

COMPETENCY TESTING GENERAL GUIDANCE:**A. PURPOSE:**

This is general guidance that will be followed by each Unit in the development of competency tests, both practical and written/oral, related to training programs for employees (new or new to a discipline) and for re-training.

The Division of Scientific Services (DSS) has specific expectations of competency testing. Competency tests are used to assess the trainees understanding of the procedures/tasks that were covered in the training. The definition of competency test from the ANAB AR3125 is “the evaluation of a person’s knowledge, skills, and/or ability to perform work.” Since these tests are assessments of an individual’s ability related to specific tasks practical competency tests and written/oral tests, when used, must be completed independently by the trainee.

B. RESPONSIBILITIES:**1. Trainee:**

- a. Follow the guidance set forth by the trainer and the procedures.
- b. Report variations from the procedures, if noted, to the trainer and the Unit Lead.
- c. Complete all training assignments.
- d. Ask questions of the trainer or Unit Manager at any time in the training if a topic is not clear.
- e. Maintain training documentation in an organized manner to include training exercises, training checklists or other records specific to the Unit where the training is occurring.
- f. Take competency tests, whether the practical portion or written/oral portion, in an ethical manner, meaning do not reach out to others for assistance or for answers when taking tests. The trainee must take the tests independently. Note this does not preclude referring to procedures, if allowed by the section.

2. Trainer or Mentor:

- a. Train the trainee based on the procedures in place.
- b. Provide fair and accurate feedback for training exercises.
- c. Ensure that the trainee is maintain training records as required by the Unit.
- d. Continuously update the Unit Lead or Manager as to the progress of the trainee.
- e. Update the Unit Lead or Manager as to issues that arise in the training process.

3. Unit Leads or Supervisors:

- a. Monitor the training process and verify that the documentation is kept and feedback is given.
- b. Verify that records of the training exercises are maintained as expected per Unit procedures.

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- c. Suggest, to the Unit Manager, the need for modified training, additional training or similar, based on the progress of the trainee.
- d. Work with Unit Managers and trainers/mentors to develop competency tests that are appropriate to the training performed.
- e. Work with the trainer/mentor and/or the Unit Manager to evaluate the trainee's test results fairly to verify their understanding/knowledge of the training materials and only recommend authorization upon successful completion of the testing.

4. Managers:

- a. Overall it is the responsibility of the Unit Managers to ensure training procedures and processes are robust enough to produce strong analysts (i.e. analysts with the knowledge and skills to perform the testing as required by the DSS).
- b. Update the training procedure(s) as needed including when changes to Unit procedure (i.e. new procedures/technologies) are implemented.
- c. Review suggestions from the Unit Lead and evaluate the training process and make modifications if appropriate.
- d. Ensure appropriate records are maintained per Unit guidance.
- e. Investigate reported deviations from the training.
- f. Recommend authorizations for trainees based on successful completion of competency tests.

C. GENERAL:

Each discipline has training programs which include competency testing to demonstrate understanding of the tasks/procedures. In general these training programs are set up in modules to introduce the trainee to specific Unit tasks/procedures. Training may be set up to have a competency tests cover all tasks within a training module or they may be set for competency tests to cover multiple modules. When possible materials from past proficiency tests will be used as at least part of practical competency tests. The Quality Manager can assist identifying appropriate materials.

Records of training exercises including competency tests must be maintained as part of the trainees training documentation. If there is a portion or module where competency testing is not required, for example for assigned readings or a general introduction to the Unit, this will be clearly indicated in the training procedure.

At any time during training if the trainee does not understand a concept or feels that a topic was missed it is their responsibility to ask questions.

1. PREPARATION OF TESTING MATERIALS:

- a. The results of competency test materials shall be known prior to the test being issued. Materials should be verified and supporting documentation maintained prior to them

being given to the trainee. Verification may vary base on the source of the materials and the Unit process.

- i. Purchased materials such as proficiency test may only require having the test provider's documentation of the expected results.
- ii. Materials prepared in house may require independent testing to ensure the results are as expected prior to issuing the test. This will depend on the nature of the sample.

Example 1: A saliva sample taken from a laboratory employee can be assumed to contain only that individuals DNA profile; verification would not be needed.

Example 2: A blood sample spiked with a certain amount of a drug would require verification for a quantitative method, but the same sample used for a qualitative method may not require verification.

- b. Materials from external proficiencies whenever possible will be used to make up all or a portion of a competency test. Materials from proficiency tests can only be used once the results are released, so that they are known by the DSS.
 - i. When possible the identifiers should be removed or masked prior to issuing the materials as a competency test. If the identifiers cannot be masked the trainee must follow ethics guidance and not look up the expected results prior to or during the testing process. It is understood that removing identifiers is not possible for most digitally downloaded test materials.
 - ii. The trainer and Unit Manager should assess the materials and determine which questions from the test provider should be used for the test. This will be based on the level of training the individual is undergoing.

Example: In Toxicology if the training is only for qualitative procedures any questions related to quantitative results would not be used as part of the competency test.

- c. Materials prepared in house:
 - i. When testing materials are prepared in house, clear documentation must be kept of how the materials were prepared, verification results (if applicable) and the expected results.
 - (a) Documentation will be maintained per Unit guidance.
 - (b) It is suggested that these records or a copy be added to the competency test case file upon completion and grading of the test.
 - ii. If certified reference materials are used the lot number and similar identifiers will be recorded.
 - iii. If reference collection materials are used documentation will contain the ID of the reference item.

- iv. If samples are “created” such as swabbing an item, spiking biological fluids or similar that information will be clearly annotated.
- v. Minimally the records will include:
 - (a) Who prepared the samples and when.
 - (b) How the samples were prepared
 - (c) The expected results

Note when using proficiency test materials a copy of the test provider’s paperwork will be sufficient to meet the above documentation requirements.
- d. Physical case materials will not be used for competency testing unless there is documented approval from the Section Manager and the Director. This should only be done for rare instances and if used the case must have been adjudicated and all identifiers to the case must be removed.

2. WRITTEN/ORAL COMPETENCY TESTS:

- a. The DNA Unit must follow QAS guidance and provide written or oral competency tests along with practical tests for new employees. Other Units may choose to include these as part of competency training; Unit SOPs will define when this is required. For current DNA employees trained in a new task written or oral competency tests are not required.
- b. Written tests are preferred over oral assessments since there is less objectivity with written tests.
- c. For both written and oral tests, there must be a key with the expected results to grade against.
- d. When oral tests are used the tester must maintain clear notes in how the trainee answered the question and if they met the expected answer. The notes must be graded and the notes must be maintained as part of the trainees training record.
- e. When written tests are used the answer sheet will be graded and maintained in the training files.
- f. The written or oral test must be sufficient to cover the topics/tasks covered in the training.
- g. Administering written/oral competency tests:
 - i. Give clear instructions including that the trainee cannot reach out to others to discuss the question or to obtain an answer. Be clear if the trainee can refer to Unit SOPs or other reference materials that were used as part of the training.
 - ii. Give a time frame for completion.
 - iii. Explain the grading requirements. A grade of 80% or higher must be achieved.
- h. After tests are graded feedback must be provided to the trainee about why anything answered wrong or partially is graded as it is.

3. PRACTICAL COMPETENCY TESTS:

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- a. Practical tests need to cover the scope of the training. It is not practical to expect that the competency test can cover every contingency but the test should cover a variety of normally expected conditions.
 - i. If there is an expectation that the trainee will write reports then report writing must be part of the practical test.
 - ii. The testing material should be set up to include negative and positive findings (this may be defined as associations/no-associations for some disciplines).
 - iii. When statistics are part of the normal reporting this should be included with the testing to include the reporting of uncertainty.
 - iv. Practical Competency tests should be added to LIMS-plus as a case. In general a prefix such as TST or CMP can be used in place of DSS when the case is entered to allow for clear delineation of case work from competency tests.
 - (a) Upon completion of the test, the Unit Lead should verify that the milestones are updated and the test closed in LIMS, this may be done administratively.
- b. Considerations for preparing practical tests:
 - i. The results must be known.
 - ii. Materials for practical tests will not be from case materials unless written approval is obtained from the Unit Manager and Director.
 - iii. Samples can be created in-house; the trainer will work with the appropriate Unit personnel (TL, Unit Manager) to develop testing materials suitable to the training.
 - (a) Some examples:
 - (i) Use of known biological fluids or mixture of fluids (DNA, FB, TX)
 - (ii) Use of Certified Reference Materials (CRM) (CS, TX, FA, GSR)
 - (iii) Use of known latent prints (LP)
 - (iv) Use of reference collection materials (FA)
 - (v) Use of proficiency testing materials (all disciplines)
 - iv. When using manufactured materials such as CRM, the lot numbers should be included as part of the documentation. For proficiency tests the proficiency test identifier must be part of the preparation documentation.
 - v. When the laboratory does not have access to very specific materials for a competency test the Unit Manager may need to initiate a deviation workflow in the QMS to address how the training will be achieved and gain approval from the Director.
- c. Administering practical competency tests:
 - i. Give clear instructions including that the work must be done independently and that Unit SOPs can be referenced.
 - ii. Give a due date. Note Unit Managers may allow for extensions to due dates if requested in advance by the trainee.

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- iii. The results obtained must meet those expected to be graded as successful (or pass). Practical competency tests are successfully completed when the correct results are obtained using the Unit procedures in the expected manner. Minor administrative issues such as missed initials would not constitute a failed practical competency test.
- iv. Upon grading the practical, feedback will be provided to the trainee. The trainee should acknowledge the feedback given, this can be achieved by initialing and dating any comments/notes from the reviewer.