1. Purpose

To provide written standard procedures for laboratory proficiency testing programs that are a means of evaluating the competency of analysts and performance of method. A proficiency testing program may be a commercially provided program, an inter-laboratory comparison, or an internally prepared sample.

2. Scope

This standard operating procedure (SOP) shall be followed by the Bureau of Food Laboratories, Division of Food Safety, Florida Department of Agriculture and Consumer Services.

3. Outline of Procedures

6.1 **SAFETY PRECAUTIONS**
6.2 Sample Rejection Criteria
6.3 Responsibilities
6.4 Proficiency Test Programs
6.5 Corrective Action

4. References

a. AOAC International. Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals. Gaithersburg, MD. External document DL03028.
b. American Association for Laboratory Accreditation (A2LA). R103 – General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories. Frederick, MD. Available from: http://www.A2LA.org./documents/docfinder.cfm .
c. USDA Microbiological Data Program (MDP). MPO-ADMIN. Administrative Procedures for the Microbiological Data Program and Pesticide Data Program. External document FL04097.

5. Materials and Apparatus, Media and Reagents, Associated Documents

5.1 Materials and Apparatus – not applicable

5.2 Media and Reagents – not applicable

5.3 Associated Documents
a. Division of Food Safety, Health, Safety and Security Manual.
b. Division of Food Safety, Chemical and Biological Hygiene Plan.
c. DL ADMIN 060, SOP Deviations.
d. DL ADMIN 061, Non-conformances and Corrective Action.
e. Bureau of Food Laboratories Proficiency Testing Schedule.
f. Worksheet FL-06161, Report of Proficiency Test Result Analysis.
g. A2LA Proficiency Testing Data Submission form (available at www.a2la.org).

6. Specific Procedures

6.1 SAFETY PRECAUTIONS – not applicable

6.2 Sample Rejection Criteria – not applicable

6.3 Responsibilities
a. The bureau chief is responsible for ensuring that sufficient resources are available for participation in/performance of proficiency testing programs.

b. The work area supervisor is responsible for ensuring that:
1. The laboratory participates in relevant and available proficiency testing programs.
2. Analyst participation in proficiency testing programs is reflective of normal work practices.
3. Results of proficiency testing are reviewed for trends indicative of a need for corrective or preventive action.
4. Report on the analysis of proficiency test results is promptly prepared and distributed to the QAU and the bureau chief. Analysts are provided with results and/or the report on the results. The work area supervisor maintains hardcopies of results and reports.
5. The QAU is notified if participation in proficiency test programs changes.

c. The quality manager is responsible for:
1. Reviewing proficiency test results and reports on result analyses.
2. Auditing analyst proficiency records.

d. The QAU is responsible for:

1. Including comments on Microbiological Data Program (MDP) proficiency testing results and suggestions for improvement in semi-annual MDP

Quality Assurance Unit reports, and notifying MPO (MDP/PDP Technical Director and assigned liaison microbiologist) of any corrective actions initiated in response to a PT result for an MDP or MDP-related method.

2. Maintaining the Food Laboratory Proficiency Test Schedule and notifying A2LA of changes in Food Laboratory participation in proficiency testing programs (for testing under the Food Laboratories scope of accreditation).
3. Promptly reporting results to A2LA (for testing under the Food Laboratories scope of accreditation).

e. Analysts are responsible for completing the analysis of proficiency samples individually, within required timeframes, and following the same procedures used for routine samples, unless otherwise directed.

6.4 Proficiency Test Programs

a. Participation

1. Proficiency testing is a key means of obtaining evidence of laboratory competence. Participation in proficiency test programs must have the aim of covering the entire scope of laboratory testing to the extent that suitable and relevant programs are available. “Covering the entire scope of laboratory testing” means that participation must consider not just methods but also the analytes and matrices for which the method is used.

2. All sections participate in at least one proficiency test activity per year for each method/test/technology. The term ‘method/test/technology’ is used to imply that when the same technology (e.g. GC, HPLC, ICP) is employed by multiple methods (e.g. HPLC Method 1, HPLC Method 2, etc.), then it may not be necessary to participate in a proficiency test activity every year for every method utilizing a particular technology.

3. In a four year period, however, participation in proficiency testing must cover the entire scope of laboratory activities (i.e. considering methods, analytes and matrices) to the extent that suitable and relevant programs are available.

4. The Food Laboratory shall participate in PT programs as coordinated by MPO, as required by MPO.

5. Results of proficiency testing for those methods covered by the Food Laboratory’s Scope of Accredition (by A2LA, to ISO/IEC 17025, for the specific tests listed in A2LA certificates 2534.01 and 2534.02) are reported to A2LA for the laboratory, rather than for an analyst. However, participation in proficiency testing must be reflective of normal laboratory

activities.

6. The Food Laboratory Proficiency Test Schedule describes all planned participation for the Food Laboratory. This schedule is maintained by the Quality Manager and posted to LabQMS. Section supervisors are responsible for notifying the Quality Manager promptly when participation changes.

7. The Quality Manager is responsible for providing the current Food Laboratory Proficiency Test Plan (i.e., FL QA 120 and the Food Laboratory Proficiency Test Schedule) to A2LA annually.

b. Analysis and Results

1. To the extent possible, proficiency samples are processed and analyzed in the same manner as routine samples (i.e. they are checked for radiation, logged in and given sample numbers; raw data is recorded in analyst workbooks and on worksheets, final reports are generated, etc.), according to any test provider instructions and method SOPs. Deviations in methodologies will be documented and approved according to DL ADMIN 060, SOP Deviations.

   Microbiology Section proficiency samples may be held on solid media (plates or slants), after discussion with and approval by a supervisor, if necessary to avoid weekend or holiday work or due to excessive workload during normal working days. The approval is recorded in the analyst's notebook. (This does not constitute a deviation because the method procedures do not state a requirement to the contrary.) Results may be reported before PFGE results are obtained if necessary to make the provider's due date and with discussion and approval by a supervisor, that is recorded in the analyst's notebook. (This also does not constitute a deviation.)

2. Analytical results are reported to the work area supervisor, who compiles and submits the data to the test provider. Work area supervisors maintain records of data submissions and reports.

3. Reports of proficiency test results are analyzed by the work area supervisor, who promptly prepares a report of the results and analysis, using worksheet FL-06161, Report of Proficiency Test Result Analysis. The report will state any corrective actions initiated (see "corrective action" below). The report is forwarded to the QAU and bureau chief. Analysts are provided with results and/or the report on the results.

4. The Chemistry Section posts summaries of results for proficiency samples in the network folder: FoodChem/Methods/ProficiencySamples, and the sample results are grouped by provider.

5. The quality manager reviews the results and analysis, and if results are related to the Food Laboratory's scope of accreditation, the results, including detailed corrective actions for unacceptable or outlying results, are promptly reported to A2LA using the A2LA Proficiency Testing Data Submission form.

6.5 Corrective Action

a. Corrective action will be initiated (according to DL ADMIN 061, Non-conformances and Corrective Action) if the result of a proficiency test sample is unacceptable or is an outlying result. An outlying result is one outside of 3 standard deviations from the mean of test results. A result will be unacceptable if any of the following are true:
   1. it is evaluated as "unacceptable" by the proficiency test provider.
   2. the absolute value of the z-score is > 3.
   3. the result is outside of the Food Laboratory's claimed estimation of uncertainty.

b. Some PT providers require that results which are below the limit of quantitation be reported as '0'. Reporting in this manner can result in a calculated z-score ≥ 3, which is not meaningful. In such (or similar) cases, corrective action is not required unless the result is unacceptable according to some other criteria.

c. z-scores between 2 and 3 will prompt a review of the data.
   1. If the proficiency results are deemed to be of acceptable quality, and the Relative Standard Deviation (RSD) of the proficiency sample is extremely small, a z-score of 2 to 3 may be acceptable if it falls within the expected method error.
   2. If the z-score falls outside of expected method error, a corrective action will be initiated. The corrective action investigation will include a data review to determine whether there is a trend of escalating z score values.

d. If unacceptable results are received on a proficiency test sample, then the Food Laboratory will enroll in the next available round of proficiency testing, if that round had not already been scheduled. Such enrollment should be documented in the corrective action initiated in response to the unacceptable result.

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TITLE: Proficiency Test Programs		
Revision: 5	Replaces: 10/01/08	Effective: 09/17/10

_____ Date:_____

Reviewed By: Stacie Hammack
Quality Manager

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_____ Date:_____

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TITLE: Proficiency Test Programs		
Revision: 5	Replaces: 10/01/08	Effective: 09/17/10

REVISION HISTORY:

Revision No: Original
Date: 02/28/06
Author: Grace Hall, Yuelian Shen, Stacie Hammack
Description: New SOP to provide instruction for Proficiency Samples

Revision No: 1
Date: 08/11/06
Author: Grace Hall, Yuelian Shen, Stacie Hammack, Brian Lane
Description:

1. Added note following 6.4.a.1 and reference to that note at 6.3.b and d.
2. Added 'promptly' to 6.3.b.4 and 6.3.c.4
3. Revised 6.3.b.4 and 6.4.b.3 regarding notifying analysts of results
4. Revised 6.4.b.3 and 6.4.b.6 to specify reporting of corrective actions initiated and require prompt reporting of results
5. Deleted 6.4.a.2.c because CFIA programs for mercury and histamines discontinued
6. Added 6.4.a.2.d and e: FAPAS and Aflatoxin Share program
7. 6.6.a expanded requirement too include outlying results per A2LA requirement

Revision No: 2
Date: 08/31/06
Author: Grace Hall
Description:
added API as alternate source for food microbiology program

Revision No: 3
Date: 11/15/07
Author: Grace Hall, Yuelian Shen, Stacie Hammack, Brian Lane
Description:

1. updated references
2. added explanatory text to purpose and deleted term 'external' from 6.4 subtitle and throughout text
3. global re-write deleting descriptions of PT programs in favor of referring to the participation and schedule in a new document: the Food Laboratory Proficiency Test Schedule
4. deleted obsolete worksheets FL-06158, -06159 and -06160.
5. deleted all references to and procedures for competency (5.3a and k., 6.3.b, 6.4.b, and 6.5

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TITLE: Proficiency Test Programs		
Revision: 5	Replaces: 10/01/08	Effective: 09/17/10

Revision No: 4
Date: 10/01/08
Author: Patricia Hanson, Brian Lane
Description:
1. Revised format of revision history table
2. Added CBHP at 5.3
3. Revised 6.4.b to provide additional instruction for micro PT's

Revision No: 5
Date: 09/15/10
Authors: Sun Kim, Yvonne Salfinger, Sue Humphries
Description:
1. Updated signature block.
2. Section 1: added 'internally prepared sample' to PT options.
3. Updated 4.c. reference name
4. Deleted 5.3.e FL SAFETY 610
5. Updated title of Proficiency Testing Schedule
6. Section 6.3 and 6.4.b.3: distributed some responsibilities from QM to QAU.
7. Section 6.3.d.1., per MPO-ADMIN, added requirement for notification of MDP when CAs are initiated in response to a PT result for MDP methods or MDP related methods.
8.

8. Section 6.5.d.: changed 'will' to 'should'.
9. Updates to references and associated documents. Note: some of these are controlled as DL external documents, without document IDs.
10. At 6.3.d.1., added: "and notifying MPO (MDP/PDP Technical Director and assigned liaison microbiologist) of any corrective actions initiated in response to a PT result for an MDP or MDP-related method." (For consistency with MPO-ADMIN requirements.)
11. At 6.4.a.4., added MPO requirement to participate in PT testing they coordinate.
12. At 6.4.a.5., added language to specify that PT results only need to be communicated to A2LA for activities within the current scope of accreditation.