7 Process Requirements

7.8 Reporting of results

7.8.1 General

7.8.1.1 Analysts will review results obtained through laboratory activities. Analyst will set the LIMS milestone to 'Draft Complete' indicating they have reviewed the technical records and authorize release of the report. The analyst's signature will be applied to the report. Any changes to the report or technical records after this date must be tracked according to laboratory policy.

7.8.1.2 TBI Laboratory personnel will accurately, clearly, unambiguously, and objectively report the results of laboratory activities in accordance with laboratory policy and Unit SOPs. The results will be provided in a TBI Official Report for testing activities or a TBI Official Calibration Certificate for breath alcohol instrument calibration activities. Reports will be retained with the technical records.

7.8.1.2.1 Results will be made available to the customer in a written report following the administrative review.

7.8.1.2.2 The TBI laboratory has procedures in place for the reporting of test/calibration results. These procedures require the following:

- TBI Official Report(s) and corresponding case file documentation will include information regarding the examinations conducted and any information necessary for the interpretation of the results. Information which is not reported to the customer shall be readily available in the case file;
- The significance of an association will be included in the test report and qualified properly. This may be achieved by a statistic or qualitative statement;
- When comparative examinations result in the elimination of an individual or object, the test report shall clearly communicate the elimination;
- When a definitive conclusion cannot be reached, the reason(s) will be clearly documented in the case file and test report;
- Where applicable, reporting of the initial database entry (e.g., CODIS, AFIS, NIBIN); and
- Where applicable, reporting of an association resulting from a database search (e.g., CODIS, AFIS, NIBIN).
- Examiners issuing findings, including writing reports and providing testimony, based on documented results, findings, and/or associations generated by another analyst will document they reviewed the work in the technical record.

Exceptions: Analytical work requiring a test report does not include research activities, training exercises, validation studies, or ten print card inter-comparisons. Activities a laboratory undertakes for the purpose of constructing

individual characteristic database or maintaining the quality and/or effectiveness of information in such a database are not considered analytical work requiring a test report.

7.8.1.2.3 Calibration certificates and corresponding documentation will include information regarding the calibration(s) conducted, all information requested by the customer, and any information necessary for the interpretation of the results. Information which is not reported to the customer shall be readily available in the calibration record. The calibration certificate will be traceable back to a specific calibration record maintained by the issuing calibration laboratory. An endorsed calibration certificate will be issued if requested by the customer.

7.8.1.3 The TBI Laboratory will report results as outlined in the Terms and Conditions for submitting evidence. All required information not reported will be available in the case file.

7.8.1.3.1 Reporting content is outlined in the Terms and Conditions for submitting evidence. Customers may request additional content if necessary.

7.8.2.1 Content of TBI Official Report and Certificate of Instrument Accuracy

The following information will be included in the TBI Official Report and Certificate of Instrument Accuracy unless specified in applicable Unit SOPs and agreed upon by the customer:

a) Title of report;
b) Name and address of the laboratory;
c) If laboratory activities took place at a location different from the address on the report, this location will be noted;
d) Unique identification on each page of the test report and all its components. A clear identification shall be made as to the end of the test report;
e) The name and agency of the customer;
f) Identification of the testing method(s) used;
g) A description and unambiguous identification of the item(s) to be tested. The condition of the item(s) will be reported when conditions affect the validity of results or ability to perform testing/calibration;
h) Date range of laboratory activities will be included on the report as the date evidence was transferred to the analyst and the date report was issued;
i) If applicable, reference to the sampling plan and procedures used by the laboratory where these are relevant to the validity or application of the results;
j) Where relevant, a statement to the effect that the results relate only to the items tested/calibrated. Items not tested must be addressed. Untested items may be addressed individually or as a whole;
k) Results with units of measurement, where appropriate;
l) If applicable, changes to the method of testing agreed upon with the

customer;
m) Identification of person(s) authorizing the report/certificate; and
n) Statement identifying results obtained from external providers. See 7.8.8.6

7.8.2.2 The analyst authorizing the report is responsible for the accuracy of the information on the report, except when the information is incorrectly provided by the customer. It will be noted on the report if customer provides quality affecting information or is responsible for sampling prior to submission to the laboratory.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 A test report may include additional information, where necessary for the interpretation of the test results, such as:

a) Information on specific test conditions, such as environmental conditions;
b) Where relevant, a statement of conformity with requirements and/or specifications;
c) Where applicable, the measurement uncertainty of the measurement result presented in the same unit as the measurand or in a term relative to the measurand (e.g. percent);
7.8.3.1.c).1 The measurement uncertainty shall:

    a) Be included in the test report when it impacts evaluation of a specification limit stated by a regulatory body, a statute, case law or other legal requirement;
    b) Be expressed as an expanded uncertainty and include the coverage probability. This measurement result shall include the measured quantity value, y, along with the associated expanded uncertainty, U;
    c) Be reported as y± U;
    d) Limit the rounded expanded uncertainty to at most two significant digits, unless the specific testing unit has a documented rationale for reporting additional significant figures;
    e) Be reported to the same level of significance for both the measurement result and the rounded expanded uncertainty.
d) Opinions and interpretations, where appropriate and needed;
e) Additional information that is required by specific methods, customers, or groups of customers.

7.8.3.1.1 If a regulatory body, statute, case law, or other legal requirement specifies the format for the reporting of a test result, which causes a conflict with this measurement uncertainty policy, then the laboratory shall report the test results in the specified format. Additionally, there shall be:

a) Objective evidence of the regulation, statute, case law or other legal requirement; and

b) Policy and procedures for applying the estimated uncertainty at the laboratory's established level of confidence prior to reporting the test result.

7.8.3.2 Test reporting requirements outlined in 7.8.5 will be followed when the laboratory is responsible for sampling activities.

7.8.4 Specific Requirements for Certificate of Instrument Accuracy

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

a) The measurement uncertainty of the measurement result presented in the same unit as the measurand or in a term relative to the measurand (e.g. percent)
   7.8.4.1.a).1 The measurement uncertainty shall:
   a) Be expressed as an expanded uncertainty and include the coverage probability. This measurement result shall include the measured quantity value, y, along with the associated expanded uncertainty , U;
   b) Be reported as y± U;
   c) Limit the rounded expanded uncertainty to at most two significant digits, unless the specific testing unit has a documented rationale for reporting additional significant figures; and
   d) Be reported to the same level of significance for both the measurement result and the rounded expanded uncertainty.
b) The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
c) Evidence that the measurements are traceable;
d) When an instrument for calibration has been adjusted or repaired, the calibration results before and after the adjustment or repair, if available, shall be documented and available upon request;
e) If relevant, a statement of compliance with an identified metrological specification or clauses thereof. The Certificate of Instrument Accuracy shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met. When statements of compliance are made, the uncertainty of measurement shall be taken into account. If a statement of compliance is made and the associated uncertainty of the measurement and/or measurement results are omitted, the laboratory shall record those results and maintain them for possible future reference; and
f) Opinions and interpretations, where appropriate and needed.

7.8.4.1.1 If a regulatory body, statute, case law, or other legal requirement specifies the format for the reporting of a calibration result, which causes a conflict with this measurement uncertainty policy, then the laboratory shall report the calibration result in the specified format. Additionally, there shall be:

a) Objective evidence of the regulation, statute, case law or legal requirement; and
b) Policy and procedures for applying the estimated uncertainty at the laboratory's established level of confidence prior to reporting the calibration result.

7.8.4.2 Test reporting requirements outlined in 7.8.5 will be followed when the laboratory is responsible for sampling activities.

7.8.4.3 A calibration certificate shall not contain any recommendation on the calibration interval except where this has been agreed upon with the customer. This requirement may be superseded by legal regulations.

7.8.4.4 If a label (in addition to the calibration certificate) is attached to a calibrated breath alcohol measuring instrument, it shall not give the impression that the breath alcohol measuring instrument itself is approved and shall include:

a) The name of the accredited calibration laboratory or its accreditation certificate number;
b) The unambiguous identification of the item calibrated;
c) The date of the current calibration; and
d) The cross-reference to the calibration certificate issued in respect to the calibration.

7.8.4.5 The Breath Alcohol Unit will have procedures for controlling the release of calibration information.

7.8.4.6 The author(s) of a calibration certificate or report shall have conducted, participated in, observed, supervised, or technically reviewed the calibration process.

7.8.4.7 Calibration personnel who issue calibration certificates, reports or labels based on calibration documentation generated by another person(s) shall complete and document the review of all relevant pages of documentation in the calibration record.

7.8.5 Specific Reporting Requirements for Sampling

7.8.5.1 In addition to the requirements listed in 7.8.2, a test report regarding sampling shall include the following, when it is necessary for the interpretation of the examination results:

a) The date of the sampling;
b) Unambiguous identification of the substance, material, or product sampled (this includes the name of the manufacturer, the model or type of designation, and serial numbers as appropriate);
c) The location of sampling, including any diagrams, sketches, or photographs;
d) A reference to the sampling plan and sampling method used;
   7.8.5.d).1 If a sampling plan is used, the report shall contain information about the sampling plan, including confidence levels and corresponding inferences of the population;
e) The details of any environmental conditions during sampling that may affect the interpretation of the test results;

f) Any information concerning the measurement uncertainty.

Refer to applicable Unit SOPs for additional reporting requirements for sampling activities.

7.8.6 Reporting Statements of Conformity

Applicable Unit SOPs will address the requirements associated with reporting a statement of conformity.

7.8.7 Reporting Opinions and Interpretations

7.8.7.1 Opinions and interpretations will only be issued by authorized personnel. Opinions and interpretations will be documented in the technical record along with the basis upon which they were made.

7.8.7.2 Opinions and interpretations will be based on the results obtained and must be clearly marked on the TBI Official Report or Certificate of Instrument Accuracy.

7.8.7.3 Opinions and interpretations communicated directly to the customer shall be documented in the case file.

Refer to applicable Unit SOPs for additional reporting requirements for reporting opinions and interpretations.

7.8.8 Amendments to TBI Official Reports

7.8.8.1 When it is necessary to issue an amended TBI Official Report or Certificate of Instrument Accuracy, the amended information shall be clearly identified.

7.8.8.2 Once a TBI Official Report or Certificate of Instrument Accuracy has been issued, any amendments must be made in the form of another TBI Official Report or Certificate of Instrument Accuracy. An amended TBI Official Report or Certificate of Instrument Accuracy will be uniquely identified as ‘Amended’ and will contain a reference to the issue date of the original TBI Official Report or Certificate of Instrument Accuracy. The analyst or Section Supervisor will notify the submitting agency when the amended report is available.

7.8.8.3 Supplemental reports will contain a reference to the issue date(s) of previously issued TBI Official Report(s) or Certificate(s) of Instrument Accuracy being supplemented.

An amended or supplemental TBI Official Report or Certificate of Instrument Accuracy will meet all requirements of policy 7.8.

7.8.8.4 Supplemental Reports Issued by Technical Reviewer

If requested by court officials, the technical reviewer/verifier may issue a supplemental report based on their review of the case. Requirements of policy 7.8 must be met.

7.8.8.5 Supplemental Reports Issued Due to Retesting of Evidence

Due to the increasing demands placed on the scientists and the desire to keep backlog/turn-around times to a minimum, the practice of retesting evidence is not recommended. However, there may be rare instances when retesting of evidence is required by the customer. Decisions to retest evidence will be determined on a case-by-case basis by appropriate laboratory management personnel. A supplemental report must be issued for the results of retesting. Requirements of policy 7.8 must be met.

Refer to applicable Unit SOPs for additional reporting requirements for amended and supplemental TBI Official Report or Certificate of Instrument Accuracy.

7.8.8.6 Testing Results Obtained from External Providers

When the TBI Laboratory utilizes the services of an external provider for forensic examinations, the external provider conducting the examinations will provide a report of their results to the TBI Laboratory. A copy of this report will be retained as part of the TBI Laboratory case file. When a TBI Official Report contains results of tests performed by an external provider, those results will be clearly identified. If the examination results are not included in the TBI Official Report, the Unit Supervisor or designee will ensure the customer receives a copy of the external provider's report.

When a calibration has been performed by an external provider, the external provider shall issue the calibration certificate.

If results of work performed by an external provider are included in a test report or certificate that makes reference to accreditation:

- Approval shall be obtained from the external provider to include excerpts from the external provider's report or certificate; and
- The accreditation symbol of the external provider shall not be used on the report or certificate if the external provider is not accredited by ANAB.