of the problem.

Monitoring of Corrective Actions: The Mortuary unit – in collaboration with the Quality Program Manager - shall monitor the results to ensure that the corrective actions taken have been effective. An internal audit process should be developed to track and record effectiveness.

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Documentation: The Mortuary unit shall maintain documentation for any corrective action identified and provide copies and/or originals to the OCME Quality Program Manager. Such documentation shall be retained in accordance with applicable Federal or state law.

PREVENTATIVE ACTIONS

The Mortuary unit shall identify needed improvements and potential sources of nonconformities, either technical or within the management system. When improvement opportunities are identified or where a preventive actions is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Note: Preventative action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

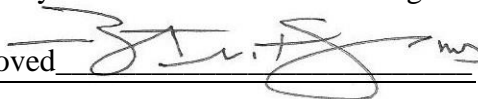
AUDIT

Mortuary unit audit program is under development. The mortuary unit is currently performing daily audits of the human remains inventory in refrigerated storage to validate decedent identification and storage location. An audit programs have also been piloted to complete daily audits for body transport, intake, and release processes and for verification of corresponding documentation in FACTS.

SAFETY

The mortuary unit participates in autopsy and analysis of biohazard materials, as well as complies with safety requirements as mandated. Universal precautions are followed when handling biohazard materials. Additional safety program will be developed for visitors and staff participating in autopsy observation and examination procedures for appropriate use of PPE.

A QA/QC PROCESS MUST BE DEVELOPED FOR HANDLING DNA AND FOR THE PROCESSING OF HISTOLOGY REQUESTS



OCME QUALITY ASSURANCE AND CONTROL PROGRAM MORTUARY UNIT-Forensic Photography

OCME QUALITY ASSURANCE AND CONTROL PROGRAM

Purpose: The purpose of the quality assurance and control program within the mortuary unit is to ensure that continuous operations are performed with improved integrity and efficiency. These practices identify the guidelines and requirements to optimize the work product and minimize nonconformities relating to photographic documentation of decedent examinations, digital media production, and archiving.

Scope: Quality assurance and control shall be implemented for mortuary unit procedures that involve the acquisition, custody, integrity, and release/transfer of digital and print photographs, radiographs, video media material, and evidence. These practices will involve peer review applications and process mapping checkpoints performed by OCME staff as well as external partners to meet the compliance standard.

Definitions: For purposes of this document, the following terms shall have the designated meanings:

CFL: Consolidated Forensic Laboratory

FACTS: Forensic Automated Case Tracking System

ME: Medical Examiner

NAME: National Association of Medical Examiners

QUALITY ASSURANCE PROGRAM

ACTIVITIES OF FORENSIC PHOTOGRAPHY:

11. Forensic Imaging Procedures:

The following activities are completed to perform photographic documentation, production, and archiving of decedent case examination, evidence, property, specimens, and administrative processes:

A. Decedent Case Examinations Types to Photograph:

- External Examinations
- Autopsy Examinations
- Storage Cases
- Anthropological Remains

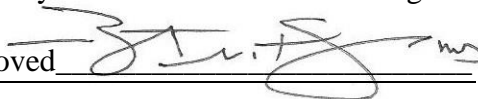
B. Forensic Imaging Process:

- Setting of Camera Settings

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-
- Preparation of Photographic Scales and Number Boards
 - Photographic Documentation of Secured Body Bag Lock
 - Photographic Documentation of First Round Photographs of Case Examination
 - Photographic Documentation of Second Round Photographs of Case Examination
 - Photographic Documentation of Identification Photographs of Case Examination
 - Photographic Documentation of External and Internal Trauma of Case Examination
 - Photographic Documentation of Evidence and Property
 - Photographic Documentation of Specimens for Consultation Review
 - Photographic Documentation of Specimens and Evidence for Presentation and Teaching
 - Documentation of Date/Time Photographs of Case Examinations in FACTS

C. Forensic Media Archiving Process:

- Uploading of Photographic Documentation and Media to FACTS
- Uploading of Photographic Documentation and Media to Local Repository (Agency Server)
- Uploading of Photographic Documentation and Media to Discs

D. Forensic Media Production:

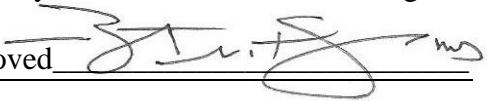
- Print Production of Identification Photographs
- Print Production of Scene and Examination Photographs
- Print Production of Consultation Case Review
- Print and Digital Production of Placards, Logos, Presentations
- Digital Production of the Scene and Examination Photographs

E. Forensic Digital and Print Media Transfer:

- Digital and Print Photograph and Media Transfer to Records Management
- Digital and Print Photograph and Media Transfer to Law Enforcement/Crime Scene Representative
- Documentation of Date/Time of Transfer of Print and Digital Production of Photograph and Media to Records Management
- Documentation of Date/Time of Transfer of Print and Digital Production of Photograph and Media to Law Enforcement/Crime Scene Representative

12. Administrative Tasks

- Supply Ordering/Inventory
- Inventory and Cleaning Photography Equipment
- Individual Performance Reporting
- Completion of Chain of Custody forms
- Documentation files for QA/QC tracking (Photographs)



FORENSIC IMAGING QA PROCESS

The digital photographic documentation of decedent case examinations shall be verified for 100% of the autopsied cases. Quality Assurance/Quality Control Checklist and Camera Settings Checklist [See Appendices] will be in future development as a reference for the Forensic Photographers to ensure compliance of procedures for acquisition of digital imaging of decedent examinations, and associated evidence, personal property, and specimens. The following are controls to ensure efficient labeling, imaging, archiving and transfer of digital media:

A. Digital Equipment Settings

1. The settings of the digital imaging equipment shall be verified and cross referenced with a Camera Settings Checklist by the Forensic Photographer prior to acquisition of photographs to ensure clarity and high quality production of images. The camera settings are established in accordance with standard forensic imaging practices.

B. Labeling System

1. The labels on the scale and settings on the number board shall be verified and cross referenced with the OCME Case Number documented on the body bag log and decedents toe tag by forensic photographer prior to obtaining photographs to ensure that the appropriate unique identifier is visible in the digital images.

2. The identifying scale and number board shall be placed on the cart or at the grossing station for imaging of the decedent, and corresponding evidence, personal property, and evidence, which shall remain affixed during the entire examination to ensure compliance with the initial unique identifier verification (aforementioned).

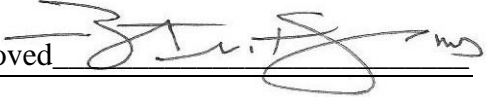
C. Digital Imaging Acquisition of Case Examinations

1. The digital images obtained during autopsied case examination shall be reviewed daily by the ME and forensic photographers to ensure that photographs are acquisitioned with the following as required by the NAME standard:

- Appropriately Labeled Scale and Number Board
- Scale and Number Board Oriented in Appropriate Anatomical Position
- Placement of Scale which Does Not Obstruct the Field of View
- To Include Orientation Photographs

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- Clean and Organized Background

2. Digital images obtained of homicide and suspicious cases, and associated evidence, personal property, and specimens shall be verified with the ME and Forensic Photographer at the time of the autopsy examination to ensure integrity of labeling, quality, and compliance of requirements for digital documentation in accordance with standard forensic pathology practices.

D. Digital Media Archiving

1. The digital media uploaded to the long term storage repositories shall be verified and cross referenced with the guidelines established on the Quality Assurance/Quality Control Checklist by the Forensic Photographer and ME during the morning meeting and by daily peer review following case examinations. The verification that the digital images are appropriately transferred to archival storage must be documented by the peer reviewer or ME to ensure integrity of operable repositories and verification that unaltered images were stored to three different locations in a timely manner including:

- Agency Server
- FACTS
- Disc

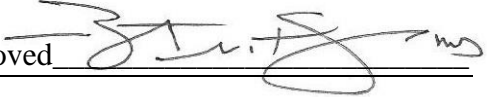
2. The file and naming convention of the photographs uploaded to the long term repositories shall be reviewed by peer reviewer daily following case examinations to ensure that the digital media is unaltered. This verification shall be documented by the peer reviewer or ME on the Quality Assurance/Quality Control Checklist.

3. The uploaded photographs in the repository shall be verified and cross referenced by the peer reviewer daily following case examinations to ensure that stored images are organized corresponding to the labeled folder with OCME Case Number and the unique identifier labeled scale and number board visually observed in the images. This verification shall be documented by the peer reviewer or ME on the Quality Assurance/Quality Control Checklist.

E. Forensic Digital and Print Transfer

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1. Print and digital media for transfer to internal staff and external partners shall be verified and cross referenced with the unique identifying scale documented on the product/evidence and OCME case number provided on the Photography Request Form. This verification shall be documented on the Quality Assurance/Quality Control Checklist by the Forensic Photographer to ensure appropriate labeling and identification of the media product prior to transfer of custody.

2. Documentation corresponding to the transfer of print and digital media (e.g. Chain /Transfer of Custody Forms and Request Forms. See Appendix] shall be cross referenced with the product/evidence by Forensic Photographer and ME prior to submission to internal units (e.g Mortuary, ID, Medical Records, Investigations, etc.) and law enforcement to ensure efficient labeling and item descriptions. This verification shall be documented on the Quality Assurance/Quality Control Checklist by the Forensic Photographer.

- Documentation on the print and digital media should be cross referenced with the documentation on the Chain/Transfer of Custody and Request Forms, and in FACTS to include:

Verification of the decedent demographics (Name, Age, Race, Gender)

Verification of the OCME Case Number

Verification of the Type of Media

Verification of the Quantity of Media Items to be Transferred

Verification of Date/Time of Acquisition and Submission

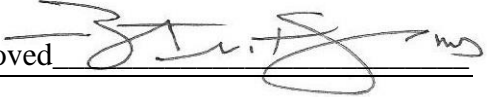
Verification of Signature for Collector/Submitter

3) Transfer of digital media shall be verified by forensic photographer with the receiving representative and documented on the Quality Assurance/Quality Control Checklist to ensure efficient documentation and chain of custody compliance, to include:

- Verification of the Identifying Labels on the Digital Media and Packaging
- Verification of the Quantity of Digital Media Items to be Transferred
- Cross reference of Digital Media with the Documentation forms (e.g. Chain/Transfer of Custody and Request Forms).

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- Completion of the Release Forms with Date, Time, and Signatures of Submitting Representative and Receiving Representative.

F. Equipment Inventory

1. The inventory and operability of photographic equipment shall be visually verified quarterly by designated Forensic Photographer to ensure the security of the equipment and compliance of integrity of authentication of images acquisitioned with agency equipment. The operability of equipment will be physically verified by the Forensic Photographer quarterly. This verification shall be documented by the Forensic Photographer on the Quality Assurance/Quality Control Checklist.

ORGANIZATION AND MANAGEMENT

The forensic photography support staff within the mortuary unit is comprised of the following area:

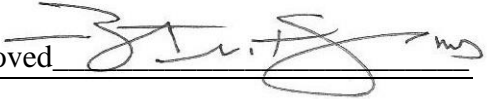
- Forensic Photography Support Services to include assistance in forensic imaging of the case examinations, digital evidence processing, and digital media archiving.

PERSONNEL

- Lead Forensic Autopsy Assistant- Must possess in-depth knowledge of chain of custody protocols, body handling, technical autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science; and use of surgical instruments. Incumbent must have knowledge of specimen collection procedures for toxicological, bacteriological, and histological analyses for special studies; and digital gross photography. Incumbent must lead and train the team of entry-level staff in daily autopsy and mortuary unit operational procedures. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator's permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education requirement is a high school diploma or the equivalent; Associates degree and 2 years work experience in related field preferred.
- Forensic Photographers- Must possess in-depth knowledge of the capabilities and limitations of digital photography, imaging equipment, digital editing software, and technical advances in the field of forensic photography. Incumbent must have basic knowledge of anatomy and medical terminology related to the field of Forensic Pathology or Forensic Science, sterile techniques, and safety precautions required during autopsy, and necessary precautions needed to handle specimens. Incumbent supports the development and modification of forensic imaging operating procedures. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and

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effectively during high stress situations. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field. Must possess a valid motor vehicle operator's permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field.

- Forensic Supervisory Pathologist Assistant- Must possess in-depth knowledge of chain of custody protocols, body handling, technical autopsy principles and practices; basic anatomy, biology, physical sciences, and radiology related to the field of Forensic Pathology or Forensic Science; and use of surgical instruments. Incumbent must have knowledge of specimen collection procedures for toxicological, bacteriological, and histological analyses for special studies; and digital gross photography. Must manage staff and coordinate daily unit responsibilities, supervise staff performance, and coordinate training, consultation, and maintenance schedules for unit operations. Incumbent provides support in histology services and develops standard operating procedures, quality assurance/quality control, and peer review programs for unit operations. Must demonstrate skill in PC software and data entry and have excellent oral and written communication skills. Incumbent should demonstrate ability to interact calmly and effectively during high stress situations. Must possess a valid motor vehicle operator's permit during the duration of employment in this position. This position has been declared as ESSENTIAL. Education preference is for Bachelor's Degree, 4 year degree, or 2 years of experience equivalent in a forensic, medical, or mortuary science field.

FACILITIES

The OCME facility has autopsy storage rooms within the mortuary unit which require authorized security access by staff. Each of the entrances into these areas is secured by card key or door lock access. Specifically the autopsy storage rooms are isolated from the general public and designated to conduct only official OCME business to maintain quality control and integrity of custody equipment and photographic evidence. Security cameras have been installed for future implementation for daily surveillance in the mortuary unit areas for safety and chain of custody compliance. Also, the Forensic Imaging office located in a secured office suite which requires card key access with additional lock key access on the immediate office door entry. In addition, all visitors entering the mortuary unit areas must be escorted at all times and must sign the OCME visitors log book on the 5th floor waiting area and Visitors Log Book located in the mortuary unit. The Consolidated Forensic Laboratory (CFL) policy also ensures that staff working in the facility must possess a security clearance, and visitors entering the CFL facility must undergo an ID verification and check-in process.

EVIDENCE CONTROL

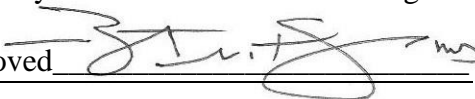
Evidence control is detailed in the Photography SOP [Reference Sections 3, 4, and 5] and in the aforementioned section of this QA/QC program

ANALYTICAL PROCEDURES

Analytical processes are under development.

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EQUIPMENT CALIBRATION AND MAINTENANCE

Equipment calibration and maintenance procedures are under development.

REPORTS

The mortuary unit produces monthly reports to identify workflow activities for the purpose of identifying improvement of processes and to develop quality assurance processes when appropriate.

REVIEW

Mortuary peer review program is under development. The peer review SOP and corresponding checklists shall be drafted in FY2016 for aforementioned areas. The mortuary unit is currently performing 100% review of all autopsied case examinations and corresponding photographic documentation to include visual verification of labeling, and archiving.

CORRECTIVE ACTIONS

The Mortuary unit shall establish and follow procedures for corrective action whenever photographic and digital media/evidence handling discrepancies and/or errors are detected, such as filling out a corrective action form and putting it into the case file.

The Mortuary unit shall maintain documentation for any corrective action identified. Such documentation shall be retained in accordance with applicable Federal or state law.

AUDIT

Mortuary unit audit program is under development. The forensic imaging office is currently performing daily audits of the autopsied case examinations to validate accuracy, quality, and integrity of photographic documentation of decedent remains and corresponding evidence, personal property, and specimens. An audit program will be drafted to complete daily audits for the transfer of custody of evidence to cross reference to FACTS, as well as equipment inventory.

SAFETY

The mortuary unit participates in autopsy and analysis of biohazard materials, as well as complies with safety requirements as mandated. Universal precautions are followed when handling biohazard materials. Additional safety program will be developed for visitors and staff participating in autopsy observation and examination procedures for appropriate use of PPE.