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LABORATORY QUALITY MANAGER

Forensic science=s crucial role in the administration of justice requires intensive measures be undertaken to ensure the overall quality of scientific findings. To accomplish this, a quality system has been created within our laboratory. To ensure the on-going effectiveness of our quality system, the Assistant Director of Crime Laboratory Services shall appoint a Crime Laboratory Services Division Quality Manager. As the division=s Quality Manager, responsibilities extend to the Western Regional Laboratory.

The Quality Manager is responsible for coordinating all of the activities required to implement and maintain quality within the Crime Laboratory Services Division.

The scope of the Quality Manager=s responsibilities and authority are as follows:

1. Ensure all required quality manuals are created, maintained, and are up to date(includes all manuals related to the quality system), and evaluate the effectiveness of all policies and procedures related to the quality system.

2. Track evaluation of testimony records to ensure adherence to all applicable standards and procedures, and to provide periodic feedback to the laboratory management team regarding annual compliance.

3. Coordinate the purchasing, creation, and tracking of proficiency tests (all types) to ensure adherence to all applicable standards and procedures and provide periodic feedback to the laboratory management team regarding annual compliance.

4. In conjunction with the appropriate Special Agent in Charge, to objectively investigate technical problems, develop and propose remedial actions, and track and verify their implementation.

5. Monitor laboratory practices to verify continuing compliance with standards and procedures.

6. Periodically assess the adequacy of report review activities throughout the laboratory.

7. Select, train, and evaluate internal auditors.

8. Conduct/coordinate annual internal quality assessment

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audits within the laboratory system.

9. In accordance with ASCLD-LAB guidelines, to prepare an annual Internal Audit Report of the Crime Laboratory Services Division.

10. Schedule and coordinate other quality system audits which may be necessary to ensure the effectiveness of the overall quality system.

11. Ensure that technical training and competency testing records of laboratory personnel are created, maintained, and are up to date.

12. Ensure the proper and thorough validation of all new technical procedures and recommend acceptance or rejection of each new procedure to the Assistant Director of Crime Laboratory Services.

13. Periodically review the overall quality system and propose corrections and improvements to the Assistant Director of Crime Laboratory Services.

The designation of a Quality Manager in no way relieves any other laboratory manager or employee from active participation in or commitment to the laboratory=s overall quality efforts.

The Quality Manager will carry out all responsibilities in a fair, impartial, and objective manner. The Quality Manager will have direct access to the Assistant Director of Crime Laboratory Services. Changes or modifications to the quality system will be reviewed with and approved by the Assistant Director of Crime Laboratory Services prior to implementation. All employees of the Crime Laboratory Services Division are expected to cooperate fully with the Quality Manager.

PROFICIENCY TESTING PROGRAM

It shall be the responsibility of the Laboratory Quality Manager, under the direction of the Assistant Director of Laboratory Services, to ensure that a comprehensive and complete proficiency testing program is being conducted in all disciplines of each laboratory. The Quality Manager will monitor the status of the laboratory=s proficiency testing program. Each Special Agent in Charge will ensure all examiners in their Sections routinely take proficiency tests, monitor the performance of examiners on proficiency tests in their

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Sections, and will provide individual feedback on their performance on proficiency tests. Special Agents in Charge will use a standard proficiency test grading report developed by the Quality Manager to document the extent of the review and to provide feedback to analysts. Any deficiencies, discrepancies, or errors will be fully documented and investigated by the Special Agent in Charge, and copies of these reports will be provided to the Quality Manager. Special Agents in Charge are encouraged to report any outstanding or exemplary results as well.

An annual status report of the proficiency testing program shall be prepared by the Quality Manager in conjunction with the annual laboratory quality assessment. The report shall be delivered to the Assistant Director of Laboratory Services.

Internal proficiency test procedures utilized may include the re-examination of actual case evidence, blind case submissions, or known standard techniques. Both external agency samples and intra-laboratory test samples may be utilized.

The laboratory will also participate in external, open proficiency test programs purchased from ASCLD-LAB (American Association of Crime Laboratory Directors - Laboratory Accreditation Board) approved vendors in each area of expertise where such tests are available.

The intent of the proficiency testing program is to ensure the validity and accuracy of all laboratory test results. There is no intent to trick or hurt any examiner in the laboratory. Any form of trickery on the part of any individual preparing test samples shall be unacceptable. Test samples found to be prepared in such a manner will be discounted and other test samples will be prepared.

All external proficiency tests will be purchased by and their distribution to the various laboratory sections coordinated by the Quality Manager. Sections which manufacture internal proficiency tests for trained analysts, or competency tests for trainees about to start independent case work analysis, will notify the Quality Manager of the administration of such tests.

The Special Agent in Charge, or the designated Section Training Officer(s) will distribute all proficiency and competency tests and notify the Quality Manager by e-mail of the individuals that have been assigned tests and the due date of the test.

For all proficiency and competency tests, the following steps will be followed when the analyst has completed the test and any reviews have been conducted.

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1. The original proficiency or competency test file will be forwarded to the Quality Manager. If the test is an external proficiency test from an ASCLD-LAB approved vendor, then the test results MUST be sent to the vendor prior to the due date for it to be a valid external test. Analysts shall allot sufficient time to meet test deadlines. The Special Agent in Charge of each Section shall ensure all assigned test results are returned by the due date and record the date the test was mailed or faxed.

2. The proficiency and/or competency test file shall contain all the relevant documentation that case files contain and notes shall be on lab approved forms.

   The files will contain a copy of the test results returned to the vendor, or in the case of internal proficiency tests, the report turned in for grading. Blind proficiency test files will be the case files themselves. Reviewer(s) names or initials will also be part of the proficiency test file.

3. Upon receipt of the proficiency and/or competency test file, the Quality Manager will review the file to ensure complete documentation is present, and make the appropriate entries in the laboratory proficiency database records. If the test is internal in nature, the Special Agent in Charge or Section Training Officer shall have graded the test prior to sending it to the Quality Manager.

4. Proficiency and/or competency tests will be returned promptly to the Special Agent in Charge for storage.

5. In the case of external proficiency tests, the laboratory may experience a delay in receiving the test booklets and/or preliminary findings from the respective vendor. The Quality Manager will forward this material to the Special Agent in Charge as quickly as possible after it is received. The Special Agent in Charge will then review the performance of the analyst, provide feedback to the analyst taking the test and to the reviewer(s), if appropriate, and document this review on approved

forms. The completed proficiency and/or competency test file, the review forms and the test answer booklets will then be forwarded to the Quality Manager for entry in the laboratory database and review.

6. All proficiency and/or competency test records will be returned to the Special Agent in Charge. Test records will be stored for five (5) years or until the next ASCLD-LAB inspection, whichever comes last. Test files where discrepancies are detected will be transferred to the Quality Manager for prolonged storage after the five year retention within the Section.

PROFICIENCY TESTING OF TRAINED ANALYSTS

Each analyst conducting forensic casework will be tested at least once each year in each discipline in which casework is performed. Test samples will be prepared or purchased to effectively measure the capability of the analyst to accurately perform casework in the discipline tested. Each Section and/or analyst will take, as a minimum, the number of proficiency tests prescribed by ASCLD-LAB. Analysts in the Molecular Genetics who conduct DNA testing will have an open, external proficiency test from an ASCLD-LAB approved vendor every 180 days.

Proficiency tests are to be treated as case work. Laboratory standard operation procedures include peer review of all cases, and proficiency tests may be treated in a similar fashion. However, **ALL WORK AND REVIEWS MUST BE INDEPENDENT.** The names of all persons completing a test (or any portion of the test) and/or reviewing the results shall be properly documented and all persons will be responsible for the accuracy of the results. If several analysts are taking an identical test at the same time, and they would ordinarily review each other=s work; then it is incumbent on the Special Agent in Charge to collect all independent tests as they are completed. Only when all completed tests have been received will they be distributed for peer review.

Anything less than 100% accuracy is unacceptable. When an erroneous identification is made on a proficiency sample or case material, the analyst shall be immediately suspended from casework until the cause of the error is determined and the

appropriate corrective action is taken.

COMPETENCY TESTING DURING TRAINING

Every individual who performs forensic examinations shall be completely trained in accordance with the written training program for the discipline(s) in which such examinations are performed. Before an individual is given clearance to perform forensic casework, the analyst shall be tested with a series of samples which will ensure competence in all areas in which casework is to be performed.

Anything less than 100% accuracy is unacceptable on competency tests of analysts in training. When results are found to be less than 100% accurate, the individual shall be retrained to the extent deemed necessary by the Special Agent in Charge in the area where the problem exists. The individual shall be retested until 100% accuracy is achieved. Each laboratory analyst shall remain in a probationary status until the laboratory training program has been successfully completed.

In the event that an individual continues to have difficulty in achieving 100% accuracy on test samples, the Special Agent in Charge, Quality Manager, and the Assistant Director of Crime Laboratory Services shall evaluate the situation. A determination must be made if the trainee has comprehension or execution problems. If problems exist in the training program, corrective steps shall be taken immediately. If the problem is determined to be with the trainee's comprehension or analytical capabilities, a decision must be made if the problem can be reasonably corrected or if steps shall be taken to remove the individual from the current laboratory assignment. Any corrective action plans must be approved by the Assistant Director of Crime Laboratory Services prior to implementation.

If it is determined an individual cannot successfully be trained to perform casework with 100% reliability, it will be necessary to dismiss the individual unless a reasonable reassignment can be made in which the individual can satisfactorily perform.

CONFIDENTIALITY OF COMPETENCY AND PROFICIENCY TEST RESULTS

The results of all competency and proficiency tests shall be treated with strict confidence and shall be discussed only with the individual, his/her Special Agent in Charge or

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Training Officer, the Quality Manager, or the Assistant Director of Crime Laboratory Services.

MISSED OR ERRONEOUS IDENTIFICATION ERRORS

MISSED OR ERRONEOUS IDENTIFICATIONS DEFINED:

MISSED IDENTIFICATION: A failure to find or identify something which is present and should have been identified. Examples include:

(A) Failure to identify a controlled substance which is present;

(B) Failure to make a latent print identification which is present; or

(C) Failure to make a bullet match.

ERRONEOUS IDENTIFICATION: The identification of something which is not present. Examples include:

(A) Reporting an identification of a controlled substance which is not present;

(B) Reporting a fingerprint, handwriting, fiber, or bullet match which is not a match; or

(C) Incorrectly reporting a DNA genotype/phenotype.

ACTIONS AS THE RESULT OF A MISSED OR ERRONEOUS IDENTIFICATION:

While the SBI Crime Laboratory Services Division does not find either type of error to be acceptable, the necessary corrective steps may differ considerably. When either type of error is made in proficiency test samples or actual case material, it shall be the responsibility of the individual's Special Agent in Charge, the Quality Manager, and the Assistant Director of Crime Laboratory Services to initiate the appropriate corrective action.

In the event of a **missed identification**, the analyst may be:

(A) Suspended from casework during a period of corrective retraining, or

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(B) Allowed to continue casework with all casework being reviewed by the Special Agent in Charge or his/her designee prior to the issuance of any laboratory reports.

Under either circumstance, the individual's Special Agent in Charge shall work with the individual to determine the cause of the missed identification. Appropriate steps shall be taken to correct the problem after which the individual shall be tested with sufficient samples to ensure the individual's capability to make such identifications and/or matches before the individual resumes independent casework.

In the event of an **erroneous identification**, the individual shall be **immediately suspended from casework** and the nature of the error will be immediately evaluated.

After the nature and circumstances of the erroneous identification are evaluated, one of the following decisions will be made:

(A) The individual will be reassigned to a job responsibility which he/she can perform satisfactorily, if such a position is available;

(B) The individual will be placed in a training status and re-evaluated under the same criteria as a new trainee and retrained in the area where the problem exists. In the event the individual is retained, he/she shall be placed on probation for a period of one year and be subject to all available disciplinary measures in the event of another erroneous identification; or

(C) The individual may be dismissed in accordance with Office of State Personnel guidelines.

In situations where a second examiner reviews and verifies the identification of another analyst and the identification is later found to be erroneous, the second analyst is considered to have made the same erroneous identification.

When situations occur which are not clearly covered by this procedure, it is the responsibility of laboratory administration to carefully evaluate the circumstances and facts and make a fair and just decision utilizing the

aforementioned procedures as a guide. An example of such a situation is a transcribing or clerical error on a proficiency test, rather than a technical error.

RESPONSIBILITY FOR QUALITY ASSURANCE AND CONTROL

The Laboratory Quality Manager is responsible for quality systems for the laboratory. Each Special Agent in Charge of each laboratory section shall develop and institute a program of on-going quality assurance for each discipline under his/her supervision. Each section of the laboratory will have and adhere to a Quality Assurance Manual outlining this program.

Appropriate and sufficient records shall be maintained to document the quality assurance program within each Section of the Laboratory.

Any problems or deficiencies identified through the quality control checks shall be brought to the attention of the Laboratory Quality Manager and fully investigated by the Special Agent in Charge and Quality Manager. Appropriate and expedient action shall be taken to correct the problem or deficiency.

VALIDATION OF NEW TEST PROCEDURES

All new test procedures, whether developed in the SBI Crime Laboratory Services Division or adapted for our use from other sources, will undergo a thorough validation process prior to use in actual casework.

Each Special Agent in Charge shall ensure that new test procedures are thoroughly validated prior to use in casework by determining:

(A) Proper controls are utilized;

(B) All analysts utilizing the new method receive training in the new procedure;

(C) All analysts utilizing the new method successfully complete a competency test in the new procedure;

(D) The progress of the validation study is

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periodically monitored either first hand or by receiving the documented test results.

Before new technical procedures are adopted in the laboratory, the Special Agent in Charge will send the validation studies and the draft new technical procedure to the Laboratory Quality Manager for review.

The developing analyst shall be required to conduct a thorough review of the scientific literature as appropriate for test development. The developing analyst shall prepare a written test procedure for dissemination to all analysts utilizing the procedure. Test development will include the testing of known standards which have been subjected to environmental conditions simulating those found in forensic casework. Quantitative test procedures involving the use of instrumentation will be checked to ensure that the instrument is calibrated, linear in its working range, and possesses a high degree of accuracy and repeatability. Qualitative test procedures involving a high degree of interpretation by the analyst must be shown to be specific, reliable, repeatable, and to yield results free of mistyping or misidentification errors. The Molecular Genetics Section will follow the Technical Working Group on DNA Analysis Methods (TWGDAM) Guidelines for developmental validation or internal validation of established procedures, as appropriate.

Prior to the introduction of any new test procedure, all analysts who will be utilizing the procedure will be given a competency test consisting of unknown samples to quantitate or proficiency samples to identify, as a final check on the reliability of the method and the ability of the analysts to correctly use and interpret the test results. The completed competency test will be routed through the Laboratory Quality Manager for tracking and will then be returned to the section where it shall be retained with proficiency test records.

If a test procedure used in this laboratory has concerns raised as to its reliability at a future date, or if new information appears in scientific literature pointing out problems with the procedure, the procedure will be immediately suspended from use in casework pending further review and evaluation by the appropriate Special Agent in Charge and the Laboratory Quality Manager.

MODIFICATION OF TEST PROCEDURES

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If a modification is made to an existing, validated test procedure, which could materially affect the results of the procedure; the modification must first be subjected to a side-by-side comparison test with the original procedure. The modified procedure must yield the same answer as the original method, but it would be expected to be more efficient, cost effective, less labor intensive, or more sensitive that the original method in order to be adopted.

Modified test procedures meeting the above criteria will be routed through the Laboratory Quality Manager for review and approval.

ANNUAL REVIEW OF SECTION MANUALS

Each Special Agent in Charge or Supervisor is responsible for conducting at least an annual review of any section-specific policy, procedure, and/or quality assurance manuals and taking any necessary actions to ensure the documents reflect currently approved operations within their section.

LABELING OF STOCK CHEMICALS

Upon receipt of stock chemicals from a vendor, the container should be clearly labeled with the date of receipt before the container is placed into the section inventory. The label should also contain appropriate spaces to record the date the container is opened, and the date of expiration (e.g., AExpiration - N/A,@ AExpiration - 90 days from the date opened,@ Expiration - 1 year from date of receipt,@ etc.).

REAGENT EXPIRATION DATE

Each section must have a reasonable and logical method for readily identifying the expiration date of all reagents. If a reagent truly has an indefinite shelf life, the expiration date may be labeled as AN/A,@ but an expiration date (or AExpiration - N/A@) must be readily identifiable on <u>all</u> reagent containers.

BROKEN AND OUT-OF-SERVICE EQUIPMENT/INSTRUMENTATION

Broken or otherwise out-of-service scientific equipment and instrumentation should not remain in laboratory work spaces for extended periods of time. Section managers should take

appropriate and timely action to remove unused, broken, or out-of-service equipment and instruments.

For short periods, while awaiting repair, a broken piece of equipment or instrument should be clearly labeled AOUT-OF-SERVICE / DO NOT USE.@ This practice, however, should not be regarded as a long-term or permanent solution.