



TOXICOLOGY LABORATORY ACCREDITATION PROGRAM

PROGRAM OUTLINE

American Board of Forensic Toxicology, Inc.
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ABFT LABORATORY ACCREDITATION PROGRAM PROGRAM OUTLINE

Preamble

The standards used in this program are based on the report of the joint SOFT/AAFS Forensic Laboratory Guidelines Committee (March 21, 1991 and subsequent revisions), additional recommendations of the Guidelines Committee (February 1994) and Accreditation Committee of the ABFT. However, it is the responsibility of the ABFT to set the criteria to be applied in deciding whether a laboratory meets the minimum requirements necessary for accreditation to be granted.

In considering this, it is important to differentiate the Forensic Toxicology Laboratory Guidelines, which were set out as a goal for laboratories to strive towards, from the minimum professional standards which must be met before a laboratory can be accredited. There is, and should be, a difference. The Preamble in the Guidelines states: "*These suggestions do not necessarily reflect our opinions about the minimum requirements of any laboratory, and have no regulatory purpose; rather, they are intended to assist laboratories engaged in the practice of forensic toxicology in achieving future goals*".

Mission of the Program

To enhance and maintain standards of practice for the detection, identification and quantitation of alcohol, drugs and other toxins in biological specimens.

Accreditation Committee

This committee is composed of a minimum of 5 people, to be appointed by the Board of Directors of the ABFT. Committee members may be Directors of the Board and/or other Diplomates in good standing. The President of ABFT is an *ex-officio* member of the Accreditation Committee.

Fees

A non-refundable fee of \$500 is required for processing and reviewing the initial application. There will be an additional cost for the on-site inspection, currently a flat fee of \$4000. This will cover the cost of the inspection, review of the inspection reports and follow up correspondence.

The fee for processing the mid-cycle review is \$500. Fees for reaccreditation application and on-site inspection are the same as for the current fees for the initial application and inspection.

Eligibility

Laboratories eligible to apply are those performing postmortem toxicology or human performance toxicology, to include at least the detection, identification and quantitation of alcohol and other drugs in biological specimens, to include whole blood. Other areas of toxicology would not normally be included (e.g. clinical toxicology, FUDT, methadone maintenance, lead program).

Overview of Application Process

Initial contact is generally made through the ABFT office in Colorado Springs. Available material includes the Program Outline, the Laboratory Accreditation Manual, an Application Form and a Checklist (to be completed by the laboratory director and sent back with the application). The material is available in one or more electronic formats on the ABFT web site. A Litigation Package (including positive results for both alcohol and one drug - which may involve different cases) and copies of Proficiency Test Summary Reports for acceptable alcohol and other drug related programs are to be sent with the application.

Instruction in the application will direct the applicant to contact the current Chair of the Accreditation Committee, who will advise how many copies of the application are required and to whom they should be sent. Generally five copies are required for an initial application or three copies for applications for reaccreditation. At least three Accreditation Committee members will review initial applications.

If the application is satisfactory, the laboratory will be invited to request an inspection date. Further information or clarification may be requested by the committee. If the laboratory wishes to proceed with the application and be inspected, the names of proposed inspectors will be prepared by the Chair of the Accreditation Committee. The names of inspectors will be conveyed to the applicant laboratory with a request to identify any perceived conflict of interest. On confirmation of the inspection team, the date for the inspection is finalized and an invoice for the inspection fee is sent to the laboratory. Travel bookings are then confirmed and the dates of the inspection finalized.

Where review of the application indicates that important deficiencies exist in the operation of the laboratory that do not comply with the ABFT standards, the Accreditation Committee may require the laboratory to address those deficiencies prior to scheduling an inspection.

If the Accreditation Committee rejects the application, the Chair of the Accreditation Committee will communicate this to the laboratory director, listing the main reasons for rejection. These will usually be major deficiencies of a type that cannot quickly or easily be resolved. If the deficiencies are resolved within a 6 month period of notification, the application may be held until supporting documentation is received, at which time the application is reactivated.

If the Accreditation Committee cannot reach a decision on the application, it will be referred for final decision (e.g. by mail or fax) by the entire ABFT Board. A two-thirds majority of the ABFT Board vote would carry, otherwise the application will be rejected.

Application Review

Review of the application will be based, to the extent practical, on the same general criteria that will be employed for the final inspection. In reaching a decision, the Accreditation Committee will make use the information provided by the laboratory, including the Litigation Package, the Proficiency Test summaries and the comments given in the Checklist completed by the laboratory director, in judging whether the "yes/no" answers given meet the intent of the question (as defined in the Laboratory Accreditation Manual).

Proficiency Testing

Effective January 1, 2010, it will be a requirement of the ABFT program that accreditation be contingent upon successful performance in the following three programs: CAP Whole Blood Alcohol, CAP Whole Blood Forensic Toxicology (FTC) **and** the CAP T-series.

For both the CAP FTC and T-series programs, laboratories must perform qualitative screening and confirmation tests, as required, on all samples. Quantitative testing must be performed for all analytes which are included in the laboratory's list of routinely quantitated substances. For the T-series quantitative testing may be limited to those analytes that the laboratory performs on a regular basis (defined as being within the reporting period set by CAP).

"Acceptable performance" will be determined by the Accreditation Committee, based on the following: no false positives; ethanol within ± 2 S.D. of the participant mean or $\pm 10\%$ weighed-in target; for drugs the challenges should be within ± 2 S.D. participant mean or $\pm 30\%$ weighed-in target for drugs. Corrective action must be documented for false negatives and other deficiencies, appropriate for the stated mission of the laboratory. The Accreditation Committee may, in its discretion, accept proficiency test results outside these ranges if the laboratory can demonstrate that appropriate action has been taken, and that the errors are not systematic and are unlikely to re-occur, or if the target concentration of the analyte is very low.

Selection of Inspection Team

After an application has been approved, the laboratory is notified, and it is confirmed that the required inspection fee has been received by the ABFT, or a purchase generated, the chairman of the Accreditation Committee will appoint an inspection team leader; (the) other team member(s) will be appointed jointly by the team leader and the Accreditation Committee Chair. Eligible inspection team members may be ABFT Diplomates, Forensic Toxicology Specialists or directors of ABFT accredited laboratories. Appropriate consideration will be given to geographic location and potential conflict of interest. Residence in the same state as the laboratory being inspected will not necessarily bar a potential inspection team member from consideration, unless prohibited by local requirements. The laboratory director will be notified of the names of the inspectors and given an opportunity to object to their appointment. The final decision as to the choice of inspectors will rest with the Accreditation Committee.

Size of Inspection Team

The inspection team will generally be comprised of at least two inspectors. It is anticipated that this will be the usual inspection team size. If a laboratory has a large or complex caseload, additional team members may be included at the discretion of the Accreditation Committee. For smaller laboratories that have been accredited for a minimum of two inspection cycles, and where no serious deficiencies have been identified in the previous two cycles, ABFT may elect to send only one inspector for a period of 2 or 3 days.

Scheduling

The accreditation program chair or the team leader would be responsible for coordinating the selection of an inspection date with the laboratory and the other team member(s).

Duration of Inspection

The on-site inspection will usually be two days and could be extended to 3 days, depending upon the caseload and complexity.

The Checklist

The checklist used for the pre-inspection self-evaluation, the on-site inspection and the annual self-assessment, are virtually identical, differing only in the style of the summary pages at the end of each section. These sheets should be used to summarize the comments and deficiencies relating to each section. In the on-site inspector version, these summary sections provide space to list (1) general comments, (2) deficiencies which need addressing at some point before or after accreditation (Recommendations), and, (3) professional advice which the inspectors may wish to give, but which is not required for accreditation to be conferred (Suggestions).

Importance of Checklist Questions

Checklist questions have been designated either **essential**, **important** or **desirable**. All **Essential** questions must be answerable "yes" before accreditation can be granted. The laboratory should also meet at least 90% of the **Important** questions and at least 75% of the **Desirable** questions before being granted accreditation.

Closing Conference

The inspection team will always conduct a closing conference with key laboratory staff, anticipated to be 15-30 minutes, depending on the extent of issues to be discussed and the time available. The exact format of the meeting and number of laboratory staff invited to attend should be at the discretion of the inspection team leader. The conference will be conducted in a manner which will be constructive and provide educational feedback.

Final Inspection Report

At the close of the inspection, or as soon as possible thereafter, all inspectors should communicate their findings to the team leader. This can be in the form of verbal communication, notes or partially completed checklist. The team leader will then prepare a composite of the entire team's findings. This will be a full and complete copy of the checklist, inclusive of the summaries at the end of individual sections and a final executive summary. The team leader should bear in mind that a full copy of the final checklist will be sent to the laboratory director. Therefore any comments which are intended only for the eyes of the accreditation committee should be submitted separately (e.g. letter, e-mail). The checklist may be submitted electronically - in fact this is encouraged, to facilitate distribution.

Inspection Report Review

The inspection report and any additional correspondence will be reviewed by the Accreditation Committee and a unanimous recommendation forwarded to the Board of the ABFT. If the recommendation of the committee is not unanimous the documentation will be forwarded to all ABFT Board members for review and decision, if necessary after discussion by conference call.

Accreditation Committee Final Decision

Possible responses are:

1. Granting of accreditation, if necessary with additional correspondence suggesting or requiring corrective action prior to the next review.
2. A request for follow-up corrective action, and supporting documentation, upon satisfactory review of which accreditation may be granted.
3. Recommendation of a re-inspection, following corrective action (upon receipt of estimated expenses for the reinspection, plus administrative costs (e.g. \$500).
4. Denial of accreditation, due to major deficiencies and the nature of corrective action required. The laboratory would be eligible to reapply for accreditation after a period of 12 months.

In the case of item 1, notification will be via the President of ABFT, otherwise correspondence would be between the Accreditation Committee Chair and the laboratory director.

On-Site Re-inspections

On-site re-accreditation inspections will normally occur once every two years.

Period of Accreditation

The period of accreditation is for two years (24 months) following successful completion of the inspection, dependent on a satisfactory 12-month review of a self-evaluation and proficiency test summaries. The initial date of accreditation is effective from the date it is formally granted by the ABFT Board (usually the first day of the month following the vote). However, the anniversary date may be changed by mutual agreement between the laboratory and ABFT.

At its discretion, the Board may extend the period of an existing accreditation for a shorter period than the usually cycle for administrative or other reasons (e.g. completion of the inspection and review process or pending receipt and review of corrective action).

Exceptions

If the general performance of a laboratory is satisfactory, but there is a deficiency with a specific assay, accreditation may be granted but the letter of accreditation may state that the assay is temporarily excluded from the scope of accreditation. The certificate of accreditation shall be withheld until such time as the deficiency is corrected. At that time a further letter shall be sent to the laboratory confirming the period of accreditation, but omitting reference to the previous deficiency.

Twelve-Month Review

Approximately 10 months after initial accreditation (or the last renewal), the laboratory director will be asked to complete a Mid-Cycle Self-Report (which consists of only the primary checklist section summaries), and to send that to the Accreditation Committee chair, together with all relevant **Proficiency Test Summaries** received since the last on-site inspection, and summaries of corrective action. There is an administrative fee for this review (currently \$500).

The purpose of this 12-month review is to provide the opportunity to review any significant changes which may have occurred since the last inspection (e.g. staffing, major changes in laboratory protocols), to ensure that the laboratory properly responds to deficiencies encountered in proficiency tests, and to encourage the laboratory to undertake other recommended corrective action in a timely manner.

Correction of Deficiencies

Following an on-site inspection or mid-cycle review, deficiencies may be identified. Where deficiencies require mandatory corrective action, the Accreditation Committee shall indicate the nature of the corrective action required and the time within which the action(s) are required to be completed. Evidence of satisfactory completion of the corrective action shall be sent to the committee for review.

Other Accreditation Program Policies

Laboratory Director Qualifications

The Director of an ABFT accredited laboratory is normally expected to have qualifications and experience equivalent to a Diplomate or Forensic Toxicology Specialist of the Board. However, the Accreditation Committee may accept lesser qualifications if it can be demonstrated that any deficiencies in experience are compensated for by other staff.

The “approval” of a laboratory director cannot occur prior to an onsite inspection but if the organization inquires, advice can be given on the qualifications expected.

If a laboratory director leaves his/her position, that person or the institution’s administrator shall notify the ABFT within 30 days.

Requirement to be Performing the Testing for which Accreditation is Being Sought

It is the policy of ABFT policy is that in order to accredit or reaccredit a laboratory, it must be currently be performing the testing of client/agency samples.

Notification of Clients of Adverse Events

Laboratories are encouraged to advise their clients if an event has occurred or situation exists that could affect the accuracy of a laboratory result.

Electronic SOPs

Electronic SOPs are acceptable so long as the program requirements of ABFT are met (e.g. appropriate approval, and tracking of changes).

POLICY FOR PROBATION, DENIAL, SUSPENSION AND REVOCATION OF LABORATORY ACCREDITATION

Accreditation Status

Accreditation - A laboratory will be accredited after having satisfied the ABFT Board that it meets the minimum program standards, including satisfactory performance in proficiency tests acceptable to the Board, submission to an on-site inspection and correction of deficiencies noted (if any). The accreditation period is for two (2) years, inclusive of satisfactory completion of a self-inspection at the end of year one plus review by the ABFT Accreditation Committee of proficiency test results for the previous 12 months.

Refusal of Application - Any laboratory may, without prejudice, have an application returned if the Accreditation Committee feels that the area of analytical testing for which the laboratory is seeking accreditation does not fall within the scope of the program (i.e. is not either Postmortem Toxicology, or Human Performance Toxicology).

Denial of Accreditation - A laboratory will be denied accreditation if it fails to meet the minimum program requirements for accreditation and is unable to undertake satisfactory corrective action within the proscribed time period. A laboratory denied accreditation shall be so notified by certified mail. When accreditation is denied, the Laboratory Accreditation Program will not accept another application for accreditation prior to one (1) year from the date of notification of denial.

Probation - An accredited laboratory is deemed to be on probation when annual review by inspection, document review or self-evaluation, reveals serious deficiencies. A laboratory on probation may continue to report results as an accredited ABFT laboratory. The purpose of the period of probation is to allow time for the laboratory to correct the deficiencies without jeopardizing the accreditation status.

“Serious deficiencies” is defined as the presence of sufficient deficiencies that, in the judgement of the Board could impact the legal defensibility of results. By definition, designation of probationary status requires Board action.

An accredited laboratory considered under probation will be so notified in writing, indicating the nature of the deficiencies which led to the probation, the corrective action required, and the date by which a satisfactory response is required.

Suspension of Accreditation - The Board may, with just cause, suspend the accreditation of the laboratory. Suspension of accreditation may occur when an accredited laboratory is determined not to be in compliance with the minimum program standards as a result of failing to satisfactorily address the deficiencies which resulted in probation, or which otherwise cast the legal defensibility of the laboratory’s result in doubt. At the time accreditation is suspended, a time limit for the suspension will be designated by the Board. The laboratory must be in compliance with the required standards at the end of that time period or the laboratory's accreditation will be revoked, unless the Board agrees to an extension.

Suspension means that a laboratory cannot continue to report results as an ABFT accredited laboratory.

Corrective actions include any or all of the following:

- a) A focused or total re-inspection of the laboratory at the laboratory's expense.
- b) Analysis of open proficiency samples refereed by two laboratories, selected by the Board.
- c) Review of appropriate documents submitted to the Board, necessary to indicate compliance with the stated deficiencies.

If accreditation is suspended, the laboratory may be reinstated as an accredited laboratory by submitting within the designated time period, documentation indicating that all required corrective actions were carried out. The Board shall respond with a decision, in writing or by electronic means, within twenty (20) working days after receipt of documentation of all corrective actions. The Board, after review of such material, including the results of a possible re-inspection, will decide whether the laboratory's accreditation will be reinstated or revoked. Appropriate notification of the laboratory will be carried out by certified mail. A suspended laboratory that is not reinstated after the review will have its accreditation revoked.

Revocation of Accreditation - The Board may revoke any laboratory's accreditation if it is determined that, during the accreditation cycle, the laboratory is not in compliance with the minimum program standards and has failed to satisfactorily correct deficiencies following a period of probation and suspension. Revocation of accreditation may also occur if the laboratory is found to have falsified its application for accreditation, or is determined to have knowingly engaged in fraudulent laboratory practices.

Revocation means the laboratory accreditation is cancelled. The laboratory may seek reaccreditation by completing the entire accreditation process, including satisfactory performance in the required proficiency surveys, and undergoing an on-site inspection. Such application requires the laboratory to satisfy the usual requirements for initial accreditation.

Revocation requires a majority vote of the Board of the ABFT, if necessary by telephone conference call and/or mail ballot.

Voluntary Withdrawal from Program

A laboratory may, without prejudice, voluntarily withdraw from the Accreditation Program for a variety of reasons. In such case, the laboratory will be required to return the certificate of laboratory accreditation to the Board. No portion of the accreditation fee will be refunded. The only action on behalf of the Board will be to remove the name of the laboratory from the list of accredited laboratories.

Confidentiality of Accreditation Data and Related Issues

Any information or material received or generated by the Board in connection with a laboratory's participation in the Laboratory Accreditation Program is considered confidential and will not be released unless release is authorized by the laboratory director or is required by law. Similarly, in the event of a dispute between a laboratory seeking accreditation or reaccreditation and the

Board, the issues involved shall be considered confidential and shall not be disclosed to a third party by either the Board or the laboratory without mutual consent. However, the fact that a laboratory is or is not accredited may be disclosed by either the laboratory or the Board.

In addition, the Board may be required to disclose findings of fraud or serious misconduct to the appropriate authorities. In such case, the laboratory concerned will normally be given the opportunity to convey this information itself.

Appeals and Reconsiderations

A laboratory may ask that a denial of accreditation be reconsidered. Similarly, any decision of the Board relating to accreditation status, may be appealed. Such requests must be made in writing to the President of the ABFT within thirty (30) days of the laboratory receiving notice of the action, stating why the laboratory director believes the decision to have been erroneous, and shall include supporting documentation of compliance with the program standards for laboratory accreditation. A request for reconsideration shall not stay the denial of accreditation, nor will a request for appeal stay a Board action to suspend or revoke accreditation. The Board shall respond within sixty (60) days of receiving notice of request for reconsideration or appeal.

An appeal or request for reconsideration of a Board action shall be reviewed by a three-member Accreditation Appeals Committee of the Board. The Appeals Committee shall consist of three members appointed by the president, two of whom shall be Diplomates of the Board who are not currently serving Directors. The committee shall report to the Board of Directors. The director of the laboratory appealing or seeking reconsideration shall be notified in writing of the receipt of the request and of the results of the review. If the request includes new information which could cause the Board to alter its decision, the director may be invited to appear at the next regularly scheduled ABFT Board meeting. If so, the director will have an opportunity to make a brief presentation explaining why the laboratory should be granted accreditation and shall answer all questions posed by members of the Board.

After such presentation, the Board shall determine whether or not to reverse its prior decision. Within fourteen (14) days of the hearing date, the laboratory will be notified of the Board's decision by certified mail. The notification shall include a brief statement of the reasons for the Board's determination.