A. PURPOSE:

Proficiency testing and Internal Tests are tools used to demonstrate and monitor 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. Additionally this is a tool to monitor the methods of the DSS, demonstrating their ability to achieve expected results. External proficiency testing is also a way for the DSS to compare the results generated by the DSS to other forensic laboratories. This allows for the DSS to ensure that the procedures used are appropriate and effective. Internal tests including observational based tests may be used to achieve the monitoring of some activities.

B. SCOPE:

As part of the Quality Management System, proficiency tests provide one basis for an assessment and on-going monitoring 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 test, observation based monitoring or external proficiency test. Additionally analysts may be challenged in the various components of testing (as listed on the DSS Scope of Accreditation) in which they perform analysis. All analysts will be provided with at least 1 external proficiency in the 4 year accreditation cycle.

In Toxicology, proficiency tests are routinely shared with individuals performing analysis on portions of a test based on normal case flow for the unit. These are used as an assessment of the unit as a whole and to assess separate testing components per analyst.

In Forensic Biology and DNA tests are typically shared. Forensic Biology analysts are paired with DNA analysts for most tests. Analysts in Forensic Biology are assigned the screening and sample preparation portion of the testing. DNA analysts are assigned based on the work they typically perform; bench work only, analysis only, technical review only or full analyst (bench and analysis work).

In reviewing proficiency testing results, the overall findings are considered and if 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. **Managers**: Responsible to provide direction to subordinate staff under their purview as indicated by the organization chart
2. **Supervisors:** Responsible to provide supervision to subordinate staff under their purview as indicated by the organization chart

3. **FSE2:** responsible as a working lead to subordinate staff as indicated on the organizational chart.
4. **FSE1 and Lab Assistants**: Responsible to adhere to this procedure as it pertains to their Unit.
5. **ECO**: Responsible to adhere to this procedure as it pertains to their Unit.
6. **Support Personnel** (however titled): Responsible to adhere to this procedure as it pertains to their Unit.

D. DEFINITIONS:

1. Interlaboratory Comparisons (ILC): defined by ANAB as "organization, performance & evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions."
2. Intralaboratory Comparison: defined by ANAB as "organization, performance & evaluation of measurements/tests on the same/similar items within the same laboratory in accordance with predetermined conditions."
3. External Proficiency Test/Proficiency Test: a type of ILC, these are used to monitor performance. They are unknown samples prepared by and obtained from an approved outside source such as Collaborative Testing Services, Forensic Testing Services, Forensic Assurance or the College of American Pathologists. The DSS must authorize the test provider to release the results to ANAB.
4. Internal Test**:** may be a type of ILC or a type of intralaboratory comparison depending on the test material source. These are used to monitor performance. Testing materials are either obtained externally or prepared internally. Certain test providers offer "internal" test materials. The results are not sent to ANAB.
5. Observational Based Monitoring: generally these are used as a tool to monitor performance in components of work not captured during a typical external or internal test.
6. Semi-annual: two times in a calendar year; as related to the DNA unit this will mean one time in the first 6 months of the calendar year and a second event no less than 4 months and no more than 8 months from the first event.

E. PROCEDURE (General):

1. The control of the proficiency testing program is assigned to the Quality Section.
   - The Quality Manager will maintain all proficiency test, internal test case files and observation monitoring forms (GL16.1 and GL16.2) for a minimum of 2 ANAB Assessment cycles.
     a. Note this does not pertain to competency test files which should be maintained with the individuals training records.

- The Quality Manager will ensure that proficiency tests purchased meet the criteria as set forth by ANAB.
- If a vendor cannot be identified that meets ANAB guidance ANAB must be contacted to obtain approval for the proposed test provider prior to use. This contact will be made through the QM or designee.

2. When possible, proficiency tests and internal tests will be entered into LIMS-plus as regular evidence.

   In the Identification Section many tests are provided through electronic downloads. For these the analyst will follow the instructions as provided by the test provider. The assigned analyst will download the materials to a CD or similar media and provide this to the Section Deputy Director, Quality Manager or their designee to have a case created in LIMS.

   The QM or designee will prepare a Request for Analysis form and provide this with the testing materials to the ERU. On the RFA the following may be used:

   - The name of the suspect and victim will be listed as 'suspect' and 'victim'
   - The town will be 'Anytown'
   - The offense will depend on the case but may be 'PT-other', 'PT- Sexual Assault', 'PT-Homicide' or 'PT-Assault'
   - The submitting agency is the Proficiency test provider
   - The Investigating officer is the Quality Manager or designee
   - The agency case number is the submitting agency case number for external tests
   - Under case history generally the name of the assigned analyst and the due date are added

3. The Quality Manager will work with the Assistant Director or Deputy Director (or their designees) and TL in DNA, to determine tasks within the Unit which cannot be monitored through normal external proficiency tests, if any. Note not every component of work performed within a section must be captured through this or other proficiency testing, the goal is to capture a sampling of activities.

   - The QM will set up a schedule to capture a sampling of the identified tasks within each four year accreditation cycle.

4. Upon completion of a proficiency test or internal 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 and CTS) a copy of the submission form receipt will be placed in the case file. The analyst is responsible for the electronic entry and submission of the data.
   - If the results must be mailed (as may occur with Resolution Video proficiencies) a track-able method will be used (UPS, Federal Express).

6. Upon completion test material will be stored as follows:
   - FB/DNA return testing materials to the ERU for storage. The ECO will transfer the materials to the LIMS-plus location 'FBDNA PT Storage'.
   - CAS maintain case materials within their Units. The items are transferred in LIMS-plus to the storage area designated by the Unit.
   - Identification Section will maintain the testing materials within their Units. The materials will be transferred to the Deputy Director or the FSE3 who will transfer the evidence to the LIMS-plus storage location 'ID PT Storage'.
7. The analyst will forward the case file to the Quality Section upon submitting the results to the test provider.
8. Upon receipt of the test results from the test provider, the Quality Section will review the documentation from the test provider. The review will include assessment for results that are outliers as compared to other participating laboratories. When necessary the Quality Section may obtain discipline expertise when reviewing proficiency results. Feedback will be provided to the analyst(s). Generally this will be through a Qualtrax workflow.
9. Electronic notifications will be sent to the analyst and notification made to the Unit Lead (DNA TL), Supervisor, Assistant Director or Deputy Director. Two Qualtrax workflows are available for notifications, a DNA specific proficiency test workflow and a workflow for Chemistry and Identification proficiency tests. Note although these workflows are titled as 'Proficiency Test' workflows, they are to provide feedback for all three types of monitoring.
10. If a response is flagged by the test provider as outside the expected results, or if an inconsistency is noted internally, 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 unexpected results. In general, a QAR will be initiated.

11. For quantitative results within the Toxicology discipline the Quality Manager will calculate the Standard Deviation Index (SDI) or use those calculated by the test provider, to assess the acceptance of the reported values.

    – The Standard Deviation Index (SDI) is a calculation that is used to indicate how close empirical values are from a group's empirical values during an inter-laboratory evaluation (i.e., external proficiency test).

        a. SDI = (DSS reported value – Consensus Group Mean)/ Inter-Laboratory Group Standard Deviation

        Note: the consensus group mean and inter-laboratory group standard deviation) are as reported from the test provider based on the results of the test population.

    – Evaluation criteria for quantitative values:

        a. SDI ≤ ±2.0 Acceptable

        b. SDI > ±2.0 Further evaluation is required to determine acceptability; this may require a QAR to be initiated.

        c. If a value is flagged by the test provider; a CAR will be initiated.

F. TESTING SCHEDULE:

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 at least one external proficiency test.

    – In the four year accreditation cycle each Component/Parameter within each discipline, as defined on the DSS Scope of testing will be challenged at least one time. External Proficiency tests are the preferred method however internal tests or observational based monitoring may be required.

    – Each analyst will be assigned at least one proficiency test, internal test or observation based monitoring, in each discipline in which they perform work, annually.

        Attempts will be made to assign at least 1 external proficiency test per accreditation cycle. This may not occur in cases where analysts are

authorized in activities which are not covered by traditional external proficiency tests.

- Attempts will be made to vary the testing assigned to an analyst throughout the accreditation cycle to ensure multiple aspects of applicable tasks, in which the analyst is authorized, are challenged.
- 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.
- The Quality Section will maintain records of the components of testing performed.
- Each analyst will be assigned at least one internal test, external proficiency test or will be observed as part of observational monitoring 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.
        - In the DNA Unit internal tests (including observation based) may be used for re-training or to capture tasks not captured by external tests, such as use of the CODIS database.
    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 Leader and Quality Section will work together to ensure all proficiency requirements within the DNA Unit are met.

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

External proficiency tests are obtained through an outside vendor that meets ANAB criteria. To be considered an external proficiency test the results must be reported to ANAB 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.

1. When a test is assigned, the Quality Section or a member of the Case Management Unit will notify the individual(s) through email. Additionally an email may be sent through the proficiency test provider.

- Most test providers require the use of their on-line portal for reporting of testing. In these cases the analyst will be required to create a logon (or account) with that test provider.
- For Collaborative Testing Services (CTS) the Quality Section will add the analyst to a group within the portal and an email will be sent to the analyst from the CTS portal inviting them to create a logon.
    a. As new tests are available the QS will assign the tests in the portal, when an assignment is made the analyst will be notified by email from the CTS portal.
    b. Results will also be entered through this portal as listed below. See references for a link to the CTS portal troubleshooting guide.
- For Forensic Testing Services (FTS) instructions for submitting results are provided as part of the documentation provided with the test packet.
- For Forensic Assurance (FA) instructions are printed on the test material envelope this generally includes a log on name and password to access the testing documents.
- For the International Society of Forensic Computer Examiners (ISFCE) the instructions are provided electronically with the emailed test information.

2. In general, the test materials will be retrieved from the Evidence Receiving Unit in the same manner as casework.
3. 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 Supervisor or 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).
4. 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 (FB and DNA analysts may be paired for a single test) 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. Conclusions should be obvious from the notes on the worksheets, analytical data or other documentation.

c. If an analyst must tailor their findings to match the categories of reporting based on choices provided by the test vendor the reasoning should clearly note this in their case file.

d. It is inappropriate for any individual participating in a proficiency test to contact any other laboratory or professional user group concerning an active test.

e. Examiners must use appropriate and approved procedures, tests, software programs and/or instrumentation per the Unit SOPs to obtain the answer(s)/conclusion(s).

f. If an analyst finds that a question is being asked that is not within the normal process for the Unit's casework, the analyst must refer to their Unit Supervisor and Assistant Director or Deputy Director for guidance. The Quality Manager will be informed of such issues, to ensure any actions are appropriate, this will be done prior to the reporting due date.

- The examiner will submit the case file, including the completed test paperwork (as provided by the vendor) for technical review per the Unit's normal practice, prior to submitting the results to the test provider.
- Whenever possible, the technical 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 Supervisor or 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 (ANAB or equivalent) can be used for the purpose of technical review. The Section Deputy Director or Assistant 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 proficiency test provider prior to the technical review being performed.

c. At no time during the review process will the reviewer change any worksheets, data or other original documentation in the proficiency test file. This includes the test provider's result sheets.

d. 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 is required to forward those issues to the Unit's Assistant Director or Deputy Director. The Assistant Director or Deputy Director is responsible to inform the Quality Section.

   - The TR need not report simple typographical errors such as clear transposition issues.
   - The QS will work with the Deputy Director, Assistant Director, and/or Unit Supervisor or Lead (TL in DNA) to determine if there is a technical 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.

   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 batch technical reviewer is required to report any significant problems with the individual batches to the Assistant Director or Deputy Director; they will then inform the Quality Section.

e. If findings are changed based on the Technical Review or batch review this will be documented and the updated findings will be submitted to the test provider. The technical reviewer is responsible to forward the information to the Unit Manager who will work with the Quality Section to initiate a review. A QAR will be opened, the designations (CAR or IR) will be dependent on the nature of the issue.

- Once the technical and administrative reviews are competed, the analyst is responsible to electronically submit the results to the test provider. For both CTS and FTS the web code provided by the test provider is required to enter the results.

  a. 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.

b. Generally, test providers will not accept appended pages. The laboratory case report will not be forwarded to the test provider.

c. As part of the entry the analyst may be asked to provide accreditation information. If this is asked the analyst must enter the information to allow the test to be reported to ANAB, failure to do so disqualifies the test as an external proficiency test. General information to be provided as asked:

- ANAB certificate number: FT-0338
- Authorized contact Person: Name of Current Quality Manager
- Laboratory Name CT DESPP Division of Scientific Services
- Location: Meriden CT

d. After entering the results into the test provider's portal and before submitting the results a 2nd person must review the data for accuracy.

- The results will be printed as entered and the reviewer will initial and date the document once reviewed, this will remain in the case jacket.
- Once the review is completed the analyst is responsible to submit the data in the portal per the test provider's guidance.

e. Record of the successful submission will be placed in the case file (generally a printed message form the portal).

f. The completed case file will be forwarded to the QS once the data is submitted to the test provider. The QS is responsible to maintain proficiency files.

- 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.

5. 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. Manufacturer's 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. This can include (but is not limited too) ensuring DSS procedures were followed and due dates were met.

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

a. In the DNA Unit a Qualtrax workflow for DNA proficiency tests will be used to notify the analysts of the results. The DNA TL is involved in the workflow to the extent necessary for compliance with the DNA QAS.

b. For all other units, a Qualtrax workflow ('Proficiency Test- Chem and ID') will be used for notification of results.

- In general, the findings from the test provider will be attached to the workflow for the analyst to review. Documentation that the analyst reviewed the test results will be in each workflow instance.

6. When the results are reviewed, if an issue is found the QS will work with the appropriate individuals (as designated by the Unit Deputy Director) 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 Supervisor.
- The QS will inform the Director of all issues with proficiency test results.
- A Corrective Action will be initiated based on the issue.

a. Corrective Actions will be used for issues where the test provider flags a response as being outside of the expected Additionally a Corrective Action may be initiated if during the review process the reviewer or Unit Manager noted something that is outside the norm for the Unit.

- When remediation is required, the QS, AD 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?
        - Does the issue warrant the review of Unit methods?
        - 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 may include the issuance of an Internal test.
        - When ANAB submits a request for information pertaining to reported proficiency test results, a CAR will be performed to document the response.
        - Note: This need not be done if the query is for clarification purposes only.
    c. If contacted concerning any proficiency test matter by ANAB, the QS will be responsible for a timely response. This may include

collaboration from the Deputy Director, Assistant Director and/or the Unit Lead (or DNA TL).

7. The QS will maintain the documentation of the ANAB inquiry. A copy of the inquiry and the final outcome will be placed in the proficiency test file.

H. PROCEDURE: Internal Tests

For Internal tests 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 Internal test shall be submitted to the Quality Section as a regular case including the report (if appropriate) and all pertinent case records.

In some instances, Internal tests may be purchased through an outside vendor. For these cases the results may be reported to the vendor, but the vendor will not report the results to ANAB. The QS will track these as internal tests.

1. Internal Tests may be used as part of the normal annual testing schedule, as a tool to remediate an issue with an external proficiency test or as requested by the Director or Deputy Director at any time outside the prescribed schedule.
2. Internal test samples may be prepared by the QS, Unit Supervisor, Assistant Directors, Deputy Director or designee, purchased externally, or taken from previously issued proficiency tests. Where appropriate the QS will attempt to maintain a store of testing materials, purchased tests that are not issued during the vendors test cycle, to be used for Internal tests. When previously issued tests/test materials are used efforts will be made to remove identifying case numbers. Note this may not be possible on some electronically submitted tests. Documentation of the test samples and expected results will be prepared prior to assigning the Internal test.
   - To ensure the quality of test samples prepared in house it may be appropriate to have the items analyzed by a competent analyst (other than the analyst to be challenged) prior to distribution for testing to document the expected results. Alternately it may be appropriate to have a second person observe the preparation of the samples and not require pre-testing. The best approach will be dependent on the type of task being tested.

     The quality of the test materials will be assumed acceptable when any of the below are used to prepare the test materials:

     a. A purchased test is used.

b. A previously analyzed proficiency test is used.

3. Certified reference materials or equivalent Generally these samples are submitted as a case through Evidence Receiving in the same manner as an external proficiency test. The test may be set up to require specific questions to be answered. In these cases the analyst will be supplied with this information with the testing materials.
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 Quality Section or their designee for review and comparison to the expected results. The test materials will be stored in the same manner as an external proficiency test.
   - If the internal test is being provided as remediation for a specific issue and it has been determined that only specific questions need to be answered no formal laboratory report will be required. If this is the case the analyst will be provided with the parameters of the test.
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. This may include re-testing of the materials by a 2nd authorized analyst if it was not initially performed during the preparation of the materials.

I. <u>PROCEDURE</u>: Observational Based Monitoring

Observational based monitoring will be used when an activity on the DSS Scope of accreditation cannot be assessed through the use of a traditional proficiency test (Internal test or External proficiency test). For this the Quality Manager will work with the appropriate Deputy Director, Assistant Director or their designee to determine the action to observe and the appropriate person(s) to perform the observation. The observation should be performed by someone authorized in the technique and may include the Unit Supervisor, the TL in DNA or a member of the Quality Section. The person(s) performing the observation will verify that the analyst being observed is performing the task as per laboratory protocols.

1. Observational based monitoring can be used to assess laboratory activities not normally captured as part of external proficiency tests, but may be used to observe/assess other tasks. This monitoring is used to demonstrate that the processes used are consistent with the Unit procedures for the activity.

2. Since observational based monitoring is concerned with verifying that the method is appropriately applied this will normally be performed while the analyst is working on regular casework.
    - For some methods it may be appropriate to provide samples for the process. In this case the guidance for Internal test samples will be followed to prepare and document the samples.
3. For each observation the Quality Section or their designee will:
    - Complete the notification section of form GL-16.1 or GL-16.2 based on the monitoring to be performed.
        a. Analyst to be monitored.
        b. The individual to monitor the activity.
        c. The activity to be monitored.
        d. Date of notification.
    - Notify the analyst and monitor of the assignment.
4. Process and Documentation:
    - The analyst and observer will work together to identify a time to perform the monitoring. In general the time frame to complete an observation will be within 1 month of assignment.
    - The observer will complete the 'Observation' portion of the form provided by the QS (GL-16.1 or GL-16.2 as appropriate).
    - The observer will mark the grade as Pass or Fail.
        a. General grading guidance:
            - Pass is for when the activity is performed in a manner consistent with the Unit procedure.
            - Fail is when the activity was not performed in a manner consistent with the Unit procedure.
            - If issues were noted that are outside the realm of the Unit procedure, or at any time if there is a question as to the appropriate grade the Unit AD, DD or the TL in DNA and QM can be consulted.
    - Upon completion the observer will return the completed form to the Quality Section.

- The Quality Section will review the submitted observation form for completeness.
    a. If issues are noted the QM will work with the appropriate personnel to determine the appropriate path for remediation (QAR or other).
    b. A 'Proficiency Test' workflow will be initiated to provide feedback to the analyst.
    c. The Quality Section will maintain the records of all observations.

J. RECORDS:

1. The Quality Manager shall maintain records of proficiency testing, internal testing and observation based monitoring; this will generally be a spreadsheet, for each DSS Laboratory section, including at a minimum:
    - who was challenged (analyst name)
    - the test identifier (as designated by the test provider)
        a. test type (internal, external, observational)
    - the due date
    - the date the results were sent to the test provider or completed for internal testing or observations.
    - the discipline and the component from the DSS Scope
    - the test outcome
        a. If results are as expected from the test provider and no internal issues were noted the spreadsheet will be marked as pass
        b. If results are not as expected (either an internal issue is noted or the results are not consistent with those expected from the test provider) the spreadsheet will be marked with the related QAR identifier this will indicate that there was an issue that is being investigated. Once the remediation is successfully completed, this can be updated to "Pass"
        c. A grade of "Fail" will only be given if the issue cannot be remediated
    - When a QAR is initiated the QAR number will be added to the spreadsheet. As part of this a note will be added to categorize the issue related to the QAR, other category's may arise but generally the reasons will be categorized as:
        a. Technical issue on the part of the analyst
        b. Technical issue caused by an unclear SOP

c. Technical issue related to the unit and improper training

d. Administrative issue such as transcription error

e. Administrative issue at the management level -such as poor GL guidance or inappropriate test provided

f. Finding reported based on laboratory policy; no issue

g. Other; (a reason will be added)

2. For External Proficiency Tests:

   – The case file, maintained in the Quality Section, will include:

      a. Normal Unit case documentation including appropriate technical records

      b. The expected results from the test provider

      c. Documentation that the results were submitted to and reviewed by the test provider

3. For Internal Tests:

   – The case file, maintained in the Quality Section, will include:

      a. Normal unit case documentation including appropriate technical records

      b. Documentation of how the test was prepared; this may be maintained electronically.

      c. Documentation of the expected results; this may be maintained electronically.

   – For Observational Based Monitoring:

      a. The Observation worksheet (GL16.1 or GL16.2) will be maintained by the Quality Manager.

      b. Documentation of the review will be maintained by the Quality Section

      c. Feedback provided to the examiner will be maintained by the Quality Section

4. Notification provided to the analyst and reviewed by the appropriate parties will be maintained in Qualtrax as part of the Proficiency test workflows ('DNA Proficiency Test' and 'Proficiency Test - Chem and ID') for Internal Tests, External Proficiency tests and Observation based tests.

5. Records of Proficiency testing, Internal Testing & Observation based monitoring will be maintained for a period of no less than 10 years.

K. REFERENCES:

CTS Portal troubleshooting guide: http://support.cts-portal.com/troubleshoot/2019/1/10/need-to-view-or-print-data-entry-forms.html