A. **PURPOSE**:

To demonstrate the ability of each examiner to perform the examinations and/or testing necessary to fulfill the request(s) of the submitting agency, using the currently validated procedures of the laboratory.

B. **SCOPE**:

As part of the Quality Management System, proficiency tests provide one basis for an assessment of the individual performance of the examiner. They also provide an opportunity to evaluate aspects of the administrative and technical (SOP's) procedures applicable to each section.

Analysts will be challenged at minimum, annually in each discipline of testing in which they perform testing. Additionally analysts may be challenged in the various categories of testing in which they perform testing.

In some sections, such as Toxicology, proficiency tests are more routinely used as an assessment of the section as a whole, since multiple analysts are routinely involved in the analytical processes for each case.

In reviewing proficiency testing results, the overall findings are considered and where issues are identified, the process is reviewed in an effort to identify and rectify (and remediate as may be necessary) the underlying cause or issue.

C. **RESPONSIBILTY**:

1. Top Management: is responsible to assure that funding is available for the proficiency testing program and that the requirements of the ASCLD/LAB International program and the FBI DNA QAS requirements are met.
2. Quality Manager and Assistant Quality Manager: responsible to oversee the Division proficiency testing program.
3. DNA TL: responsible to review the results of all proficiency tests within the DNA section. Additionally the DNA TL is required to assure that the Quality Section is informed if there are changes to the FBI DNA QAS documents in concern to proficiency testing requirements.
4. Section Supervisors (or section Leads): responsible to work with the Quality Section to support the proficiency testing program. Additionally section Leads are required to assure proficiency tests assigned within their section are completed and forwarded to the Quality Section prior to the due date assigned by the Quality Section.

5. Analysts (however titled): responsible to analyze proficiency tests in a manner consistent with typical case work (or as closely as reasonable) using current laboratory procedures. Additionally they are responsible to complete proficiency tests in a timely manner and forward the case file and testing materials to the Quality Section prior to the due date assigned by the Quality Section.
6. DNA Analysts: responsible to work all DNA proficiency tests using all technologies/platforms of testing in which deemed competent. Additionally they are responsible to complete proficiency tests in a timely manner and forward the case file and testing materials to the Quality Section prior to the due date assigned by the Quality Section.

D. **PROCEDURE (General)**:

1. The control of the proficiency test program is assigned to the Quality Section.
    a. The Quality Section will maintain all proficiency test case files for a minimum of 2 ASCLD/LAB Assessment cycles.
    b. The Quality Section will assure that proficiency tests purchased are ASCLD/LAB approved vendors (when possible).
2. Each analyst will be provided with a minimum of one test per year (two in DNA) in each discipline or sub-discipline in which they normally perform case analysis.
    – Sections with multiple categories of testing (as listed on the accreditation Scope of testing) will be challenged in these categories no less than once per accreditation cycle.
3. Proficiency tests will be distributed through the Quality Section.
4. Upon completion of a proficiency test the analyst must submit the case file with all case documentation including the completed test provider paperwork to the section Supervisor prior to the date designated by the QS.
5. The Supervisor/or section Lead (or designee) is responsible to assure that the case has received a technical review, administrative review and that the results are submitted to the test provider by the date designated by that provider. Note: that the Deputy Director may require review prior to submitting the test results to the provider. The section Supervisor will arrange for this to occur as requested.
    – If the results are submitted electronically (as required by test providers such as FTS) a copy of the submission form receipt will be placed in the case file. The analyst is responsible for the electronic entry of the data.
    – If the results must be mailed (as with Resolution Video) a track-able method will be used (UPS, Federal Express).

6. The Supervisor will forward the case file and test materials to the Quality Section upon submitting the results to the test provider.
7. The Quality Section will maintain proficiency test files and case materials until receipt of the test results from the provider.
8. Upon receipt of the test results from the test provider the Quality Section will review the documentation (when necessary the Quality Section may obtain discipline expertise when reviewing proficiency results) and provide feedback to the analyst. Notification may be through form GL-16.2 or GL-16.3 or via electronic notification (email or Qualtrax). ~~This~~ When form GL-16.2 or GL-16.3 are used the form is given to the analyst of the test for signature, a copy of the completed form is given to the section Supervisor the original is maintained by the Quality Section.
9. If an unacceptable grade is obtained the Quality Section will work with the Director, Deputy Director and/or the Section Supervisor to determine a remediation plan. The Quality Section will inform the Director of all unsatisfactory results. In general a QAR will be initiated.

E. TYPES OF PROFICIENCY TESTS:

Proficiency tests for each section shall consist of one of the following:

1. *External:* Proficiency tests obtained through an ASCLD/LAB International approved provider . A list of tests ordered each year and the provider of each test shall be maintained by the Quality section. The schedule of these tests will be dependent on the schedule of availability from the provider. Note: if an ASCLD/LAB approved vendor cannot be used for any reason, the Proficiency Review Committee must be contacted to obtain approval for the proposed test provider prior to use. This contact will be made through the QM or designee.
   - If no ASCLD/LAB *International* vendor is available for a category of testing the Quality Section will work with the section Supervisor to design an internal test.
2. *Internal:* the TL or Quality Section member or designee with or without the knowledge of the section supervisor may issue samples that have been created to simulate case samples or situations. The expected results of analyses of these samples shall be known to the test preparer. The completed proficiency test shall be submitted to the TL, Quality Section as a regular case including the report and all pertinent case records.
3. *Double Blind:* these samples shall be prepared by/in consultation with the Director, Deputy Director, TL, or Quality Section. The samples shall simulate a case and shall be submitted by an outside agency to the appropriate lab as a routine case. It

will be unknown to all personnel handling the "evidence" that this case is a proficiency test. The TL, QM/AQM shall be notified directly when the results are returned to the submitting agency. At this time, the lab case number for this double blind proficiency test will be given to the TL, QM or designee so that all documentation and case records can be reviewed.

F. **TESTING SCHEDULE**:

1. Each examiner in each section shall either be assigned, or participate (Toxicology section) in the analysis of one external proficiency test at least once per year. A test must be provided in all discipline of testing in which the analyst performs case work. The tests shall be purchased from an ASCLD/LAB approved provider (or PRC approved provider). In the event that an external PT is not available, the quality manager shall consult with the section head and/or outside agencies to obtain or fabricate an appropriate test. If it becomes necessary to fabricate a proficiency test the Quality Section will maintain all records of how the proficiency was developed.
    - When possible, each analyst will also be provided with a proficiency test in categories of testing in which they perform work. For sections with multiple categories of testing the test may need to be administered in alternate years based on availability from the test providers.
2. Members of the DNA sections shall complete an external proficiency test at least twice per year. No longer than 183 days shall lapse between the completion of one external DNA test and the start of the next one.
    a. DNA analysts shall comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Data basing Laboratories. DNA proficiency tests shall be reviewed by the DNA technical leader. The DNA technical lead and Quality Manager/ Assistant Quality Manager will work together to assure all proficiency requirements within the DNA section are met.

G. **PROCEDURES**: External proficiency tests

1. Each examiner shall receive a Proficiency Test Notification memo (GL-16.1) when a proficiency test is being assigned or an electronic (email or Qualtrax) notification by the QS.
    - Note that this form will not be used in the Toxicology section since proficiency tests are not assigned to single analysts within the section. Toxicology Proficiency tests will be submitted to Evidence receiving for

entry into Justice Trax and the section will be notified of the test in the same manner as any case and electronically by the Quality Section.

2. To allow for notice to test providers of any problems with a proficiency test as purchased, all tests must be opened and assessed upon assignment. Any issues with the proficiency test samples e.g. unclear images shall be reported to the section supervisor who will then notify the Quality Section. The QM/AQM or designee will contact the test provider to discuss the issue(s).
3. To address the need to test individual proficiency and the desire to mimic the lab casework process:
   a. Examiners shall conduct *independent, individual* examinations, analyses and tests of the proficiency samples (see note below). Noted exceptions to this is the DNA and FB section who share proficiency tests and the Toxicology Section where individual tests are rarely assigned. All conclusions, including "inconclusive" must be based on the examiner's own work. It is inappropriate for any individual participating in a proficiency test to contact any other laboratory or professional user group concerning an active test. Those individual conclusions should be obvious from the notes on the worksheets, analytical data or other documentation. Examiners *must* use <u>appropriate</u> procedures, tests, software programs and/or instrumentation per the section SOPs to obtain the answer(s)/conclusion(s).

      E.g. FT/IR, microscope(s), UV/vis and fluorescence for paint chip analysis.

   b. The examiner will forward the test materials and case documentation to the section Supervisor/Lead. Whenever possible, the review shall be conducted by an examiner who is <u>not</u> taking the same proficiency test. At *no time during this review should the examiner change any worksheets, data or other original documentation in the proficiency test file. If issues are discovered during the technical review the TR must forward those issues to the section Supervisor if appropriate the section Supervisor will enlist the help of the QS on how to proceed.* After the review, additional notes or conclusions may be made but should be clearly initialed and dated as subsequent material. After this review, the final test providers answer sheet should be completed.

      In the event there are no analysts in-house that can perform a technical review in the discipline, an analyst from another ISO accredited laboratory can be used for the purpose of technical review. The section Deputy Director with the Quality Section is responsible for arranging the review to be performed in a manner consistent with laboratory practices. In these cases for proficiency

tests the test results can be forwarded to the provider prior to the technical review being performed.

c. Note: For the Toxicology section; the analysts work proficiency samples in the same manner as regular cases. Proficiency samples are incorporated into extraction batches as routine samples. The technical reviewer of the batch reports significant problems of the individual batches to the section Supervisor. If the Supervisor is the analyst the issue is reported to the Deputy Director.

d. The section Supervisor or designee has the responsibility to assure that all work is completed (including case review) prior to the date assigned by the test provider. The section Supervisor or designee will forward the completed case paperwork (forms supplied by the test provider) to the test provider prior to the due date. The laboratory case report should not be forwarded to the test provider.

- If the provider asks how an item would be reported by our laboratory, the analyst should simply copy the normal verbiage into the documents supplied by the test provider.

e. Once the Section Supervisor has submitted the test results to the provider they will forward the case file, testing materials and documentation that the report was sent to the Quality Section.

4. The Quality Section shall keep and maintain records as to who analyzed each test; copies of the reports and all supplemental materials.

   a. When the summarized individual results of a proficiency test are released by the provider, those results shall be reviewed by the TL, QM/AQM or designee. These results shall be used as the primary criteria for the evaluation of the tests. The results of the review shall be forwarded to the examiner. Each person tested shall sign and receive a copy of the review notice (GL-16.2, GL-16.3 for DNA) and if requested, a copy of the test providers test results. The section supervisor will be issued a copy of the review form. In lieu of form GL-16.2 or GL-16.3 electronic notification (an email with a read receipt, or Qualtrax) can be used to provide feedback to the analyst.

5. If any discrepancy exists between the expected results supplied by the test provider and the test results of the analyst, the TL (when appropriate), QM/AQM shall consult with the appropriate management and supervisory staff, and initiate an investigation into the root cause of the discrepancy. A QAR shall be initiated and

assigned by the DNA section TL (when appropriate), or QM/AQM as appropriate. When the ASCLD/LAB Proficiency Review Committee submits a request for information a QAR will be performed to document the response.

6. Possible sources of errors include, but are not limited to, the following:
   a. Administrative – clerical: eg. transcription error
   b. Documentation errors during testing: documentation of the physical evidence onto worksheets or subsequent marking of test vials, tubes, etc.
   c. Discrepancies in test results: faulty test reagents, improper SOP's/ procedures, incorrect conclusions or interpretations

   Following the full QAR process, the TL (in DNA), and/or the QM/AQM shall evaluate the seriousness of the error(s). Depending on the nature of the error remedial training may be necessary, and before the examiner can return to casework, it may be required that he or she pass a competency test in the area(s) in question. If re-training is required as part of the QAR all materials relating to the re-training and additional competency testing will be maintained by the section Supervisor appropriate documentation summarizing the retraining will be forwarded to the Quality Section, this will be maintained in the Professional Development file and attached to the related QAR.

   Response to an ASCLD/LAB Proficiency Review Committee (PRC) inquiry also may be required. All responses to the Proficiency Review Committee will be addressed through the Quality Manager. When contacted by the PRC the QM/AQM will work with the Deputy Director and/or Section Supervisor to assure that any remediation fully addresses the issue brought forth by the PRC. The Quality Section will maintain all correspondence and supporting documentation, a copy of such documentation, including a copy of the PRC inquiry will be maintained in the case file.

H. **PROCEDURE:**

Internal Proficiency Tests

1. Appropriate "mock case" samples may be prepared by the QM, TL, section Supervisor or designee. These samples shall be given to an individual examiner for examination and/or analysis according to the pertinent SOP's.
2. Upon completion of the test, the entire case file and the report of findings will be forwarded to the test preparer (QM, Section Supervisor or designee) for review and comparison to the expected results.

3. The results of this review will be issued to the analyst per GL-16.2 or electronically. If any discrepancy is noted between the expected and the actual results, the test preparer will initiate via a QAR an investigation into the root cause of the discrepancy. If necessary, a plan of remedial action will be formulated and completed.
4. Before resumption of casework another proficiency test must be successfully completed. This may be an in-house or external test, which closely addresses the issues of the original discrepancy.

I. **PROCEDURE**: Double Blind Proficiency Tests:

1. Samples simulating actual case materials may be prepared by the QM, TL or designee for submission to the appropriate lab according to standard SOP's. The "evidence" will be transported to the lab by the submitting agency.
2. No information that would indicate these samples are proficiency test materials will be given to any lab personnel at the time of submission.
3. Double blind samples will be assigned to the examiner according to standard SOP's. The results of examinations/analyses shall be returned to the submitting agency in the usual manner.
4. The test preparer shall be notified when the report of results of the double-blind are received by the submitting agency. At that time, the agent for the submitting agency will provide the lab case number to the test preparer.
5. Upon receipt of the lab case number, the test preparer will review all documentation and/or files related to the case, and will compare the results to the known materials/files.
6. After review by the test preparer, the examiner will be informed in writing (QM-16.2) that the case was a double blind test. All related personnel shall be notified of the results at this time. Any discrepancy between the actual and expected results will be handled via a QAR.

J. RECORDS:

1. The section Quality Manager shall maintain records of proficiency testing for each DSS Laboratory section, including as a minimum:
   a. Test set identifier
   b. Sample source
   c. Analyst

d. Analysis and completion dates

e. All analytical and associated data

f. Findings

g. Any discrepancies noted

h. Documentation of review and feedback for analyst

i. Corrective and/or remedial action (if appropriate)

2. Records of Proficiency testing will be maintained for a period of no less than 10 years.