A. PURPOSE:

Proficiency testing is a tool to demonstrate the ability of each examiner to perform the examinations and/or analysis necessary to fulfill the request(s) of the submitting agency, using the currently validated procedures within the discipline.

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 unit.

Analysts will be challenged at minimum, annually in each discipline of testing in which they perform testing; this may be through an internal or external test. Additionally analysts may be challenged in the various categories of testing in which they perform analysis. All analysts will be provided with at least 1 external proficiency in the 4 year accreditation cycle.

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

In reviewing proficiency testing results, the overall findings are considered and when issues are identified, the process is reviewed in an effort to identify and rectify (and remediate if necessary) the underlying root cause.

C. RESPONSIBILITY:

1. Top Management: is responsible to ensure 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 (QM) and Forensic Biology/DNA Quality Manager (FB/DNA QM): 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 ensure that the Quality Section is informed if there are changes to the FBI DNA QAS documents regarding proficiency testing requirements.
4. Assistant Director/Unit Supervisors/Leads: responsible to work with the Quality Section to support the proficiency testing program. Additionally, are required to ensure proficiency tests assigned within their unit are completed and forwarded to the Quality Section by 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 (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 by the due date assigned by the Quality Section.
6. DNA Analysts: responsible to work all DNA proficiency tests in accordance with the FBI DNA QAS. Additionally they are responsible to complete proficiency tests in a timely manner and forward the case file and testing materials to the Quality Section by the due date assigned by the Quality Section.

D. DEFINITIONS:

1. External Proficiency Test: unknown samples prepared by and obtained from an approved outside source such as Collaborative Testing Services, Forensic Testing Services, or the College of American Pathologists. The test provider must submit the results of the test directly to ASCLD/LAB.

2. Internal Proficiency Test**:** these are testing materials either obtained externally or prepared internally. Certain test providers offer "internal" test materials. The results are not sent to ASCLD/LAB.

E. PROCEDURE (General):

1. The control of the proficiency testing program is assigned to the Quality Section.
   - The Quality Section will maintain all proficiency test case files for a minimum of 2 ASCLD/LAB Assessment cycles.
   - The Quality Section will ensure that proficiency tests purchased meet the criteria as set forth by ASCLD/LAB.
2. Each analyst will be provided with a minimum of one test per year (two in DNA) in each discipline or category of testing in which they normally perform case analysis.
   - Units 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 Unit Supervisor/Lead (TL in DNA), Assistant Director or Deputy Director by the date designated by the QS.

5. The Supervisor/Lead (or designee) is responsible to ensure 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 the Quality Section. The Deputy Director or Assistant Director may require a review prior to submitting the test results to the provider. The unit Supervisor/Lead 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 analyst will forward the case file and test materials to the Quality Section upon submitting the results to the test provider; the QS may submit the test results for some test providers.
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). When form GL-16.2 or GL-16.3 are used, the form is given to the analyst of the test for signature. The original or a copy is maintained by the Quality Section.
    - Electronic notifications when used will be sent to the analyst with a copy to the unit Supervisor/Lead, Assistant Director and/or the Deputy Director. The analyst is required to respond to the email as documentation of having received the feedback.
9. If an unacceptable grade is obtained the Quality Section will work with the Director, Deputy Director, Assistant Director, and/or the unit Supervisor/Lead (TL in DNA) to determine a remediation plan. The Quality Section will inform the Director of all unsatisfactory results. In general, a QAR will be initiated.

F. TYPES OF PROFICIENCY TESTS:

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

1. *External:* Proficiency tests obtained through an outside vendor that meets ASCLD/LAB International criteria. To be considered an external proficiency test the results must be reported to ASCLD/LAB by the test 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 a vendor cannot be identified that meets ASCLD/LAB International guidance ASCLD/LAB 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 Deputy Director, Assistant Director and/or the unit Supervisor/Lead (TL in DNA) to design an internal test.

2. *Internal:* the unit Supervisor/Lead or Quality Section member or designee 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 Quality Section as a regular case including the report and all pertinent case records.

   Internal test may be purchased through an outside vendor. For these cases the vendor will not report the results to ASCLD/LAB. The QS will track these as internal proficiency tests.

3. *Double Blind:* these samples shall be prepared by/in consultation with the Director, Deputy Director, Assistant Director, DNA TL, Unit Lead or Quality Section. The samples shall simulate a real case and shall be submitted by an outside agency to the appropriate unit as a routine case. It will be unknown to all personnel handling the "evidence" that this case is a proficiency test. The TL and Quality Section 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.
   - Note: Currently the laboratory does not routinely use double blind tests.

G. <u>TESTING SCHEDULE</u>:

1. Schedule Overview: the Quality Section is responsible to order external tests. The schedule will be prepared on a 4 year accreditation cycle basis.
   - Each year, each discipline of testing (as listed on the DSS Accreditation Scope of Testing document) will be challenged with one external proficiency test.

- In the four year accreditation cycle each category of testing will also be challenged at least one time with an external proficiency test. (This is per unit not analyst).
- Each analyst will be assigned at least one external proficiency test, in each discipline in which they perform work, at least once in a four year accreditation cycle.
    a. If a unit performs proficiency tests as a unit, such as with Toxicology, each analyst will take part in at least 1 proficiency test. Each analyst will be responsible for the portion of the testing they perform.
- Each analyst will be assigned at least one internal or external proficiency test each year in each discipline in which they perform case work.
    a. Members of the DNA unit shall complete an external proficiency test semiannually as defined in the FBI DNA QAS document.
        - Internal proficiency tests will generally not be used in the DNA unit, although they may be utilized for purpose of re-training.
    b. DNA analysts shall comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories. DNA proficiency tests shall be reviewed by the DNA Technical Leader. The DNA Technical Lead and FB/DNA Quality Manager will work together to ensure all proficiency requirements within the DNA section are met.

H. <u>PROCEDURES</u>: External proficiency tests

1. When a test is assigned, the Quality Section will notify the individual.
    - DNA Unit analysts will be notified by the use of form GL-16.1 Proficiency Test Notification. This may be done electronically.
    - Analysts for all other units will be notified via email. The Unit Lead will be copied on the notification email.
2. When possible, proficiency tests will be entered into Justice Trax as regular evidence. Note: This cannot be done for tests that are provided to the DSS electronically, such as with Computer Crimes.
3. In general, analysts will be notified by Case Management when the proficiency test has been entered into Justice Trax and can be picked up.

4. Upon receiving the proficiency tests, analysts should inspect the contents for suitability. Due to the time limitations associated with these tests, this step should be completed early in the process.
    - If there are any issues with the proficiency test samples e.g. unclear images, broken samples etc. they shall be reported to the Unit Lead who will then notify the Quality Section.
    - A member of the Quality Section or their designee will contact the test provider to discuss the issue(s).
5. To address the need to test individual proficiency and the desire to mimic the lab casework process:
    - Examiners shall conduct independent, individual examinations, analyses and testing of the proficiency samples. Noted exceptions to this is the DNA/FB Section who share proficiency tests and the Toxicology Unit where individual tests are rarely assigned.
        a. All conclusions, including "inconclusive" must be based on the examiner's own work.
        b. It is inappropriate for any individual participating in a proficiency test to contact any other laboratory or professional user group concerning an active test.
        c. Those individual conclusions should be obvious from the notes on the worksheets, analytical data or other documentation.
        d. Examiners must use appropriate and approved procedures, tests, software programs and/or instrumentation per the section SOPs to obtain the answer(s)/conclusion(s).
    - The examiner will submit the case file, including the completed test paperwork for technical review per the unit's normal practice.
    - Whenever possible, the review shall be conducted by an examiner who is not taking the same proficiency test.
        a. When all analysts in a unit are taking the same test, the Unit Lead is responsible to ensure an individual assigned to perform the technical review has completed their own analysis of the test.
        b. In the event there are no analysts in-house that can perform a technical review in the discipline, an analyst from another accredited laboratory (ASCLD/LAB or equivalent) 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. At no time during the review process should the reviewer change any worksheets, data or other original documentation in the proficiency test file. This includes the test provider's result sheets. In general the test provider's result sheets will be submitted to the test provider as completed by the analyst, edits will not be made due to case review.

d. If the provider asks how an item would be reported by our laboratory, the analyst should simply copy the normal verbiage (as would be included in a case report) into the documents supplied by the test provider.

e. Test providers will not accept amended pages. The laboratory case report will not be forwarded to the test provider.

f. If issues are discovered during the technical review that cause the reviewer to question the findings, or if they determine inappropriate testing was performed, the reviewer must forward those issues to the Deputy Director. The Deputy Director is responsible to inform the Quality Section.

   - 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 will report any significant problems with the individual batches to the Assistant Director or Deputy Director; they will then inform the Quality Section.
   - The QS need not be involved for simple typographical errors.
   - The QS will work with the Deputy Director, Assistant Director, and/or Unit Lead (TL in DNA) to determine if there is an issue and if so how to proceed.

- As with any case, after the review, additional notes or conclusions may be made by the analyst but should be clearly initialed and dated as subsequent material.

- The analyst is responsible to forward the completed case file including the completed forms supplied by the test provider and the evidence to the QS prior to the due date.
- If the test provider requires the results to be submitted electronically, the analyst is responsible to follow the directions provided by the test provider to submit the results. The electronic receipt is to be printed and filed in the case file.
    a. For the DNA Unit the DNA TL will review all proficiency case files prior to the QS forwarding them to the test provider.
- The Unit Supervisor/Lead or designee has the responsibility to oversee the process and ensure that all work is completed (including case review) prior to the date assigned by the test provider.

6. The Quality Section is contacted by the test provider when the results of the testing are available for review.
    - Generally, test providers may provide:
        a. Manufacturers report which generally describes how the test materials were prepared
        b. Summary document which contains compiled results based on all test participants reported findings
        c. Individual report which contains the analysts results
            - if there are inconsistencies (as compared to the expected results) these are generally highlighted in some manner
    - In the DNA Unit, the DNA TL is responsible to compare the results reported by each analyst to the results expected by the test provider.
    - For all other units the QS is responsible to compare the results reported by each analyst to the results expected by the test provider.
    - The results provided by the test provider will be used as the primary criteria for the evaluation of the tests. Any results identified as being outside of the expected by the test provider will be investigated.

a. The DNA TL and the QS may use other criteria in evaluating results. Thus can include (but is not limited too) assuring DSS procedures were followed and due dates were met.

- The results of the review shall be forwarded to the examiner.

a. In the FB/DNA unit the form GL-16.3 will be used to notify the analysts of the results. The analyst is required to sign this document after signing the analyst and unit Supervisor/Lead will be given a copy.

b. For all other units the analyst will receive an email notification of the results. The unit Lead and Deputy Director should be copied on the email.

- In general the findings from the test provider will be attached to the email for the analyst to review.
- Analysts are required to promptly respond to the email as documentation of having received the feedback.

7. When the results are reviewed, if an issue is found the QS will work with the appropriate individuals to assess the extent of the issue and determine what remediation (if any) is required.

- DNA Unit, the QS will work with the DNA TL and Assistant Director and/or Deputy Director.
- All other units, the QS will work with the Assistant Director and/or Deputy Director and Unit Lead.
- The QS will inform the Director of all issues with proficiency test results.
- An incident report or corrective action will be initiated based on the issue.

a. Incident reports will be used for issues where remediation is not required such as administrative errors (typos or minor transcription errors).

b. Corrective Actions will be used for issues were remediation is required. Corrective actions will be activated for issues such as:

- Incorrect conclusions
- Quantitative values that are outside the excepted range
- Incorrect identifications

- Occasions where the reported results are not part of the majority answer (example: 80% of test takers answered "x" and the DSS analyst answered in another category where only 10% of the test takers answered)
- Improper documentation

– When remediation is required, at the level of a Corrective Action, the QS and DD (or TL in DNA) will work together to determine the needed steps (following the normal QAR process) to address the issue.

a. Each event will vary. Generally, the following are issues that may need to be determined:

- Is the issue serious enough to warrant taking the individual off of case work until remediation is complete?
- Does the issue warrant the review of past casework?
- Were proper methods followed?
- Was there an instrumentation or reagent error?
- Is retraining needed?
- Was the test appropriate?

a.) Is the issue caused by the test provider asking the DSS to answer questions outside of normal testing?

b.) Were expected results outside of something the DSS would report (Example – in a chemical unknown case if a heavy metal was the expected result – the chemistry section may not have the methodology to detect that).

b. In cases where a corrective action is opened the remediation will include the issuance of an internal proficiency test.

- When ASCLD/LAB submits a request for information pertaining to reported proficiency test results, a QAR will be performed to document the response.
- Note: This need not be done if the query is for clarification purposes only.

c. The QS will be responsible for a timely response to ASCLD/LAB. This may include collaboration from the Deputy Director, Assistant Director and/or the Unit Lead (or DNA TL).

d. The QS will maintain the documentation of the ASCLD/LAB inquiry. A copy of the inquiry and the final outcome will be placed in the proficiency test file.

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

- A summary document of all testing will be maintained, this will include:

a. who was challenged (analyst name)

b. the test identifier (as designated by the test provider)

c. the date the results were sent to the test provider

d. the discipline and/or category of testing the test pertains to

e. the test outcome (pass/fail)

- if results from a proficiency test are not as expected the document will be marked "QAR" this will indicate that there was an issue that is being investigated.
- Once the remediation is successfully completed, this will be updated to "Pass"
- A grade of fail will only be given if the issue cannot be remediated

I. <u>PROCEDURE:</u> Internal Proficiency Tests

1. Internal Proficiency Tests may be used in two ways.
   - As part of the normal annual proficiency test schedule as determined by the Quality Section.
   - As requested by the Director or Deputy Director at any time outside the prescribed schedule.
2. Internal proficiency tests samples:

- may be prepared by the QS, TL, section Assistant Directors, Deputy Director or designee
    a. When an internal test is prepared the following documentation must be maintained:
        - who made the samples
        - how the samples were prepared
        - the expected results
- may be purchased through a test provider
- may be taken from previously issued proficiency tests (or those previously purchased but never issued).

3. These samples shall be submitted as a case through Evidence Receiving in the same manner as an external proficiency test.
4. The examiner will follow the normal unit procedures and case flow. (See External Proficiency tests above).
5. Upon completion of the test, the entire case file and the report of findings will be forwarded to the test preparer (QM, Unit Supervisor or designee) for review and comparison to the expected results.
6. Review, grading, notification of results and remediation (if required) will be performed in the same manner as for External Proficiency test.
7. If results are not as expected, an evaluation shall be performed in order to determine the cause of the deviation.

J. <u>PROCEDURE</u>: 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 (GL-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.

K. <u>RECORDS:</u>

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.

L. REFERENCES

1. ASCLD/LAB Proficiency Testing and Review Program