



AMERICAN SOCIETY FOR  
HISTOCOMPATIBILITY AND IMMUNOGENETICS

ACCREDITATION REVIEW PROGRAM

OPERATIONS MANUAL

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ARB Approved: TBD 2019

ASHI BOD Approved: TBD 2019

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**Chapter A**

**The**

**ASHI**

**Accreditation**

**Program**

## MISSION, PURPOSE AND GOALS

The ASHI Accreditation Program is established by the ASHI Bylaws and is administered by the Accreditation Review Board (ARB). The **mission** is to promote quality laboratory practice in Histocompatibility and Immunogenetics through the objective and consistent evaluation of compliance with ASHI Standards.

The **purpose** of the Accreditation Program is to evaluate laboratory personnel, procedures and facilities to determine if they are in compliance with those published Standards of ASHI and with those Standards of organizations by which ASHI is deemed and which apply to the activities of that laboratory. Laboratories will be evaluated for the technologies utilized and, if applicable, the clinical services provided.

The **goals** of the Accreditation Program are:

1. To perform the evaluation process in an ethical, objective and timely fashion.
2. To promote the educational aspects of the Accreditation process.
3. To provide to various committees of the Society, data obtained in the Accreditation process, which are useful to maintaining the Society's awareness of standard and novel procedures and methodologies.

The ASHI Accreditation Program is a voluntary program which accredits laboratories for:

1. Area(s) of Accreditation which are defined as the clinical service-specific activity supported by the laboratory (i.e. HSC/BM, Solid Organ, etc.); and,
2. Testing categories and systems used by the laboratory to support the area(s) of accreditation

### I. Deeming Organizations

#### A. General

The American Society for Histocompatibility and Immunogenetics (ASHI) has been deemed by the United Network of Organ Sharing (UNOS) and the Centers for Medicare and Medicaid Services (CMS). Two additional organizations involved in hematopoietic stem cell transplantation require ASHI or the European Federation for Immunogenetics (EFI) Accreditation for those laboratories performing Histocompatibility and Immunogenetics for recipient-donor matching. These are the National Marrow Donor Program (NMDP) and the Foundation for the Accreditation of Cellular Therapy (FACT). Add CA State info here once approved.

#### B. Accreditation Program-CMS Interactions

Since the ASHI Accreditation Program has deemed status as a CMS Accrediting Organization (AO) to ensure that ASHI Accredited laboratories testing samples from U.S. patients are in compliance with all relevant CLIA regulations, mechanisms to ensure continuity and up-to date communication with the appropriate CMS staff members are essential. Such continuity and currency can only be ensured if the individuals who are currently responsible for all Accreditation Program activities are primarily involved in the communication process.

To ensure continuity and currency for communication with the appropriate CMS staff members, the key members of the ARB who need to be involved in the communication process are the Current ARB Program Director, the Senior ARB Co-Chair (who will become the next ARB Program Director), and the ARB Accreditation Manager (permanent position)

- i. CMS sponsors a "Partners meeting" at least annually to ensure that all AOs are kept informed about changes in CMS Interpretative Guidelines for CMS regulations (Guidelines change frequently but the regulations change only very infrequently). To ensure continuity in communication with the ASHI ARB, the current ARB Program Director, Senior ARB Co-Chair, and Accreditation Manager (if applicable) will attend the CMS Partners Meeting
- ii. CMS sponsors a Surveyors Training Course approximately once every 2 years to ensure that all CMS State Surveyors are kept informed about changes in CMS Interpretative Guidelines for CMS regulations. AOs are invited to send 1 or 2 (as space permits) individuals to attend this course. Expenses, with hotel costs at CMS government rates, are included in the ASHI ARB budget).
  - a. If the current ARB Program Director has not yet attended this Training course, that person would have the first priority to attend the Training course. Any Senior, Middle or Junior Co-chair who has not yet attended this Training Course would have the next priority, in that order, to attend the training course.
  - b. If all current Co-chairs have already attended this Training course, the next priority would go to an individual selected by the current Program Director and Co-chairs as a nominee for the next vacant co-chair position.
- iii. The CMS liaison to the ASHI ARB will be invited to attend at least one meeting of the ARB each year; the CMS liaison's attendance at the ASHI Inspector training session during the annual meeting will also be considered on an ad hoc basis, as needed to ensure effective communications. The CMS liaison's travel and hotel expenses to attend any ARB meeting or ASHI Inspector training session would be paid by CMS. The ARB would request approval from the ASHI Board to provide courtesy registration for any Annual ASHI meeting the CMS liaison might be invited to attend.
- iv. The current ASHI Program Director will be charged with primary responsibility for communications with the CMS liaison to the ASHI ARB (with copies to the ARB Co-Chairs and Accreditation Manager) and for ensuring that the ASHI Executive Board and membership are kept informed about all important changes. These communications include but are not limited to:
  - a. Requests for CMS approval of new ARB policies following each ARB meeting after approved by the ARB and the ASHI Executive Board
  - b. Requests for CMS approval of revised ARB policies, ASHI Standards and Guidelines and the revised ARB Operations Manual on an annual basis, after approval by the ARB, the ASHI QA/S Committee, and the ASHI Executive Board (usually in November or December of each calendar year, following the annual ASHI meeting).
  - c. Requests for CMS clarification of CMS regulations in relation to specific ASHI Standards and Guidelines
  - d. Requests from CMS for clarification of ASHI Standards and ARB policies and for expert advice in relation to the fields of Histocompatibility, Immunogenetics and Transplantation

- e. Blast e-mails to all ASHI accredited laboratories and/or items in the ASHI Quarterly's Accreditation News to ensure that ASHI accredited laboratories are aware of changes in CMS interpretative guidelines that affect compliance with CMS regulations, as applicable
- f. Submission of applications for renewal of CMS deemed status or additions to specialties for CMS deemed status, as applicable.

#### C. Accreditation Program-CA State Department of Public Health Operations

ASHI entered into an agreement with the state of California on xx/xx/xxxx.

Per this agreement, in addition to all other ASHI standards and policies, ASHI agrees to the following actions affecting the laboratories in this agreement with CA state licenses:

- i. ASHI will notify the CA Department of Public Health, Laboratory Field Services of any deficiency that poses an immediate jeopardy to the laboratory's patients or a hazard to the general public. This will be done by email to the point of contact person at the state office. This email will be sent immediately after the ARB Executive board deems an immediate jeopardy situation. ASHI will provide details on the deficiency and action of the ASHI/ARB Executive Board for follow-up.
- ii. ASHI will provide any records or other information to the CA Department of Public Health, Laboratory Field Services, its agents, or contractors, as the department may require.
- iii. If there is any violation of condition level requirements by any of the laboratories affected by this agreement, including the actions taken by ASHI as a result of the violation, ASHI will notify the CA Department of Public Health, Laboratory Field Services within 30 days of the initiation of the action.
- iv. ASHI will notify the CA Department of Public Health, Laboratory Field Services if any of the laboratories affected by this agreement withdraw their accreditation with ASHI.
- v. ASHI will provide quarterly inspection schedules to the CA Department of Public Health for the purpose of conducting on-site validation inspections. Quarterly and annual reports of laboratories requested by the department will also be sent by ASHI as needed.

## II. THE ACCREDITATION REVIEW BOARD AND LEVELS OF REVIEW

The Accreditation Review Board (ARB) is comprised of the commissioners, co-chairs, the Program Director, Inspector Training Coordinator and the Accreditation Manager and meets after each inspection cycle. The Commissioners present the Summary Reports to the entire Board and Accreditation for the laboratory is granted or denied following a vote by the Board. This helps to ensure consistency in interpretation and application of the ASHI Standards.

The ASHI Board of Directors also has oversight of the entire Accreditation process under the following hierarchy:





The accreditation process involves three levels of review:

- A. The **Inspector** who reviews the application packet, inspects the laboratory, and submits an inspection report to the Laboratory Director and to the Commissioner.
- B. The **Commissioner** who:
  - i. Acts as primary reviewer of the application packet for Regions assigned.
  - ii. After review of the application packet, communicates any deficiencies, concerns, or previous deficiencies and laboratory response to deficiencies in order to ensure that corrective actions have been effective to the Inspector.
  - iii. Reviews the Inspector's report within one week of the inspection to approve the cited deficiencies and sends a signed copy back to the laboratory.
  - iv. Reviews and approves responses to deficiencies.
  - v. Communicates with Laboratory Director/Technical Supervisor or Supervisor when follow-up information or documentation is needed.
  - vi. Prepares Summary Report to be sent to co-Chair for review and to be presented at the Accreditation Review Board meeting.
  - vii. Reviews final letter/certificate from the co-Chair to the laboratory for accuracy, completeness, and consistency.
  - viii. Informs the Inspector of comments or complaints that were made during the inspection process. Advises the Inspector on the proper interpretation of standards when a citation is overruled by the commissioner or the ARB.
- C. The **Accreditation co-Chair** who
  - i. Acts as secondary reviewer of application packet.
  - ii. After review of the application packet, communicates any deficiencies, concerns, or previous deficiencies and laboratory response to deficiencies in order to ensure that corrective actions have been effective to the commissioner.
  - iii. Consults with Commissioner to resolve problems.
  - iv. Reviews Commissioner's Summary Report
  - v. Prepares letter summarizing inspection results for the Laboratory
  - vi. Reviews ASHI certificate for accuracy and completeness

### III. CONFLICT OF INTEREST

- A. No Inspector or member of the ARB may solicit or accept business or job opportunities from any laboratory for which he/she is currently providing ARB review services (i.e. there may be no conflict of interest by any persons directly involved in the inspection process).
- B. If the Inspector is providing any other service to the applicant institution during the inspection visit or at a time contiguous to the inspection visit, the Inspector may not accept any fee, honorarium, or gratuity for such service.
- C. Any conflict of interest or potential conflict of interest should be reported to the Program Director and/or Accreditation Manager and noted in the individual's profile.

#### **IV. SOFTWARE**

The current ARB software is the LearningBuilder system from Heuristic Solutions, LLC. There are 4 levels of access in this software:

A. Admin access: Only granted to the Accreditation Manager and Executive Director. Functions include adding/deleting/editing members and applications, setting up inspections, and updating the applications as appropriate (adding new standards, instructions, etc.) Admin access also includes all of the other functionalities listed below.

B. Reviewer access: Granted to ARB commissioners and co-chairs during their term on the ARB. Allows the commissioners and co-chairs to view applications with in their respective regions and complete the ARB summary reports, recommendation to the full ARB for accreditation, recording contingencies, etc. Reviewer access is discontinued after the term on the ARB ends.

C. Inspector access: Allows inspectors to access certain laboratory applications they have been assigned to inspect. This access is granted by the admin and is discontinued when the inspection is recorded/completed.

D. Laboratory application access: The most basic of access to the LearningBuilder system, allows anyone from the general public to begin an application in the system. Once an application is started, the admin will be notified to set up a profile which will be secure to that user. Existing Laboratory profiles using the software for applications year after year will not have to enter duplicate information, much of the past application data carries over. This type of access never expires. One login and password is used for each laboratory.

#### **V. PERSONNEL**

The Accreditation Program will be administered through an Accreditation Manager, Program Director, three co-Chairs, 12 Commissioners and a pool of Inspectors. The Program Director, the immediate past Program Director, and three Co-Chairs constitute the ARB Executive Board. The immediate past Program Director serves as the liaison to the Director Training Review and Credentialing (DTRC) Committee, as the coordinator for the Inspector Training Program and is also a member of the accreditation program. Additional members of the Accreditation Program include the Advisory Committee members and the Ombudsperson(s).

The Accreditation Review Board (ARB) works closely with the Director Training Review and Credentialing (DTRC) Committee. The DTRC committee Chair will provide a report for each ARB meeting with an update of approval of Directors for new Areas of Accreditation.

At the request of ASHI Board and/or the Program Director, the Accreditation Program will utilize the consultation of various individuals acting as liaisons to relevant Committees of the Society or to other societies.

All ARB members must be members of ASHI and must be from ASHI accredited laboratories

#### A. ACCREDITATION PROGRAM DIRECTOR (PD)

The Accreditation Program Director will be appointed by the members of the Accreditation Review Board (ARB) each year at the ASHI annual meeting. This individual is usually the person who has finished serving as the Senior co-Chair. The appointment is contingent upon ASHI Board of Directors approval.

- i. Appointment and Term
  - a. Selected by the members of the review board
  - b. Appointment contingent upon ASHI Board approval
  - c. Term is for one (1) year beginning at the end of the ARB Business Meeting at the annual ASHI Meeting but, if necessary, may be extended upon approval by both the ARB and ASHI Boards
- ii. Qualifications
  - a. Has provided outstanding service as a co-Chair
  - b. Able and willing to commit the time necessary to fulfill responsibilities and to represent ASHI in a positive light
  - c. An ASHI member
  - d. Is employed in an ASHI accredited laboratory
- iii. Responsibilities
  - a. Oversees the program's operations and the lab evaluation process to ensure timelines are met
  - b. Prepares ARB program reports and presents to ASHI Board, the ASHI membership, deeming agencies, contract organizations and others
  - c. All reports to the ASHI Board of Directors should include:
    - (1) The number of reviews performed since the last report, categorized by on-site, renewal, or ad hoc
    - (2) Any appeals in progress
    - (3) Any complaints received and actions taken
    - (4) Any meetings, teleconferences with other organizations
    - (5) Any policy changes
    - (6) Any workshops, articles, website hits, etc.
    - (7) Any items on list of materials requiring ASHI Board review
  - d. Presents the Accreditation Update at the ASHI Annual meeting at which he/she becomes the new Program Director.
  - e. Presents the Annual Report (presented at Annual ASHI Business Meeting at which he/she becomes the new Program Director.) The report should include:
    - (1) Summary of fulfillment of obligations to other organizations (e.g., CMS validation surveys, data submission, renewal applications, reports, etc.)

- (2) Changes in the ARB members
- (3) CMS Validation Survey outcomes
- (4) Summary of accredited laboratories, by Areas of Accreditation
- (5) Budget

- f. Organizes and chairs meetings; ensures follow-up on outstanding issues and projects.
- g. Ensures maintenance and revisions of the Operations Manual and all forms.
- h. Mentors, provides guidance to, and consults with co-Chairs.
- i. Communicates information to Program members.
- j. Appoints interim Commissioners when necessary.
- k. Reviews and signs certificates.
- l. Works with the Inspector Training Coordinator to plan Inspector Training Workshops and Online Training Modules.
- m. Presides over the Inspector's Reception at the ASHI Annual meeting.
- n. Gets approval for the next Program Director, new Co-Chair, and new Commissioners at the mid-term meeting of the ASHI Board.
- o. Serves as the ASHI liaison to CMS, attending CMS Partners meetings and other relevant CMS sponsored activities as applicable. Responsible for reviewing Federal Regulations (Federal Register) for changes, at least quarterly.
- p. Provides an Accreditation Update for the ASHI Quarterly

## B. CO- CHAIR(S)

There are three co-Chairs. The co-Chairs serve a three-year term, advancing each year from Junior co-Chair to Middle co-Chair, to Senior co-Chair. At the end of the three-year term, the Senior co-Chair is expected to serve as the new Program Director.

- i. Appointment and Term
  - a. Selected by the Accreditation Review Board
  - b. Term will begin at the end of the annual ARB business meeting at the annual ASHI meeting
- ii. Qualifications
  - a. Is employed in an ASHI accredited laboratory
  - b. Has a minimum of two (2) years outstanding service as Commissioner
  - c. Is CHS, CHS-qualified, qualified Director, or has comparable expertise
  - d. Has no known or relevant conflict of interest or conflict of commitment.
  - e. Is an ASHI member
- iii. Responsibilities
  - a. Each co-Chair oversees 4 Regions and works with the 4 Commissioners appointed to those regions.
  - b. Acts as the secondary reviewer of application packet
  - c. Consults with the Commissioner to resolve problems
  - d. Reviews the Commissioner's Summary Report
  - e. Finalizes the letter summarizing inspection results to the Laboratory
  - f. Reviews ASHI certificate for accuracy and completeness
  - g. Along with Program Director, Accreditation Manager, and other co-Chairs, is responsible for selecting appropriate Inspectors for laboratories being inspected each cycle

- h. Maintains, in electronic or hard-copy form, a minimum of the following documentation for each lab for the previous two years, including a minimum of the last interim and on-site applications:
    - (1) Summary Reports, Accreditation Letters and Certificates
    - (2) Deficiency Reports
    - (3) Relevant correspondence concerning individual laboratories with Commissioners (paper and/or electronic)
    - (4) Validation Checklists
  - i. Co-Chairs should retain copies of critical correspondence, (paper and/or electronic) such as correspondence relating to a laboratory's requirement for Enhanced Proficiency Testing, contingencies, limitations or suspension, indefinitely, for transfer to the next Commissioner or co-Chair.
  - j. At the end of the two-year retention period, shreds or destroys other non-critical materials that identify particular laboratories in a manner compliant with HIPAA.
- iv. Senior co-Chair
- a. Serves as back-up to the Program Director (PD).
  - b. Will advance to the position of Program Director, if approved by the ARB and ASHI Board.
  - c. Is responsible for reviewing contracts for Deemed Status Agencies and for initiating re-applications when they are due.
  - d. Serves as liaison to the ASHI QAS Committee and presents summary reports of the committee's activity at each ARB meeting
  - e. Ensures that interpretation guidelines are meeting the spirit of the Standards.
  - f. Reviews and updates the Interpretation Guidelines as needed.
  - g. Prepares document for CMS that summarizes changes to ASHI Standards and/or Interpretative Guidelines
  - h. Attends the CMS Partners Meeting to ensure continuity of communications with CMS.
  - i. Trains new Commissioners at ASHI Annual meeting at which he/she becomes the senior co-chair.
- v. Middle co-Chair
- a. Serves as liaison to the ASHI PT Committee, attends PT meetings and presents summary reports of the committee's activity at each ARB meeting
  - b. Reviews Packet instructions and application packet content. Suggests corrections and updates to full ARB for approval.
- vi. Junior co-Chair
- a. Reviews the ARB Operations Manual (OPs) and recommends updates to full ARB for approval.
  - b. Composes the rough draft for changes to the OPs that result from decisions made at ARB meetings. Updates will be presented to the full Board for approval.
  - c. Prepares document for CMS that summarizes new Policies and changes made to ARB Operations Manual.
  - d. Serves as a committee member of the ASHI National Clinical Affairs Committee, seeks and provides the ARB's input as needed, and presents summary reports of the committee's activity at each ARB meeting.

## C. COMMISSIONER

### i. Appointment and Term

- a. Is appointed by the Accreditation Review Board.
- b. Serves a minimum two (2) year term with option to stay on for an additional 2 year term.
- c. The ARB welcomes new commissioners each year at the ARB business meeting during ASHI's annual meeting. The table below is a timeline developed to assist the incoming and outgoing ARB members with the transition of files and other information

DATE	ACTION
April - May	New Commissioners are selected by the ARB Co-Chairs, PD and past-PD and their willingness to serve is confirmed by correspondence from the PD
June	Approval of new commissioners by the ASHI ARB and then the ASHI Board of Directors
June	New commissioner sent welcome email along with schedule for the ASHI Annual Meeting by the Accreditation Manager
July	Accreditation Manager to send new commissioners the following: <ul style="list-style-type: none"> <li>• Letter of Appointment</li> <li>• ARB Operations Manual</li> <li>• Spreadsheet of labs in respective regions</li> <li>• Cycle timelines</li> </ul>
1 August	Outgoing Commissioners contact the new commissioners to initiate communications
August	ARB meeting (review of cycle 1 labs) – only current Commissioners attend
September	Accreditation Manager to send both old and new commissioners & incoming co-chair copies of cycle 2 packets
15 October	Interim reports completed by old Commissioners; On-site reports in progress. Cycle 2 Inspections completed – outgoing commissioners to share inspection summaries, deficiency reports, etc. with new commissioners
October	ASHI Annual Meeting (both outgoing and incoming Commissioners attend) File transfers begin after Annual Meeting and will include all paper and electronic correspondence from the respective region of laboratories. This should include but is not limited to the following: <ul style="list-style-type: none"> <li>• official letters &amp; certificates of accreditation</li> <li>• validation</li> <li>• correspondence from laboratories regarding relocation, changes in key personnel, etc.</li> <li>• any adverse actions implemented on the laboratory (complaints, sentinel events, repeat deficiencies, etc.)</li> </ul>
15 October	Both old and new Commissioners participate in Conference Call to approve Interim labs
1 November	File transfers complete
15 November	New packets (cycle 3) sent to New Commissioners.
December	New Commissioners attend their first regular ARB meeting and present summaries for the cycle 2 labs in their regions.
20 December	Letters & certificates for cycle 2 labs reviewed by new Commissioners and sent

- ii. Qualifications
  - a. Is employed in an ASHI accredited laboratory
  - b. Is CHS, CHS-qualified, qualified Director, or has comparable expertise
  - c. Performed at least one inspection for the ASHI Accreditation Program
  - d. Has the time commitment to process inspection packets according to guidelines
  - e. Shows diplomacy, patience and organizational skills
  - f. Displays clear understanding of ASHI Standards
  - g. Has the ability to make decisions and to work with laboratories to solve problems
  - h. Is an ASHI member
  
- iii. Responsibilities
  - a. Reads and reviews the Operations Manual of the Accreditation Program annually.
  - b. Reviews all applications submitted by laboratories within thirty (30) days of receipt of packet.
  - c. Determines laboratory compliance during the intervening, non-inspection year.
  - d. Completes the Commissioner's Summary Reports during the non-inspection year.
  - e. Contacts Inspector(s) prior to inspection to discuss any concerns after the Commissioner's review of the inspection packet.
  - f. Sends Inspector a list of previous deficiencies cited at the last on-site inspection and laboratory response to deficiencies in order to ensure that corrective actions have been effective.
  - g. Monitors the inspection process.
  - h. Reviews the Inspector's Summary Report and contacts the inspector and/or laboratory Director within one week to document review. If there are laboratory complaints or apparent inappropriate deficiencies, discusses and resolves these with the Inspector and Co-Chair unless the Co-Chair considers that full ARB discussion is warranted.
  - i. Prepares a Commissioner's Summary Report listing the findings from the inspection, responses of the laboratory and recommendations for Accreditation.
  - j. Reviews laboratory report with the co-Chair prior to the ARB meeting to resolve remaining issues.
  - k. Presents review of laboratories at ARB business meetings. The primary review shall include:
    - (1) A brief history of the lab
    - (2) Years of experience of key personnel
    - (3) Number of techs and ABHI-certified personnel
    - (4) Compliance with continuing education requirements
    - (5) Workload volume
    - (6) Current deficiencies
    - (7) Repeat deficiencies
    - (8) Response to deficiencies
    - (9) Recommendation for action
  - l. Participates in four (4) meetings annually.
  - m. Maintain, in electronic or hard-copy form, a minimum of the following documentation for each lab for the previous two years, including a minimum of the last interim and on-site applications:
    - (1) Accreditation Applications (parts not online), Summary Reports, Accreditation Letters and Certificates
    - (2) Deficiency Reports and Responses to Deficiencies
    - (3) Relevant correspondence with laboratories and Inspectors (paper and/or electronic)

(4) New Validation Checklists.

- n. Retain copies of critical correspondence, (paper and/or electronic) such as correspondence relating to a laboratory's requirement for Enhanced Proficiency Testing, contingencies, limitations or suspension, indefinitely, for transfer to the next Commissioner.
- o. Send any out of cycle new test validation materials to the Accreditation office.
- p. At the end of the two-year retention period, shreds or destroys non-critical materials that identify particular laboratories in a manner compliant with HIPAA.
- q. Reviews final letter/certificate from the co-Chair to the laboratory for accuracy, completeness, and consistency.
- r. Informs the Inspector about any cases in which deficiencies cited have been over-ruled or deficiencies added after review of the laboratory by the ARB.

D. INSPECTOR TRAINING COORDINATOR

- i. Appointment and Term
  - a. The immediate past Program Director of the Accreditation Review Board shall serve in this position.
  - b. Serves a one year term
- ii. Qualifications
  - a. Has previously served as a Commissioner for the ARB.
  - b. Provided outstanding service as an ASHI Inspector.
- iii. Responsibilities
  - a. Plans and organizes Inspector Training workshops; plans and organizes new on-line Inspector Training modules and the update of previous modules, as needed.
  - b. Works with ARB Manager and ASHI staff as needed in planning workshop.
  - c. Attends all ARB meetings and the annual ARB business meeting to keep abreast of the most common deficiencies being cited and to be aware of problems the Inspectors may be having in interpreting the Standards or guidelines.
  - d. Reviews Inspector Evaluation Forms and New Inspector Trainee Forms.
  - e. Recommends approval of new Inspectors.
  - f. Determines if second inspection as trainee is needed.
  - g. Provides a report for each meeting of the Accreditation Review Board.
  - h. Sends necessary feedback to Inspectors following each ARB meeting. Assists the Accreditation Manager in maintaining a continuing record of Inspector evaluations that can be passed on to the next Inspector Training Coordinator for use in future Inspector selections
  - i. Annually monitors and reviews the online inspector training materials for accuracy, updates, etc. and coordinate changes as needed.

E. ADVISORY COMMITTEE

- i. Appointment and Term
  - a. The Accreditation Advisory Committee will be composed of the last three ARB Program Directors. If necessary, the Committee may have additional members to meet special needs. The senior-most member shall serve as Chair



- b. If the departing Program Director cannot fulfill the role of service on the Advisory Board, the most senior Commissioner rotating off the ARB may be asked to assume those duties.
  - c. Is appointed for by the ARB
  - d. Serves a three year term.
- ii. Qualifications
    - a. Past Program Directors, but may be a Commissioner or co-Chair who has rotated off the ARB.
    - b. Is an ASHI member
    - c. Is employed in an ASHI Accredited Laboratory
- iii. Responsibilities
    - a. Provides additional support to reduce the workload of the members of the Accreditation Review Board.
    - b. Acts as the Appeal Board when necessary. Any member with potential conflicts of interest must excuse themselves from the appeals process.
    - c. Notification of Possible Insurance Claim - The ASHI Executive Director is responsible for notifying the insurance company when there is a threat of an action against the society.
- iv. Attendance at ARB Meetings
    - a. Members of the Advisory Committee may be invited to ARB business meetings, excluding participation in the actual laboratory reviews.
    - b. Advisory Board members may attend the ARB business meeting, but attendance is not required. Travel expenses will be covered by ASHI only when attendance is required.
    - c. Advisory Board Members will receive current ARB manuals, minutes, and other information relevant to staying knowledgeable about the Program.

## F. OMBUDSPERSON

- i. Appointment and Term
  - a. Is appointed by the Accreditation Review Board.
  - b. Serves 1 two-year term and reappointment is allowed.
  - c. Two ombudspersons shall serve at all times.
- ii. Qualifications
  - a. Is a past Commissioner, co-Chair, or Program Director who has been off the ARB for at least one year.
  - b. Is an ASHI member
  - c. Is employed in an ASHI Accredited Laboratory
- iii. Responsibilities
  - a. Serves as diplomat for the Accreditation Program and is to be receptive to all suggestions, complaints, inquiries, etc.
  - b. Investigates complaints about general practices to determine if they involved an incident or a perception.
  - c. Investigates complaints about specific incidents to determine as accurate an account as possible.

- d. Communicates suggestions to the Program Director.
- e. Reports complaints and findings to the PD or, if the complaint involves the PD, reports to the Senior co-Chair who will issue a written response summarizing the action taken. If anonymity is desired, the PD's report may be sent to the Ombudsperson for follow-up with the complainant.
- f. Provides the PD with a brief summary of activities for inclusion in the annual report to ASHI Board of Directors.
- g. May attend ARB business meeting, but attendance is not required; travel expenses to be covered by ASHI only when attendance is required.
- h. Receives and reviews current ARB manuals, minutes, and other information (excluding any confidential information) relevant to staying knowledgeable about the Program.
- i. Signs a Conflict of Interest and Statement of Confidentiality.

#### G. ARB AD-HOC MEMBERS

- i. Appointment and Term
  - a. *Ad hoc* members may be appointed by vote of the ARB, at the discretion of the Program Director;
  - b. The terms of such appointments would be determined by the Program Director, subject to the appointment vote of the ARB
- ii. Responsibilities
  - a. May serve as liaisons to other Committees and the ASHI Board;
  - b. May undertake special projects;
  - c. May perform other functions as deemed necessary by the Program Director.

#### H. ABSENCES OF ARB MEMBERS

Vacations, illnesses, meeting attendance, and other leaves of absence may result in prolonged delays in processing Accreditation applications.

- i. When an absence of two months or less is planned, the Board Member should make arrangements that will prevent or minimize such delays. Such arrangements may include having materials forwarded to one of the other members holding the same position who can assume responsibility during the absence.
- ii. When arrangements cannot be made in advance or an absence of longer than two months is to occur, the Accreditation Program Director should be contacted at the earliest possible time. Every effort should be made to provide a mechanism by which the Board Member can serve out his/her term. Such arrangements may include designating other members to assume temporary responsibility for those laboratories or appointing an interim individual. The Ombudspersons and Advisory Committee Members are qualified to assume such temporary positions on the Board.
- iii. If the efficiency and efficacy of the program is seriously compromised, the Accreditation Program Director may, at his/her discretion, appoint another individual to serve the remainder of the term.
- iv. Co-chair and Commissioner approval is necessary for interim laboratories to be included on the pre-ARB Meeting conference call pass-through list. Co-chairs must be present on the conference call or have provided prior approval for laboratories to be included on a "pass-

through” list. Commissioners may give prior approval of laboratories to the appropriate Co-Chair.

## I. ACCREDITATION MANAGER

The Accreditation Manager is a staff position. It can be filled by an employee of ASHI, an employee of ASHI's management company or an independent contractor. Should the accreditation Manager become unavailable, ASHI's Director of Operations and Executive Director will be responsible for the list below as needed. The Executive Director will become the point of contact for CMS. Annual training of backup personnel is performed. In addition, the Accreditation Manager's data, software, and electronic files (including email) will be backed up on a daily basis through Association Headquarters policy.

### i. Responsibilities\*

- a. Issues, upon request, the appropriate materials to new applicants as follows:
  - (1) Application Packet;
  - (2) Standards and Guidance
- b. Issues to ASHI accredited labs, at least 240 days prior to expiration of Accreditation, electronically, the appropriate renewal materials as follows:
  - (1) Application Packet (if an inspection year);
  - (2) Standards and Guidance
- c. Forwards to Commissioners, co-Chairs and Program Director a report informing them of the name and ASHI number of applicants receiving Accreditation renewal packets and a report on any laboratories delinquent in returning the laboratories Accreditation packet.
- d. Forwards to ASHI Board updates and quarterly reports on Accreditation.
- e. Forwards packets and all documentation to Commissioners, co-Chairs and Inspectors
- f. Maintains, for each laboratory, a file containing the information on when each laboratory has received their Accreditation materials.
- g. Maintains, for each laboratory evaluated, a file containing all evaluation materials, including correspondence, documentation, application forms, etc.
- h. Provides clerical and secretarial support and supplies to the Accreditation Chair(s) and Commissioners as deemed appropriate by ASHI.
- i. Assists the Accreditation Program Director in arranging board meetings.
- j. Provides reports required by agreements with Organizations for which ASHI has deemed status such as inspector evaluation forms as required by UNOS and numbers of laboratories performing testing in each specialty or sub-specialty as required by CMS.

*\*ASHI's Director of Operations will fulfill these responsibilities in the Accreditation Manager's absence.*

### ii. Application Processing\*

- a. Receives applications & interim reports each cycle:
  - (1) Accreditation Office copy
  - (2) Commissioner copy
  - (3) co-Chair Copy
  - (4) Inspector(s) Copy(ies)
- b. Provides quantitative review of applications (bounce-backs).

*\*ASHI's Director of Operations will fulfill these responsibilities in the Accreditation Manager's absence.*

iii. Evaluation Tracking\*

- a. Tracks which lab applications are due.
- b. Sends applications/interim reports out.
- c. Tracks each lab through the evaluation process.
- d. Ensures that labs are inspected within established timeline.
- e. Monitors Commissioner's review of inspection reports and responses.

*\*ASHI's Director of Operations will fulfill these responsibilities in the Accreditation Manager's absence.*

iv. Database Management\*

- a. Maintains databases for:
  - (1) Accredited labs
  - (2) Trained Inspectors
  - (3) Potential Inspectors
  - (4) Approved Directors
  - (5) Invoicing and Directory Information
  - (6) Inspector Training Workshops
  - (7) Inspector On-Line Training
  - (8) Actual Inspector Assignments
- b. Designs queries and reports for databases.
  - (1) Dates for applications/interim reports
  - (2) Steps in the evaluation process as accomplished for each lab
  - (3) Inspectors qualified to inspect in specific categories
  - (4) Labs accredited in specific categories
- c. Program Management
  - (1) Provides day-to-day management of the Program.
  - (2) Policies and Procedures
  - (3) Keep permanent file for ARB policies and procedures
  - (4) Be knowledgeable about precedents for policies
  - (5) Financial Information
  - (6) Budget Development and Monitoring
  - (7) Travel Approval and Reimbursement
  - (8) Assists Program Director with reports and communications
  - (9) ASHI Quarterly Reports
  - (10) ASHI Board Reports
  - (11) Document Development and Review
  - (12) All Accreditation applications and forms
  - (13) Operations Manual
  - (14) Inspector Training Materials
  - (15) Retention of Deemed Status documentation with Regulatory Agencies
  - (16) Updates the CMS CLIA database with current laboratory information
  - (17) Runs PT monitoring reports regularly from the CMS Database
- d. Communication Conduit
  - (1) ARB Program Director and co-Chairs

- (2) Commissioners
- (3) ASHI Board
- (4) Committees of the ARB
- (5) Inspectors
- (6) Accredited Laboratories
- (7) Labs seeking initial Accreditation
- (8) Executive Director
- (9) Regulatory Agencies – it is the responsibility of the Accreditation Manager and if necessary the ASHI Executive Director (in the Accreditation Manager's absence) to interface with organizations contracted with ASHI for various services
- (10) CMS
- (11) The Joint Commission
- (12) UNOS
- (13) NMDP
- (14) AFDT (formerly SEOPF)
- (15) Other Accrediting Agencies
- (16) The ASHI Director Training Review and Credentialing Committee

e. Inspections

- (1) Works with ARB Executive Board and Inspector Training Coordinator in choosing Inspectors.
- (2) Facilitates communications between Inspector and lab.
- (3) Forwards inspection materials to Inspector(s).
- (4) Forwards copies of the Inspector's Summary Report and evaluations to the Commissioner and Co-Chair electronically.
- (5) Forwards copies of the Inspector, Trainee and Trainer Evaluations to the Inspector Training Coordinator and Commissioner; sends reminder notices if not received within 2 weeks of the inspection.

f. Meetings and Workshops

- (1) Primary Staff to the ARB, Co-Chairs and Program Director.
- (2) Plans and attends meetings and workshops scheduled for the ARB, Inspector Training and the Director Training Review and Credentialing Committee.
- (3) Responsible for registrations for all Inspector training workshops.
- (4) Attends regulatory agency meetings and workshops as appropriate.
- (5) Responsible for minutes of all ARB and Co-Chair meetings and conference calls.
- (6) Coordinates the Inspector Reception at the ASHI Annual Meeting.

*\*ASHI's Director of Operations will fulfill these responsibilities in the Accreditation Manager's absence.*

g. Record Management

The following broad principles apply to the record keeping and records management practices of ASHI:

- ASHI follows sound procedures for the creation, maintenance, retention and disposal of all records, including electronic records.
- The records management procedures of ASHI comply with legal requirements.
- ASHI follows sound procedures for the security, privacy and confidentiality of its records.

The Accreditation Manager is ultimately accountable for the centralized record keeping and records management practices of the ASHI ARB. Commissioners and Co-Chairs of the ARB are instructed to copy the Accreditation Manager on all paper and electronic records that need to be filed.

The Accreditation Manager is committed to enhance accountability, transparency and improvement of service delivery by ensuring that sound records management practices are implemented and maintained. The Accreditation Manager also performs such duties as are necessary to enhance the record keeping and records management practices of ASHI to enable compliance with legislative and regulatory requirements.

The Accreditation Manager supports the implementation of this policy and requires all ARB members to support the values underlying in this policy including commitment to centralization and back up assurance.

#### **(1) Electronic Records**

Heuristic Solutions, LLC is responsible for the day-to-day maintenance of the ARB's centralized electronic system (with the exception of email records, see below) that stores records and shall work in conjunction with the Accreditation Manager to ensure that public records are properly managed, protected and appropriately preserved for as long as they are required for business, legal and long-term preservation purposes.

Heuristic Solutions, LLC shall ensure that all data, audit trail data, operating systems and application software are backed up on a daily, weekly and monthly basis to enable the recovery of authentic, reliable and accessible records should a disaster occur.

#### **(2) Email Records**

This policy applies to e-mail in the same way as it does to records that are created using any other media. The records must be properly stored, preserved and available for access. The ARB email management is the primary responsibility of the Accreditation Manager through Outlook, which is backed up software on a daily basis through Association Headquarters, Inc. (both active & archived materials.) Commissioners and Co-Chairs are instructed to copy the Accreditation Manager on any emails that need to be filed.

- An e-mail message should be filed appropriately if it: contains unique, valuable

- information developed in preparing position papers, reports, studies, etc.
- reflects significant actions taken in the course of conducting business (i.e. is relevant to a laboratory's accreditation status).
- conveys unique, valuable information about ASHI's programs, policies, decisions, or essential actions.
- conveys statements of policy or the rationale for decisions or actions.
- documents oral exchanges (in person or by telephone), during which policy is formulated or other business activities are planned or transacted.
- adds to the proper understanding of the formulation or execution of ASHI's actions or of ASHI's operations and responsibilities.
- documents important meetings.
- protects the financial, legal, and other rights of ASHI and of the persons directly affected by ASHI's actions.
- approves or authorizes actions or expenditure.
- signifies a policy change or development.
- has value for other people or ASHI as a whole.

### **(3) Paper Records**

No records shall be removed from paper-based files without the explicit permission of the accreditation manager. No alterations of any kind shall be made to records other than correspondence files without the explicit permission of the Accreditation Manager. Commissioners and Co-Chairs are instructed to copy the Accreditation Manager on any paper records that need to be filed. Disposal of records is managed on an annual basis by the Accreditation Manager; offsite records that are over 5 years old (7 years old for DTRC portfolios) are destroyed by a paper shredder in a secure manner.

a. Onsite Storage: Each laboratory has a file labeled with its ASHI number that is kept indefinitely at the accreditation office and temporarily at the Commissioner and Co-Chair's office, until their terms on the ARB are complete. (see below re: transition policy.) Each paper file can include the following:

- official letters & certificates of accreditation
- validation
- correspondence from laboratories regarding relocation, changes in key personnel, etc.
- any adverse actions implemented on the laboratory (complaints, sentinel events, repeat deficiencies, etc.)

Other paper files kept onsite solely at the accreditation office include all correspondence with regulatory agencies and other accrediting organizations and all director training documentation.

b. Offsite Storage: Paper-based correspondence files are kept in the custody of Little Canada Mini-Storage a secure facility located at 55 County Road B East, Roseville, MN 55113 for up to 5 years (DTRC portfolios for 7 years). These records are under the control of the accreditation manager who is mandated to ensure that they are managed properly. Although most records are stored electronically at the moment, if anything is

moved offsite it will be tracked and logged by the Accreditation Manager using an internal log book.

#### **(4) Transition Instructions**

Within one month of the ASHI Annual Meeting, the file transfer from outgoing to incoming commissioners and co-chairs will begin and must be complete by the end of the year. Most files are electronic and should be transferred to the new ARB personnel via email, flash drive or CD. Any paper applications or validations over 2 years old should be sent to the Accreditation Manager.

Files to transfer to new ARB personnel should include the following:

- official letters & certificates of accreditation
  - validation under 2 years old
  - correspondence from laboratories regarding relocation, changes in key personnel, etc.
  - correspondence with the laboratory regarding the accreditation/accreditation process
  - any adverse actions implemented on the laboratory (complaints, sentinel events, repeat deficiencies, etc.)
- Applications in LearningBuilder assigned to outgoing commissioners and co-chairs should be completed and date stamped under both commissioners' review. A detailed transition timeline can also be found in this Operations Manual – chapter A, section V, part C.
- h. Certificate Production and Distribution
- (1) Produces and distributes, upon approval, letters and certificates of Accreditation to labs.
  - (2) Forwards copies of the certificates to other accrediting agencies as needed and appropriate.
- i. Invoices and Reimbursements
- (1) Invoices and processes all payments received for laboratory evaluation according to the policies of ASHI.
  - (2) Maintains accurate records of all requests for reimbursement, all invoices issued, all payment received and all expenses paid which are related to the Accreditation Review Board.
  - (3) Issues appropriate notification to the applicant, Accreditation Program Director, co-Chair, and Commissioner whenever payment has not been received in a timely manner.
- j. Maintenance of Manuals, Forms and Web Site
- (1) Copies of all manuals and forms must be available for distribution.
  - (2) These should be maintained in a central location and be readily accessible to the Accreditation Manager.



- (3) The Accreditation Manager will provide the most recent versions of manuals and forms to relevant individuals, including all ARB members, Advisory Committee Members, and Ombudspersons.
- (4) The Accreditation Manager will ensure that the ARB Website includes the most current contact information for ARB Program members and the most recent versions of the ARB Operations Manual, ASHI Standards and Guidance, and ARB Policies
- (4)(5) The Accreditation Manager will ensure that the inspector training modules online are updated at least every other year. This will consist of a full ARB review, ASHI Board approval, and Publications review of any updates.

## J. INSPECTORS

- i. Appointment and Term
  - a. Approved by the Accreditation Review Board after successfully completing one or two training inspections.
  - b. No set appointment time.
- ii. Qualifications
  - a. Active in the computer database for specific areas of expertise
  - b. Employed by an ASHI accredited laboratory.
  - c. Willing to perform on-site inspections in a timely, professional and confidential manner as a voluntary service to ASHI with reimbursement of usual and customary expenses.
  - d. One (1) full day training workshop must be attended prior to becoming a "trainee".
  - e. To maintain active status, the Inspector must attend either an update session(half day workshop) every other year or complete an Accreditation self-study program (on-line).
  - f. The on-line continuing education requires:
    - (1) ARB Update module every year
    - (2) three additional modules during a two year period.
  - g. Performed at least one on-site inspection as a trainee.
  - h. Performs one inspection within one year of transitioning from a trainee to an Inspector.
  - i. To maintain current Inspector status, must perform at least one inspection every two years.
  - j. Meets or exceeds the criteria of General Supervisor as defined in the ASHI Standards. (See also, the Statements of Competence for Histocompatibility Personnel).
  - k. Has a minimum of two (2) of the following criteria:
    - l. Is CHS or meets qualifications for an HLA Supervisor;
    - m. Is an ABHI Diplomat or meets qualifications as an HLA Director or Technical Supervisor
    - n. Has documented technical competency. It is recommended that an Inspector be proficient in at least two of the specific approved technologies listed below:
      - (1) Serology,
      - (2) Molecular, (SSP and SSO)
      - (3) Sequencing/Fragment analysis,
      - (4) Flow cytometry,
      - (5) Solid phase (i.e. ELISA, Microarray beads, etc.)
      - (6) Cellular.
  - o. Inspector continuing training requirements will be met by active service on the Accreditation Review Board and will be equivalent to the requirement of one Inspector Training Workshop (1/2 day) and one inspection every other year.

- iii. Responsibilities
  - a. Performs inspections according to the guidelines in this manual.
  - b. Electronically submits copy of the Inspector's Summary Form and the Checklist to the Accreditation Manager within 2 business days (or by fax if there is a problem with the electronic checklist)
  - c. Notifies the Commissioner whenever there may be a conflict of interest.
  - d. Signs a Conflict of Interest and Statement of Confidentiality annually.
- iv. Selection of Inspectors
  - a. Inspectors must have the qualifications required by ASHI for an Inspector, have completed the requirements for Inspector Training, and are currently "active" in the ARB Inspector database.
  - b. To remain active in the Inspector Database, Inspectors must have performed at least one inspection in the last two years and must attend either an update session (half-day workshop) or completed an Accreditation self-study program (on-line) every other year thereafter. The on-line continuing education requires:
    - (1) ARB Update module every year
    - (2) Three additional modules during a two year period.
  - c. Inspectors must read, sign and adhere to confidentiality agreements each year they are active.
  - d. Inspectors must have appropriate expertise in the Accreditation Areas and technologies in which they will serve as an Inspector.
  - e. The ARB Executive Board consisting of the Program Director, the three co-Chairs, the Inspector Training Coordinator, and the Accreditation Manager select Inspectors.
  - f. Inspectors are asked to volunteer for each cycle by e-mail sent by the Accreditation Manager. The Inspectors may reply that they are available for doing an inspection during that cycle and may request to be sent to a particular location. However, the Inspector Selection group (see above) makes the final selections.
  - g. The Inspector Database is used to match the expertise of the Inspector to the Areas of Accreditation and Technologies to be inspected.
  - h. Individuals eliminated as candidates for inspection of a particular laboratory include the following:
    - (1) individuals employed at the same institution as the applicant laboratory;
    - (2) individuals for whom performance of the inspection involves a conflict of interest;
    - (3) individuals whose objectivity regarding the applicant laboratory, applicant institution, or individuals employed in the applicant laboratory is questionable;
    - (4) individuals lacking expertise in Areas of Accreditation or Technologies for lab being inspected.
  - i. A single Inspector should be utilized whenever possible; however, for large facilities with many Areas of Accreditation, two (or more) Inspectors or one Inspector for two days may be required.
  - j. Laboratories with new Directors or with previous deficiencies related to Director involvement should be inspected by other Directors or Inspectors with ARB experience.
  - k. An Inspector may not accept gifts, honoraria, or other incentives that may be perceived as a conflict of interest during the inspection process.
  - l. The ARB may on its own discretion dismiss individuals from the inspector pool based on poor evaluations, complaints from laboratories, commissioner input, or as deemed necessary.

#### K. USE OF ARB MEMBERS AS INSPECTORS

The ARB should not be perceived as biased toward any lab and the integrity of the three-tier review process should be maintained. However, since the terms of service on the ARB may be four years or longer, it is recommended that ARB members may serve as an Inspector under the following guidelines.

- i. New Commissioners are strongly discouraged from serving as an Inspector during the first 2-year term.
- ii. Other members of the ARB may be used as an inspector, if needed. However, this should be limited to no more than one full inspection per year.
- iii. If any member of the Board serves as an inspector, they are to recuse themselves from the ARB vote for that laboratory.
- iv. Inspector training requirements will be met by active service on the Accreditation Review Board.
- v. Co-Chairs cannot inspect laboratories in their 4 regions

#### L. INSPECTORS FOR INTERNATIONAL LABORATORIES (OUTSIDE CONTINENTAL NORTH AMERICA)

- i. Inspectors for International Laboratories also serve as ambassadors for ASHI and should be individuals who have superior knowledge of the ASHI Standards and interpretative guidelines. They should also have had much experience in performing inspections and outstanding ratings as an Inspector.
- ii. Inspections for International Laboratories should be first offered to a past member of the ARB or an ARB member who has served at least one term.
- iii. If no past ARB member or current member who has served at least three years is available for the inspection, then the inspection can be offered to an individual from the inspection pool who has been noted to be an outstanding Inspector.
- iv. Effort is being made to train inspectors in other countries as more laboratories are obtaining ASHI Accreditation. This should promote a greater sense of "membership" for the non-USA members of ASHI and should help reduce the costs of foreign inspections.

#### M. NOTIFICATION OF INSPECTOR APPOINTMENT TO APPLICANTS

- i. After the Executive Board has appointed an Inspector, the Accreditation Manager will notify the Commissioners of the Inspectors selected for their laboratories.
- ii. If the Commissioner notices a problem with any of the Inspectors chosen, he/she should contact the co-Chair immediately.
- iii. The Accreditation Manager will inform the applicant laboratory by telephone or e-mail of the Inspector appointment.
- iv. The Laboratory Director has one week to appeal the appointment and request a different Inspector. (See Appeal of Inspector's Appointment)
- v. It is recommended that the Commissioner make contact with the laboratory personally to explain the inspection process, if needed. This is especially important for new Commissioners to introduce themselves and for new laboratories that may not understand fully the three-tier review process.

#### N. APPEAL OF INSPECTOR'S APPOINTMENT

- i. If the applicant laboratory has justifiable reason/just cause to believe that the named Inspector cannot perform the inspection without bias, the applicant may request appointment of a different Inspector.
- ii. Such a request must be made in writing to the Accreditation Manager.
- iii. The co-Chairs, Program Director, and Inspector Training Coordinator will be notified and another Inspector shall be appointed.
- iv. The laboratory shall submit to inspection by this Inspector.
- v. The applicant may notify the Commissioner, in writing, if he/she has justifiable reasons to believe the inspection was biased. The Commissioner shall consider such information in rendering a decision about Accreditation.
- vi. All correspondence regarding this matter shall become part of the permanent file

# **Chapter B**

## **The Inspection & Accreditation Process**

## I. INSTRUCTIONS FOR INSPECTORS

### A. GENERAL INSTRUCTIONS

The responsibilities of the Inspector are to evaluate the laboratory personnel, activities and facilities for compliance with the ASHI Standards and to participate in an education process. The evaluation should be thorough, impartial and thoughtful. The interaction between the laboratory personnel and the Inspector has, traditionally, involved a mutually beneficial exchange of information. This educational exchange is a valuable part of the Accreditation process in which the Inspector is encouraged to participate.

The Inspector is a representative of ASHI and is expected to behave in a courteous and professional manner during the inspection and to use discretion in any subsequent discussions about the inspection. The Inspector may not accept any payment or gratuity in the course of performing the inspection. No individual may perform an inspection which involves a conflict of interest or for which the individual's objectivity or impartiality is questionable. It is the Inspector's responsibility to be aware of and adhere to all timetable deadlines.

- i. Upon notification from the Accreditation Manager that the Inspector appointment is acceptable to the laboratory, the Accreditation Manager will promptly forward all materials to the Inspector.
- ii. At the time the Inspector accepts the assignment, he/she should be provided with the blackout dates so the Inspector can proceed with arranging an inspection date as soon as possible.
- iii. The Inspector should be informed that he/she will receive the application materials, (completed Packet from the laboratory), ASHI Standards and Guidance, , travel reimbursement form and a set of instructions.
- iv. The Inspector must review all materials thoroughly prior to the inspection date.
- v. The Commissioner should provide the Inspector with
  - a. A copy of the previous deficiencies of Standards and laboratory response to deficiencies in order to ensure that corrective actions have been effective;
  - b. A copy of deficiencies or special concerns found by the Commissioner after review of the application materials. The Inspector will check these items during the inspection and report as deficiencies, if verified.
- vi. Inspectors should be informed of all applicable deadlines.
  - a. Inspections occur within an 8 week period designated by the Accreditation Manager.
  - b. The Inspector must electronically complete the Inspector's Summary Report and
  - c. leave a copy with the laboratory. Any other comments, clarifications, or overall impression of the laboratory should be submitted to the Commissioner within one week of the inspection.
- vii. A trainee can accompany the Inspector if this can be accomplished without incurring significant additional cost to ASHI. In all instances the ARB Executive Board must approve this in advance.

### B. INSPECTION SCHEDULING

- i. Upon acceptance of a non-USA inspection assignment, the Inspector should contact the applicant at the earliest opportunity to establish a mutually agreeable inspection date. The inspection must be scheduled when the Director and other key personnel will be present. However, at that time, the Inspector should also contact the laboratory to discuss the planned arrival time and to ask for directions to the laboratory, as appropriate.
- ii. For USA inspection assignments, once the laboratory approves the inspector, the inspector is to make travel arrangements **without** contacting the laboratory – in consideration of the blackout dates provided by the laboratory. Once the inspector has set a date and made travel arrangements he/she must immediately notify the Accreditation Manager. The Accreditation Manager will notify the laboratory (Director and Supervisor) exactly two weeks prior to the inspection date. Prior to that time, only the Accreditation Manager and the laboratory's Commissioner will be notified of the inspection date.
- iii. The inspection is scheduled within the 8 week period designated for the specific cycle of inspections. The most economical form of transportation must be utilized.
- iv. If air travel is necessary, the inspection must be scheduled on a date, which allows utilization of discounted airfares. The designated ASHI Travel Agent should be used in most cases to make airline reservations.

#### C. PERFORMANCE OF THE INSPECTION

- i. For domestic labs, the inspection should be a single day procedure, in most cases. Larger laboratories may require two (2) Inspectors for one (1) day or one (1) Inspector for two (2) days, depending upon the size of the lab and numbers of the Areas of Accreditation and Technologies being inspected.
  - a. For a one (1) day inspection, the inspector will be reimbursed for up to two (2) nights of hotel/lodging fees.
  - b. For a two (2) day inspection, the inspector will be reimbursed for up to three (3) nights of hotel/lodging fees.
- ii. For international labs (outside of North America) since the cost of international travel may exceed the Accreditation fee, particularly when there are time constraints on travel. These additional expenses should not be borne by the other laboratories through a general increase in Accreditation fees.
  - a. The applicant laboratory is responsible for lodging costs of the Inspector(s). A one day laboratory inspection will allow for no more than three nights expense, a two day inspection will allow for a 4 night expense. Multiple laboratory inspections during the same trip have to have the length of stay pre-approved by the ARB Executive Board before booking.
  - b. Airfare costs that exceed the annual Accreditation fee may be billed to the laboratory upon discussion with the Accreditation Manager.
- iii. Prior to the inspection, the Inspector should thoroughly review the appropriate version of the Standards;
  - a. Review the application packet and materials to become familiar with the size and scope of the laboratory service and to ensure that the following meet ASHI, CLIA, State or other deeming agency requirements:
    - (1) Personnel

- (2) Continuing Education Credits
  - (3) Proficiency Testing
  - (4) Adequacy of staffing
  - (5) Appropriate resolution of typing is done for categories desired
  - (6) Review protocols for appropriateness to Area of Accreditation
  - (7) Review Reports and case files for completeness and appropriate interpretations
  - (8) Review Quality Assessments for appropriate monitoring of indicators of quality
  - (9) Check to see if appropriate corrective actions were taken
- b. Customize a checklist by selecting appropriate Areas of Accreditation and Technologies online for the laboratory to be inspected.
  - c. Review the Commissioner's summary of concerns or issues found during review of inspection materials.
  - d. Review previous deficiencies and laboratory response submitted by the Commissioner.
  - e. Contact the Commissioner to discuss any potential problems that may need to be investigated with the laboratory.

#### D. REVIEWS AND AUDITS DURING THE INSPECTION

- i. Randomly check reports and use audit method to check for documentation that testing was done according to laboratory procedures and policies. Examples of what may be checked during an audit are
  - a. Select random reports within the last 2 years (since the last onsite inspection) and check for ASHI requirements. Use these reports to perform audit.
  - b. Review worksheets for accuracy of interpretation of raw data.
  - c. Check for tech initials and documentation of review.
  - d. Check that tech that performed test had competency documented to perform test. Check training records.
  - e. Check that QC performed the day of testing met criteria for acceptance of results. Check that QC for the reagents used in the tests met criteria
  - f. Check that periodic maintenance was done on equipment used for this test.
  - g. Check that proficiency tests reflect reported results.
  - h. Check that proficiency testing is done for all methods used in reporting results
  - i. Check that turnaround time meets laboratory policy
  - j. Check flow of specimen through lab and safeguards to prevent sample mix-up
- ii. Internal Proficiency Checks
  - a. Each histocompatibility-testing individual must perform a periodic (as defined in ASHI Standards) internal proficiency quality control or blind unknown sample testing to assess competency of technologists.
  - b. For each technology the individual is authorized to perform, at least one internal PT exercise must be completed each year.
  - c. Internal proficiency may include testing of unknowns such as external proficiency samples or previously tested samples.
  - d. Internal proficiency can also be designed to evaluate tech-to-tech variations in scoring, reproducibility, or interpretation of results or case studies.



- iii. Review of Procedure and Policy Manuals
  - a. Review the procedure manual(s) to determine if there is evidence of review by the Director at least every 2 years.
  - b. Check to see that the Laboratory Director has signed every procedure.
  - c. Observe as many techniques as possible to determine that the procedures performed follow and agree with those described in the manual.
  - d. Determine if procedures are being updated as needed.
  - e. Check to see that old procedures are kept for at least two years.
  - f. Determine if the laboratory has a system in place to track when procedures were changed.
  
- iv. Review of Laboratory Practices
  - a. The Inspector should spend some time in the actual laboratory observing techniques and questioning technologists about the testing process.
  - b. Observe laboratory processes or preparations such as:
    - (1) Observe a cell suspension or DNA prepared that day and note the quality of the preparation.
    - (2) Read a tray taken at random and note the quality of the cell preparation and the accuracy of the scoring of results.
    - (3) Specimen handling and identification throughout the testing process (from specimen receipt to final reporting).
    - (4) New Lot Validations such as
      - (a) Parallel testing with reference DNA (previously typed);
      - (b) Include as many different alleles as possible for number of samples tested;
      - (c) Include alleles that have been problematic in past;
      - (d) Include alleles for primer sets that have changed since last lot, if possible;
      - (e) False positive and False negative results should be documented
      - (f) Date in Use should be recorded
    - (5) QC of New Shipments, including:
      - (a) Ensure that all components are working properly;
      - (b) Test with Reference DNA or non-critical patient sample;
      - (c) Assess quality of reactions and ability to give clear interpretation;
      - (d) Document QC check and record Date in Use.
    - (6) Water quality, keeping in mind that reagent water that comes from a manufacturer with a quality certificate is acceptable and does not require conductivity tests or cultures. The laboratory must keep a copy of the manufacturer's certificate on file. Water that is purified locally does require conductivity tests and cultures at intervals determined by the laboratory.
  
- v. Review of Quality Assessment and Facilities
  - a. Review documentation and observe the facilities sufficiently to determine if the applicant is in compliance with the standards. Carefully review the QA policies and ascertain that these are implemented in the laboratory. Check for documentation in all areas, such as:

- (1) Determine that a formal Quality Assessment Program is established and functioning in the laboratory;
- (2) Determine if the Indicators of Quality are being monitored appropriately (ex. QC checks, PT performance, turnaround time, specimen problems, lab errors, amended reports, etc.);
- (3) Determine that corrective actions are appropriate;
- (4) Determine if appropriate follow-up is being done to ensure the effectiveness of corrective actions

vi. Review of Case Files

- a. Inspectors must review case files representing each Area of Accreditation and each Technology for which the applicant is seeking Accreditation (histocompatibility testing for living-related solid organ transplantation, etc.).
- b. There should be interpretive notes, if applicable entered by the Laboratory Director in at least some case files in each area of Accreditation.
- c. If such evidence is absent, interview the Director to determine the extent of review and interpretation provided.
- d. Review case files to ascertain that proper nomenclature is used and that phenotypes and genotypes are assigned correctly.
- e. Review crossmatch test results to determine if the procedures followed are in compliance with the Standards.
- f. Review antibody testing analysis to determine if correct specificity is being assigned.
- g. Review the process to determine how antibody testing information is incorporated into the crossmatch analysis.
- vii. Audit reviews include evaluation of reagent quality control, employee training and competency evaluation and PT outcome associated with the cases reviewed.
- viii. Review engraftment studies, if performed, to determine if chimerism results are correctly analyzed.
- ix. Review cell surface phenotyping studies, if performed, to determine if the results are correctly interpreted.
- x. The Inspector is encouraged to make notes during the inspection process to be used in preparing the Summary Report. The evaluation of any individual item should be discussed with the applicant so that there is no surprise deficiencies cited during the exit summary. If the applicant requests information about the overall evaluation or decision regarding Accreditation, the Inspector should caution the applicant that the on-site inspection is only one part of the Accreditation process and that any information provided by the Inspector is not to be interpreted as a final decision regarding Accreditation.

E. CLIA LABORATORIES

- i. For laboratories using ASHI for CLIA inspection, the Inspector must:
  - a. Review CLIA certificate for testing categories approved by CLIA.
    - (1) A laboratory doing HLA typing of donors for inclusion in the NMDP donor registry must meet the lab requirements of CLIA and have a CLIA number if located in the U.S.

- ii. Determine if there are any testing categories on the Accreditation certificate that are not being inspected by ASHI.
  - a. If so, determine if another Accrediting Organization inspects for these additional tests. Report this finding on the Inspection report.
- iii. The ASHI Accreditation Office will notify the appropriate CMS Regional Office when a laboratory is found to be testing beyond its approved specialties and subspecialties without appropriate oversight by another accrediting organization.

#### F. PREPARATION OF THE INSPECTOR'S SUMMARY REPORT

- i. Before the exit interview or summation, the Inspector must complete the Inspector's Summary Form from the Inspector's observations during the inspection and subsequently printed on the electronic Inspector's Checklist.
- ii. Inspectors are expected to provide a complete description of the deficiencies and recommendations including what was observed and why it is considered a deficiency/recommendation. This description should include commentary on completeness and/or severity of the deficiency or recommendation. For example if a laboratory performs competency assessment, but does not have full observation of equipment function, the inspector should provide this level of detail.

#### G. EXIT INTERVIEW (Summation)

- i. One of the most important duties of the Inspector is to inform the Laboratory Director and other appropriate staff of all deficiencies noted during the inspection process. This is accomplished at the close of the inspection via an "exit interview" or summation. Should a Director refuse an Exit Interview, he/she must indicate such on the signoff sheet.
- ii. The Inspector must go through the complete checklist and inform the laboratory staff of his/her findings and any deficiencies noted.
- iii. The Inspector must also stress that the function of the Inspector is to observe and record findings based on the appropriate checklist.
- iv. There should be no big surprises at the Exit Interview, as the Inspector should be communicating his/her findings during the inspection process. Often the staff or the Director can clear up what may appear to be a deficiency by supplying additional documentation that was not immediately evident to the Inspector. Some small deficiencies may be corrected immediately. These will still be listed as deficiencies with a note "corrected onsite". In this situation, as applicable, the laboratory must submit documentation of corrective action in LearningBuilder.
- v. If the Laboratory Director does not agree with the Inspector, there will be an opportunity to express those opinions when responses to the deficiencies are submitted to the Commissioner.
- vi. Inspectors are also encouraged to provide the Laboratory Director with appropriate corrective actions suggestions, for any deficiencies noted whenever possible.
- vii. The intent of the ASHI inspection is to assist laboratories into being compliant with current ASHI Standards.
- viii. The Laboratory Director must sign the Inspector's Summary Report before the Inspector departs from the laboratory. The Inspector will leave a copy of the Inspector's Summary Report with the laboratory as well as electronically submit to the Accreditation Manager within 2 days.

## H. CONFIDENTIALITY of LABORATORY DATA

- i. The Inspector must sign a confidentiality agreement prior to performing an inspection.
- ii. Inspectors must leave their copy of the laboratory's Application packet with the laboratory at the end of the inspection, unless parts are required for further review by the Inspector post-inspection. In this case, the application materials must be submitted to the Commissioner along with all other inspection documentation materials.

## II. INSTRUCTIONS FOR COMMISSIONERS

### A. PRIOR TO INSPECTION

- i. The Commissioner completes a review of the inspection materials in the same manner as the Inspector, and documents date and issues identified in the LearningBuilder summary report under Commissioner Findings.
- ii. The Commissioner informs the Inspector of any issues, concerns, or possible deficiencies that were noted during the Commissioner's review of the inspection materials. Communication is dated and documented as above in LearningBuilder.
- iii. The Commissioner sends a copy of the deficiencies cited during the previous on-site inspection and last interim inspection within two weeks of the inspection.
- iv. Commissioners may opt to use the "commissioner inspection report" template (Appendix VII) to document ongoing inspection processes in place of documenting each step in LB. If so, the final document MUST be uploaded at "Commissioner Response to Inspection."
- v.

### B. AFTER THE INSPECTION

- i. The Accreditation Manager will send the Inspector's Summary Report to the Commissioner and Co-Chair upon receipt.
- ii. The commissioner reviews the Inspector's Summary Report and contacts the inspector and/or laboratory Director within one week to document review. The review is documented and any additional issues listed under "Commissioner Findings" in the summary review of the LearningBuilder application.
- iii. If the Commissioner does not concur with the interpretations made by the Inspector, he/she will discuss this with the co-Chair, then discuss with the Inspector and the Laboratory Director. The Commissioner may then make changes to the inspection report such as adding or removing deficiencies prior to sending the report back to the Laboratory Director within one week. Such changes are made and documented in LearningBuilder.
- iv. The Laboratory Director has 30 days from the inspection to respond to Deficiencies. The responses and corrective actions are uploaded into LearningBuilder for review by the Commissioner. The commissioner documents the date of the CA and any comments under the Corrective Actions section of the summary report in LB.
- v. The ARB will review the deficiencies during the ARB meeting and may decide to add or remove a deficiency. The laboratory and Inspector will be notified of the ARB's decision, if applicable. The date and detail of this decision will be documented under "Remaining Issues of Concern."

### C. PREPARATION FOR ARB PRESENTATION

- i. Once all deficiencies have been satisfactorily addressed or the laboratory's action plan for resolving them has been accepted, a Review Board Online Summary Form is completed for presentation at the appropriate meeting of the Accreditation Review Board. This Summary is to contain an overall evaluation of the inspection and the respective recommendations of the Inspector and Commissioner regarding Accreditation. Deficiencies are listed and the laboratory's response to deficiencies is included either after the citation or in the corrective action box. The Commissioner and co-Chair present this information to the full Accreditation Review Board and a vote is taken of the entire board as to the Accreditation status of the applicant laboratory.

## III. ARB REVIEW AND ACTIONS

### A. GRANTING ACCREDITATION

- i. The Commissioner, Inspector, and ARB recommend that Accreditation be granted. The respective Co-Chair notifies the Director in writing that no deficiencies were found or that any deficiencies found were satisfactorily resolved, accompanied by an Accreditation certificate listing those areas for which the laboratory has been accredited. This summary letter should indicate that the applicant was found to be in compliance with all mandatory standards (and recommended standards, if applicable) relevant to the Accreditation areas designated and should also include the categories and systems for which the laboratory is approved. Any appropriate recommendations relevant to the standards must be included in the report.

### B. CONTINGENT ACCREDITATION

- i. Under rare circumstances a laboratory will be unable to complete required corrective actions prior to the date that their accreditation expires (complex deficiencies, deficiencies added or recommendation upgraded by the full ARB). In these cases, the Commissioner recommends granting Accreditation contingent upon additional corrective action. These contingencies are reviewed by the full ARB which will decide whether or not to accept the recommendations and to decide the timeframe for submission of the corrective actions. All outstanding issues must be resolved within 30 days of the lab's accreditation expiration. The contingency and due date for corrective action must be documented in the contingency section of the commissioner summary report in LB and stated in the accreditation letter to the laboratory. The application will remain open until the contingency has been satisfied.
- ii. The laboratory will be informed that written evidence of correction of the deficiencies is to be sent to the commissioner and the Accreditation Office prior to the deadline set by the ARB. If the response meets the requirements as stated by the full ARB, the commissioner documents/dates this response in LearningBuilder. The co-chair will review and the application is accepted by the Accreditation Manager. Documents are uploaded to the LearningBuilder application (where possible) or maintained by the AM (electronic or paper). A new accreditation letter will be sent to the laboratory. In the event that the laboratory does not satisfy the contingency, their accreditation will be suspended and the lab notified

within 7 days that they must cease testing. All laboratories with contingencies will be reviewed at the next Board meeting to document that the conditions for Accreditation were met. The Accreditation Manager will maintain a contingency list for each cycle. The commissioner is responsible for ensuring that all contingencies have been resolved prior to the next ARB meeting.

#### C. DENYING ACCREDITATION

- i. If the Commissioner and Inspector recommend denying Accreditation, the respective co-Chair may either choose to support this decision or not. In case of the latter, the Accreditation Review Board must be informed in detail by the co-Chair as to the reason for the variance. In either case, a poll of the Accreditation Review Board will determine the Accreditation status of the laboratory and the scope and timeframe of any further requirements to complete the process. The Accreditation status, as well as the timeframe for submission of any outstanding documents, will be communicated to the applicant by the respective co-Chair as in "B-i" above.
- ii. In those cases the co-Chair chooses to recommend denial of Accreditation despite favorable recommendations from the Commissioner and Inspector, he/she must inform the Accreditation Review Board in detail as to the reason for the variance. The Accreditation Review Board will then vote on granting or denying Accreditation.
- iii. If the Commissioner and Inspector disagree as to granting or denying Accreditation, the Accreditation co-Chair will carefully critique the full packet and supporting documentation and report his/her findings in detail to the Review Board, emphasizing those points in which the Commissioner and Inspector are at odds. A vote from the Accreditation Review Board will determine the Accreditation status of the laboratory and the scope and timeframe of any further requirements to complete the process. The Accreditation status, as well as the timeframe for submission of any outstanding documents, will be communicated to the applicant by the respective co-Chair as described in "B-i" above.
- iv. If a deficiency cited by the Inspector is overruled by the ARB during the review process, the deficiency must be noted as overruled in the ARB Summary Report. The laboratory and the Inspector will be notified of the ARB's decision in a letter, if applicable. The deficiency is removed from the Summary Report for subsequent lab inspection follow up.

#### D. MANDATORY DEFICIENCIES

- i. Four deficiencies are considered to be Mandatory Deficiencies by CMS in the case of labs testing samples from US patients. These Mandatory Deficiencies are:
  - a. Failure to fill a "key" laboratory personnel position (Director, Technical Supervisor, Clinical Consultant, General Supervisor, or necessary testing personnel) with a qualified individual for any time period.
  - b. Failure to enroll in Proficiency Testing (or equivalent) for any approved test system.
  - c. Exchange of information or samples with another laboratory involved in reporting Proficiency Testing results, until after the cut-off date for submitting PT results to the provider.
  - d. Failure to successfully participate in Proficiency Testing
    - (1) Unsuccessful participation in Proficiency Testing occurs when any two of three consecutive Proficiency Testing results are unsatisfactory using a rolling timeframe. Three consecutive unsatisfactory performances or three of four are considered to be two unsuccessful performances and therefore a repeat deficiency.

- ii. Repeat deficiencies are serious occurrences since they could only happen in the face of a laboratory's previously having submitted a corrective action plan for a previous deficiency and that plan having been approved by the ARB. ASHI has deemed status for CMS and CMS regulations require that actions be taken in response to repeat deficiencies.
- iii. A Repeat Deficiency Report (Appendix VI) is created for all repeat deficiencies by the laboratory's Commissioner. The completed form is sent to the Accreditation Office for record keeping. A summation of the findings or a copy of the report is documented in the laboratory's most recent accreditation application in Learning Builder.
- iv. If a mandatory or repeat deficiency involving the same problem and the same standard is reported to the Commissioner by an on-site Inspector or is observed by the Commissioner in the course of reviewing the laboratory's next on-site or next Interim re-accreditation application, the following sequence of events will occur:
  - a. If a laboratory is cited for a different standard, but it appears to be a repeat deficiency, the ARB can and if deemed appropriate cite the previous standard as a repeat deficiency. The sequence of events below will occur:
    - (1) The Commissioner will verify that there indeed is a mandatory or repeat deficiency by contacting the Inspector and/or contacting the Laboratory Director, as appropriate.
    - (2) If it is verified that there is a mandatory or repeat deficiency, the Commissioner will make a preliminary assessment of the seriousness of the deficiency in relation to its potential to affect patient care.
    - (3) The Commissioner will then contact the Co-Chair and they will determine together whether or not immediate action is necessary. If immediate action is necessary, a Conference call involving the Commissioner, all Co-Chairs and the Program Director will be arranged.
    - (4) If immediate action is not deemed to be necessary, the situation will be discussed at the next full ARB meeting or during a full ARB Conference call if such a call is scheduled in any case for other reasons.
    - (5) Outcomes from the immediate or full-ARB consideration of the situation will depend on the Mandatory Deficiency status of the deficiency, the seriousness of the deficiency in relation to patient care, the reasons for failure of the laboratory's previous corrective action plan and the track-record of the laboratory in relation to its compliance with other ASHI Standards. These outcomes may include, as examples:
      - (a) Complete or limited suspension of the laboratory's accreditation with an obligation for outsourcing all or limited testing to an ASHI accredited or ARB approved laboratory until re-instatement of the accreditation has been approved. For a second instance of unsuccessful CMS regulated analytes; the suspension of testing is mandatory for laboratories testing samples from U.S. patients and would be for a minimum of 6 months.
        - 1. Reinstatement of testing requires satisfactory performance in 2 consecutive new PT send-outs from CMS approved vendors.
      - (b) A scheduled or unannounced ad-hoc laboratory inspection
      - (c) A recommendation that the laboratory seek expert advice from a particular ASHI member and then submit a new corrective action plan
    - (6) In cases in which the decision involves a complete or limited suspension of the laboratory's accreditation, the laboratory will be informed about and given the

- opportunity to appeal the decision of the ARB Executive Board or of the full ARB, as applicable, according to processes described in the ARB Operations Manual.
- (7) In addition to the above steps, mandatory deficiencies and subsequent corrective actions will be reported to CMS within 30 days.

## E. EVALUATION OUTCOMES

The Accreditation Review Board defined five evaluation outcomes based on the Federal Regulations paradigm as follows:

- i. Grant or Renew Accreditation
  - a. Accreditation is given in this Area of Accreditation if a laboratory is in compliance with all relevant Standards, regulations, and requirements and there are no issues that require immediate follow-up. Accreditation is granted or renewed outright, but may also be accompanied by recommendations.
  - b. A laboratory can maintain Accreditation for a Testing System that is not currently used by continuing to successfully participate in Proficiency Testing that uses that Testing System.
- ii. Grant or Renew Accreditation with Contingencies
  - a. Accreditation is granted contingent upon the resolution of an issue that is described in the Accreditation letter. Contingencies may include such issues as approval of the Director by the DTRC, review of blind parallel testing that is not yet complete, successful performance on enhanced proficiency testing, quarterly submission of PT, etc. The approval with contingencies may only be granted if:
    - (1) The deficiencies, collectively, do not represent a threat to patient care or a hazard to the general public (this includes lab personnel);
    - (2) The deficiencies can be corrected within a reasonable time (usually, but not necessarily, 30 days). Notable exception to the 30-day rule is when the deficiency is inadequate or unsatisfactory space/facilities. In this case, the authorized individual from the parent institution must submit a letter outlining a plan of corrective action.
  - b. The Accreditation Manager will compile a contingency list of the labs that were approved with contingencies. The list will indicate the Laboratory, Director, Commissioner, and contingency requirement. The list will be distributed to all members of the ARB within two weeks following the meeting.
  - c. Commissioners must report at the next ARB meeting on the progress of the lab in meeting the contingency requirements. The laboratories that have met the requirements will be removed from the list.
  - d. The Review Board will decide upon appropriate action for labs that have not met the requirements of their contingencies. Appropriate action may include denial, revocation, suspension, or limitation of accreditation. The follow-up action must be communicated to the laboratory, monitored, and recorded in LearningBuilder. [493.557(a)(4)]
- iii. Deny or Revoke Accreditation
  - a. The deficiencies collectively, represent a threat to patient care and/or a hazard to the general public that the lab is unwilling or incapable of correcting immediately, OR



- b. There are substantial deficiencies and the deficiencies cannot be corrected in a reasonable amount of time, OR
- c. The laboratory fails to have satisfactory evidence that it has taken steps to correct the problem.
- d. In the case of laboratories with CLIA Certificates using ASHI for deemed status, CMS is notified within 30 days by the Accreditation Office.
- e. The laboratory must cease reporting results until the laboratory is re-Accredited, unless the laboratory has its CLIA certification from another Accrediting Organization. Testing must be sent to a qualified reference laboratory in the interim.
- f. In the case of laboratories using ASHI for deemed status with UNOS, NMDP, The Joint Commission or other exempt state, those organizations will be notified of this decision within 30 days by the Accreditation Office.
- e-g. \_\_\_\_\_

iv. Suspend Accreditation

- a. Used when the operation of the laboratory poses a threat to patient care and/or a hazard to the general public and there is evidence that the laboratory is capable and willing to correct the problem(s) in a reasonable time.
- b. There has been no clinical activity in an Area of Accreditation in the last 12 months with the exception of the areas "Testing for Other Clinical Purposes" and "Transfusion Support" when test methods used are the same as those used for other clinical testing. The Area of Accreditation may be re-instated when the laboratory shows that clinical activity has resumed and has validated technical competence (the lab must have remained active in proficiency testing). Reinstatement requires notification from the laboratory in writing that activity has resumed.
- c. In the case of laboratories with CLIA Certificates using ASHI for deemed status, CMS is notified within 30 days by Accreditation Office. Notification should occur within 10 days in cases of immediate jeopardy.
- d. The laboratory must cease reporting results for tests no longer accredited until the laboratory is re-accredited, unless the laboratory has its CLIA certification from another Accrediting Organization.
- e. When suspension of accreditation occurs, a notification letter is sent to the laboratory. The letter will instruct the lab to cease testing. If the laboratory accepts specimens for referral, they must be referred to a CLIA certified laboratory.
- f. Suspended laboratories must apply for reinstatement by the start of the next accreditation cycle (March 1, July 1, or November 1) or ASHI accreditation will be revoked.
- g. In the case of laboratories using ASHI for deemed status with UNOS, NMDP, The Joint Commission or other exempt state, those organizations will be notified of this decision within 30 days by the Accreditation Office.
- f-h. \_\_\_\_\_

v. Limit Accreditation

- a. Accreditation is granted in some but not all areas for which the laboratory has applied.
- b. Limited Accreditation is given when:
  - (1) Deficiencies sufficient to deny Accreditation are limited to certain areas of Accreditation, OR
  - (2) There are insufficient data submitted for evaluating a certain Area of Accreditation

- c. In the case of laboratories with CLIA Certificates using ASHI for deemed status, the Accreditation Office notifies CMS within 30 days.
- d. The laboratory must cease reporting results for tests no longer accredited until the laboratory is re-Accredited, unless the laboratory has its CLIA certification from another Accrediting Organization.

e. Testing must be sent to a qualified reference laboratory in the interim.

f. In the case of laboratories using ASHI for deemed status with UNOS, NMDP, The Joint Commission or other exempt state, those organizations will be notified of this decision within 30 days by the Accreditation Office.

e.g. \_\_\_\_\_

v.i Circumstances for enforcement

a. Accreditation may be revoked, suspended, or limited when the owner, operator, or any employee of the laboratory:

- (1) has been guilty of misrepresentation in obtaining the accreditation;
- (2) has performed or represented the laboratory as entitled to perform laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized by the accreditation organization;
- (3) has failed to comply with the accreditation organization's requirements or the standards;
- (4) has failed to comply with reasonable requests for any information or materials, or work on materials that is necessary to determine the laboratory's continued eligibility for its accreditation or continued compliance with the standards;
- (5) has refused a reasonable request for permission to inspect the laboratory or its operation and pertinent records during the hours the laboratory is in operation;
- (6) has violated or aided and abetted in the violation of any provisions of the sections of the law or of any of the implementing regulations
- (7) has not complied with an "intermediate" type sanction

b. If the laboratory intentionally refers proficiency testing samples to another laboratory for analysis, CMS is notified and accreditation is revoked for a period of at least 1 year.

#### F. ISSUANCE OF ACCREDITATION CERTIFICATE AND LETTER

- i. Following approval by the full ARB, the laboratory will be issued a new Certificate after on-site inspections with a 2 year expiration date. The Certificate will list the Laboratory Name, the ASHI number, Director name(s), and the Areas of Accreditation and the CLIA number as applicable.
- ii. After each on-site or interim inspection and upon approval by the ARB, the laboratory will be issued a letter summarizing the decision of the ARB, listing any contingencies, and listing the Areas of Accreditation and Testing Categories and Systems approved for the laboratory.
- iii. The ARB reserves the right to share copies of the accreditation letter & certificate (and final accreditation decisions) with deeming agencies, hospital administration, and laboratory clients, as appropriate, especially in cases of serious ASHI standards violations, immediate jeopardy situations, and sentinel events.

#### G. RE-ISSUE OF AN UPDATED ASHI CERTIFICATE

- i. A laboratory may occasionally require an updated certificate due to changes in information on the certificate. When warranted, an updated certificate will be prepared and released to the laboratory upon receipt of the original certificate by the ARB Accreditation Manager. The laboratory should not be in possession of multiple certificates with overlapping Accreditation periods.
- ii. In the event of a change in Director, the existing certificate may remain in the laboratory until such time that the focused "Change of Director Ad hoc Inspection" is completed or waived and the new Director is approved by the ARB. At that time a new certificate will be issued.

#### **IV. AD HOC INSPECTIONS**

Ad hoc inspections during off-site inspection or interim years are needed to clarify questions Commissioners or co-Chairs may have related to the laboratory's continued compliance with ASHI standards. Ad hoc inspections and other non-routine inspections (surveys) may be scheduled or unannounced as warranted by the condition. All expenses for an ad hoc inspection are to be charged to the laboratory. There will be additional processing fee charged to the laboratory.

##### **A. CONDITIONS WHICH WARRANT AN AD HOC INSPECTION**

- i. A request by the applicant to add new Areas of Accreditation and/or in some cases new Technologies before the next on-site inspection.
  - a. The Laboratory must submit Test Data (see Test Data Submission requirements for new labs);
  - b. The Laboratory must submit a Validation Packet (see the Validation Checklist);
  - c. The Director/Technical Supervisor must submit a portfolio and get DTRC approval for addition of a new Area of Accreditation;
  - d. The Accreditation Manager will process the packet during the next available cycle
  - e. The Laboratory will bear the cost associated with arranging the appropriate inspection and the cost of the application process;
  - f. Following approval of the ARB, an updated certificate, using the same dates as the original certificate, will be issued with an effective date of the new Area of Accreditation noted.
  - g. The focused inspection for adding a new area of accreditation may be waived by a vote of the full ARB if documentation is submitted to the Commissioner before the new area is added. The following criteria must be met:
    - (1) The director is DTRC approved for the area of accreditation;
    - (2) All methods, systems and categories associated with the new area of accreditation are already established (no new validations);
    - (3) Technical staff experience is adequate;
    - (4) There has been no change in General Supervisor within 1 year;
    - (5) There are no outstanding contingencies on their accreditation status in the past year.
    - (6)
- ii. Changes in procedures or personnel which are sufficiently expansive to render the applicant's compliance indeterminate without on-site evaluation.
- iii. Relocation of the laboratory

- (1) On-site inspections are required for some labs that have re-located, even if the new location is within the same building.
- (2) The inspection shall occur within a reasonable time (generally 3-6 months after the move)
- (3) The ad hoc inspection for re-location may be waived if the laboratory is inspected by another agency for this purpose (ex. State inspection for re-location).
- (4) The inspection for re-location may also be waived by a vote of the full ARB if documentation is submitted to the Commissioner within 3 months of relocation and if the following criteria are met:
  - (a) Documentation that the new lab square footage is comparable or better than the old lab square footage
  - (b) Photographs of the new space can be provided
  - (c) A plan for handling of Protected Health Information (PHI) is provided
  - (d) A hazardous waste storage/disposal plan is provided
  - (e) A description of the refrigerator/freezer alarm system is provided
  - (f) A plan for assessment of or documentation of relocated equipment function at the new location
  - (g) The new Floor Plan demonstrates:
    1. Adequacy of space
    2. The location of safety equipment
    3. Fire exit routes
    4. Office space/paperwork areas
    5. The location of wet lab areas
    6. Placement of equipment
    7. Traffic Flow
    8. The location of pre-amp and post-amp areas
    9. Room temperature charts

iv. Investigation of a complaint, if deemed necessary by the ARB Executive Board.

v. Change in Director/Technical Supervisor

- a. An on-site inspection will normally occur after a reasonable time (generally 3-6 months) after the change.
- b. The inspection should involve a single day by a single Inspector.
- c. The focus will be those items that directly involve the Laboratory Director/TS.
- d. The Inspector will include an evaluation of the new Lab Director/TS role in the laboratory in relation to the responsibilities outlined in the Standards and Guidelines.
- e. In cases of temporary/interim Directors, an inspection will reoccur in 3-6 months if a new permanent Director has not been identified.
- f. The inspection may be waived if there is another qualified Director already onsite.
- g. The inspection may be waived by a vote of the full ARB if documentation is submitted to the Commissioner within four (4) months of the initial notification that the following criteria are met:
  - (1) The director is currently responsible for no more than 2 ASHI accredited laboratories;
  - (2) The qualifications of the Director match the Areas of Accreditation and Technologies in the new lab;
  - (3) No Director involvement problems existed at the previous labs;
  - (4) The Lab has successfully completed one send-out of PT in each test category under the new Director; sent to commissioner as available

- (5) There has been review of laboratory protocols, procedures, and QA program by the Director as documented, e.g. by copies of signed coversheets for protocols and procedures OR a letter listing procedures, protocols and QA program reviews;
- (6) Evidence is provided for resolution of pre-existing issues, deficiencies, and contingencies in new laboratory;
- (7) Technical staff experience is adequate;
- (8) There has been no change in General Supervisor within 1 year;
- (9) A written plan for coverage is submitted if the Director position is part time;
- (10) A written plan for delegation of Director responsibilities is submitted.

## V. SPECIAL CIRCUMSTANCES

### A. INVESTIGATION OF COMPLAINTS/GRIEVANCES

Accreditation awarded by ASHI is valid only as long as a laboratory remains in compliance with ASHI Standards. Normally, a laboratory's compliance is evaluated during the annual renewal, but instances may arise when a laboratory's adherence to Standards may be in question and may warrant evaluation prior to the next annual review.

- i. A complaint is a report made to ASHI that alleges noncompliance with ASHI Standards or with Federal and/or State laws and regulations
- ii. Complaints may be received by the ASHI Executive Office, ARB Members, or ASHI Board Members.
- iii. Calls or complaints received from any source must be immediately forwarded to the ARB Program Director and/or Senior Co-Chair as appropriate. All complaints will be initially evaluated by the ARB Executive Board that will develop a plan of action to investigate and resolve the issues put forth in the complaint. Then the ARB Executive board will request approval of its plan of action from the ASHI President and/or President Elect, who will decide if legal review and/or ASHI Board of Directors review is needed. Throughout the review process and as much as possible during the entire complaint investigation, the identity of the complainant(s) will be kept confidential among the individuals listed above, to the extent allowed by law. Situations involving immediate jeopardy threats will be acted upon within 2 working days.
- iv. Plans of action may include a decision that the complaint is not warranted, communication with the laboratory commissioner, a request for additional information from all appropriate parties involved, and/or ad hoc inspections. If inspection is warranted, it will be unannounced. Inspectors will be chosen by the ARB Executive Board. Prior to the inspection a conference call will be held with the Program Director, Senior Co-Chair, Inspector, and the Accreditation Manager. This call will clarify the approach to the inspection to be taken by the inspector to ensure that the issue(s) identified in the complaint are assessed in as complete a manner as possible while maintaining confidentiality and protecting the identity of the complainant(s).
- v. A formal report will be generated upon review of the investigation by the ARB Executive Board. A copy of the report will be sent to the ASHI President and/or President Elect, who will decide if legal review is needed prior to communicating the summary of results to the

laboratory and appropriate deeming agencies. The report will include a means for communicating results of the investigation to all involved parties, as applicable.

- vi. If deficiencies are found during the complaint investigation, the laboratory is required to submit corrective action within 30 days of receiving the investigation report. The ARB will require that the laboratory provide a follow-up assessment of the effectiveness of the corrective actions within a specified timeframe.
- vii. The full ARB will be notified about the outcome of the investigation at the next ARB meeting, as appropriate. In addition the complainant will be notified of the outcome of the investigation, either by the PD or the ombudsman, depending on the sensitivity of the complaint.
- viii. The outcome of the complaint investigation and effectiveness of any corrective actions will be assessed at the next onsite inspection of the laboratory. If necessary, the inspector will be made aware of the complaint and be instructed to examine the laboratory's records verifying the effectiveness of the corrective action. The findings related to the complaint will be included in the complaint tracking document (see appendix III) and forwarded to CMS and the ASHI Executive Board as the final step. Should there be no concerns related to the original complaint the complaint investigation will be considered closed.
- ix. See Appendix III for a template form to track all complaints.

## **VI. CMS VALIDATION SURVEYS**

- A. The validation review methodology focuses on the actual implementation of the Accreditation organization's Standards described in its request for deeming authority. For each laboratory in the validation survey sample, any findings from the validation survey that result in deficiencies are evaluated with the Accreditation organization's inspection results to determine comparability. A disparity is defined by the presence of condition level deficiencies cited by CMS and not by ASHI.
- B. Validation surveys are either "look back" or simultaneous. "Look back" surveys occur independently of each other while simultaneous surveys take place at the same time with Inspectors from both organizations present. The accreditation manager will inform the laboratory if the survey will be occurring simultaneously with ASHI's inspection.
- C. All discrepant validation surveys will be evaluated by the ARB Executive Board who will develop a plan of action.
  - i. Plans of action will include communication with the laboratory commissioner, a request for additional information from all appropriate parties involved, and/or ad hoc inspections (announced or unannounced)
  - ii. If a follow-up inspection is warranted, inspectors will be chosen by the ARB Executive Board.
  - iii. A formal report will be generated upon review of the investigation by the ARB Executive Board. The report will include a means for communicating results of the investigation to all interested parties, as applicable.
  - iv. If deficiencies are found during the follow-up investigation, the laboratory is required to submit corrective action within 30 days of receiving the investigation report. The ARB will require that the laboratory provide a follow-up assessment of the effectiveness of the corrective actions within a specified timeframe.
  - v. The full ARB, CMS, and other appropriate parties will be notified about the outcome of the investigation.

## VII. GENERAL GUIDELINES FOR ACCREDITATION PROCESS

The guidelines below describe the procedures to be followed for documentation review in the various Accreditation formats. These are general guidelines. Detailed instructions for specific activities are found in the Accreditation Timeline Chart (Appendix II) and should be reviewed thoroughly by the individuals involved in those activities. All ASHI laboratories are responsible for the yearly accreditation fees and if CLIA certified, laboratories must pay the applicable CLIA fees as required in subpart F, 42 CFR §493.638 and 42 CFR §493.645(b). [42 CFR §493.551(b)]

### A. APPLICATION BY A NEW LABORATORY (NOT CURRENTLY ACCREDITED)

- i. Within one week of receipt of a written request, the Accreditation Manager must forward to the applicant:
  - a. An Application Packet;
  - b. A copy of the currently applicable ASHI Standards (the most recent version published at least one year prior to application);
  - c. A list of those recently approved Standards not yet used as a basis for citing deficiencies but already used as recommendations.
  - d. Inspection Guidelines;
  - e. DTRC instructions and portfolio guidelines with contact information, including Director Credentials Checklist and Director Portfolio Checklist;
  - f. Instructions for Test Data Submission for New Laboratories
- ii. The Accreditation Manager assigns the laboratory to a specific cycle based on when the laboratory can submit a completed packet.
- iii. The Accreditation Manager informs the laboratory about its cycle and provides it with a timetable of all deadlines.
- iv. Within three weeks of receipt of application materials, the Accreditation Manager must carefully review the packet and complete the Accreditation Manager Report (bounce back) Form. The packet is returned to the laboratory if there is any missing documentation.
- v. Upon completion of review, the Accreditation Manager must send a copy of the Application packet to the Commissioner within three weeks.
- vi. The Commissioner has three weeks to thoroughly review all documents to determine compliance with the current ASHI Standards and to determine whether the Accreditation process should proceed or not.
  - a. If the Commissioner determines from the application materials submitted that there is sufficient information to deny further processing, a summary report shall be forwarded to the appropriate Accreditation co-Chair for further action. A detailed summary report must be prepared by the co-Chair informing the Laboratory Director of the deficiencies. The co-Chair should provide recommendations to assist the laboratory in meeting the requirements of the Standards. The evidence of failure to comply with the ASHI Standards must be unquestionable. In all other cases, an inspection should be performed
  - b. If the Commissioner determines that the application is complete and the laboratory appears to be ready for an on-site inspection, the following must be done.
    - (1) Notify the Accreditation Manager that the laboratory application is acceptable and to proceed with the Inspection.

- (2) Request the Accreditation Manager to notify applicant of the appointment of the Inspector and to verify that the Inspector is acceptable to the applicant. The applicant will have one week in which to appeal the appointment.
  - (3) Request that the Accreditation Manager forward a copy of the application packet to the Inspector(s)
  - (4) Complete the review of packet and inform the appointed Inspector(s) of any concerns prior to the inspection.
- c. After notification of his/her appointment, the Inspector(s) must schedule the inspection with consideration of the blackout dates provided by the laboratory, make travel arrangements and inform the Accreditation Manager of the date.
  - d. The inspection must occur within an eight-week period established for each Cycle.
  - e. The Accreditation Manager will alert the laboratory two weeks prior to the inspection. (Note: For non-USA laboratories, the Inspector may contact the laboratory directly to set the inspection date.)
- vii. Immediately upon completion of the inspection, the Inspector must
    - a. Conduct an Exit Interview and supply to the Laboratory Director a copy of the Inspector's Summary Report. This report should also include any additional deficiencies that were noted by the Commissioner upon review of the packet.
    - b. The Inspector must electronically complete the Inspector's Summary Report and leave a copy with the laboratory. Any other comments, clarifications, or overall impression of the laboratory should be submitted to the Commissioner within one week of the inspection.
    - c. Request the laboratory to evaluate the Inspector and inspection process using the electronic form.
    - d. Submit to the ASHI Central Office the Inspector's reimbursement form.
  - viii. Within one week of receipt of the inspection report from the Inspector, the Commissioner is to review the report. If the Commissioner disagrees with any of the citations, he/she will immediately contact the Inspector to discuss the problem and get clarification, if needed. If changes to the Inspection report are warranted, the Commissioner will contact the Laboratory Director immediately to discuss the changes before the Laboratory Director responds to the deficiencies. The Inspector's Summary Report (or corrected Inspector's Summary Report) will be signed by the Commissioner and sent to the Laboratory Director.
  - ix. The Laboratory Director has 30 days from the date of inspection to respond to the deficiencies cited by the Inspector and Commissioner. The Director must submit written evidence to the Commissioner that the necessary corrective actions have been taken or that there is a corrective action plan, as appropriate.
  - x. If there were no deficiencies cited or if the Commissioner receives a satisfactory response from the laboratory, the Commissioner will prepare a Review Board Summary Form in which all the pertinent information is summarized in order for the entire Review Board to make an informed decision as to the laboratory's accreditation status. This report should be available at least two weeks prior to the ARB meeting so that the co-Chair has time to review the materials prior to the meeting.
  - xi. If the Commissioner receives a response that is unsatisfactory, he/she is to contact the applicant to clarify any questions and may request additional documentation of corrective action. The laboratory does not receive any additional time to provide clarification and/or further documentation. The Commissioner should contact the co-Chair to discuss unusual problems or whenever there is uncertainty as to whether the response adequately addressed the deficiency.



xii. Some deficiencies may require more than 30 days to correct, i.e. implementation of new QA policies, facilities renovations, rewrites of policy or procedure manuals. The Commissioner should discuss an implementation plan with the Laboratory Director. The laboratory must submit a corrective action plan within the 30 days, but implementation generally should be phased in within the next quarter. The laboratory must submit quarterly reports to the Commissioner to verify that implementation is being accomplished. The Commissioner must first discuss this action plan with the entire Review Board prior to notifying the Laboratory Director.

~~xiii.~~ The Accreditation Manager and staff have two weeks to prepare all laboratory Summary

~~xiv-xiii.~~ Review Forms for the Accreditation Review Board Meeting. The Co-Chair will receive a copy of the application packet at the same time as the Commissioner (approximately four months prior to the next ARB meeting) and will review all applications for the purpose of providing secondary review of the application and all information submitted by the laboratory. The co-Chair will be in contact with the Commissioner after the inspection to discuss any problems and to review the Summary Report for completeness and accuracy prior to the ARB meeting.

~~xv-xiv.~~ The Accreditation Review Board makes a decision on the Accreditation status of every laboratory in the cycle.

~~xvi-xv.~~ If Accreditation is granted:

a. The laboratories will receive an ASHI Accreditation Certificate before the last day of the current accreditation cycle (usually within 3 -4 weeks of the ARB meeting showing the Name of the Laboratory, the Laboratory Director(s), and Areas of Accreditation. This certificate will be good for two years pending successful completion of the Interim inspection process.

b. A letter of congratulations that also lists the technologies and major methods that were accredited will be sent. This letter will be drafted by the co-Chair and will contain any contingencies for Accreditation (example: may require lab to do enhanced Proficiency or submit PT results when received for the next year, etc.)

(1) Accreditation Manager sends rough draft to co-Chair

(2) Co-Chair reviews Areas of Accreditation, Testing Categories and Systems accredited, any contingencies, and modifies letter as appropriate.

(3) Letter is sent to the Commissioner to also review for accuracy and completeness.

(4) If both co-Chair and Commissioner are satisfied with the letter, it is sent to the Accreditation Manager to be placed on ASHI letterhead and sent to the laboratory.

c. If Accreditation is denied:

(1) The Accreditation co-Chair will notify the applicant within 5 business days, in writing, of the decision and also sends a copy of the Appeal Process.

(2) The Accreditation Office notifies CMS within 30 days.

## B. RENEWAL OF ACCREDITATION OF A LABORATORY (NON-INSPECTION YEARS)

i. Accreditation is granted for two (2) years, contingent upon a satisfactory self-inspection report in the interim year, satisfactory participation in Proficiency Testing, and demonstration of compliance with ASHI Standards

ii. 240 days prior to expiration of renewal, the Accreditation Manager will forward Checklists; Standards and Guidance, Declaration of Intent; Proficiency Testing Summary; and Continuing Education Form to the applicant and notify the Commissioner via a monthly report.

- iii. The completed application packet must be sent to the Accreditation Manager by the laboratory within 60 days. Any deficiencies that were cited during the self-inspection should have corrective actions included with the packet.
- iv. Within three weeks of receipt of application materials, the Accreditation Manager must carefully review the packet and complete the Accreditation Manager Report Form. The packet is returned to the laboratory if there is any missing documentation.
- v. Upon completion of review, the Accreditation Manager must send a copy of the Application packet to the Commissioner and co-Chair within three weeks.
- vi. The Commissioner and co-Chair have 8 and 12 weeks, respectively, to review the application. The Commissioner is primary reviewer and the co-Chair is secondary.
- vii. If there are minor questions or deficiencies, which can be clarified by written communication, the Commissioner should request a response from the applicant prior to the ARB meeting.
- viii. At least 2 weeks prior to the ARB meeting, the Commissioner must to prepare a Review Board Summary Form summarizing all the pertinent information, to enable the entire Review Board to make an informed decision as to the laboratory's Accreditation status.
- ix. The Accreditation Manager will have one week to submit all Laboratory Review Forms for the Accreditation Review Board Meeting.
- x. The Accreditation Review Board makes a decision.
  - a. If renewal is approved, a letter of congratulations confirming the techniques used in the laboratory is sent from the co-Chair before the end of the accreditation cycle.
  - b. If the Accreditation Review Board determines that an interim/ad hoc inspection is warranted, the Commissioner is to inform the applicant by phone, notify the Accreditation Manager to appoint an Inspector. An invoice will be issued for an amount equal to the cost of the ad-hoc inspection.

**C. RENEWAL OF ACCREDITATION OF A LABORATORY (INSPECTION YEARS)**

- ~~i.~~ 240 days prior to expiration of Accreditation, the Accreditation Manager will forward Application Packet; ASHI Standards, any pending ASHI Standards, and
- ~~ii.~~ Inspection Guidelines and Checklists to the applicant.
- ~~iii.~~ii. The Accreditation Manager will notify the Commissioner via a monthly report.
- ~~iv.~~iii. The laboratory must send the completed Packet to the Accreditation Manager within 60 days.
- ~~v.~~iv. The Accreditation Process will proceed in the same manner as the initial application procedure, as Section C A iv. (New Labs) above.

**D. ACCREDITATION APPLICATION DUE DATES**

<b>Cycle</b>	<b>Due Date</b>	<b>Inspections</b>	<b>ARB Meeting</b>	<b>Renewal Date</b>
Cycle 1	March 1	Apr - June	August	September 1
Cycle 2	July 1	Aug - Oct	December	January 1
Cycle 3	November 1	Dec - Feb	April	May 1

- i. When the Accreditation Application due date falls on a weekend, holiday, or day that the office is closed, the due date will be adjusted to the next business day. The application packet must be received in the office of the Accreditation Manager by the due date.
- ii. If a laboratory does not submit its packet by the deadline, the Accreditation Manager will contact the laboratory and notify the Director that the Packet is late.
  - a. The laboratory must pay a Late Processing Fee of \$1000 and submit the completed Packet within 15 days in order to remain in the same inspection cycle. Otherwise, the laboratory will be moved to the next inspection cycle and its ASHI Accreditation will expire for a minimum of four months.
  - b. CMS will be notified by the ASHI Accreditation office that the laboratory Accreditation has lapsed, if the laboratory is using ASHI for its CLIA certification.
  - c. A lapse in Accreditation will require outsourcing of testing until the Accreditation is reinstated. The ASHI Accreditation office will notify CMS when the laboratory's Accreditation has been reinstated and may resume testing. Lapse in Accreditation may subject the laboratory to additional fees and inspections by CMS.

## **VIII. APPEAL OF REVOKED, DENIED OR LIMITED ACCREDITATION**

### **A. INTRODUCTION**

- i. The ASHI Laboratory Accreditation process involves a multilevel evaluation by a Commissioner, Co-Chair, and, on alternate years at a minimum, an on-site Inspector. The final review is performed by and the outcome of the evaluation determined by the entire Accreditation Review Board, which is comprised of the Program Director who serves as a non-voting chair (except when a tiebreaker is needed), the Co-Chairs, and the Commissioners. The structure of this process provides a high assurance of a thorough, fair, and impartial evaluation of compliance with the minimum standards that must be followed to ensure reliable test results.
- ii. When Accreditation is denied, revoked, suspended or limited, the applicant shall have the opportunity to appeal the decision.
- iii. Applicants who refuse to cooperate with reasonable requests for information, data, or documentation; who deny an Inspector access to the laboratory for purposes of performing an on-site inspection; or who knowingly and willfully obstruct the evaluation process shall not have the right to appeal the Board's decision.

### **B. APPEAL PROCESS**

- i. A copy of the appeal process must be sent to each applicant whose Accreditation has been denied, revoked, suspended or limited with the notice of this decision from the Accreditation Review Board.
- ii. Following receipt of the decision, the applicant will have 30 calendar days in which to file an appeal.

- iii. If Accreditation was suspended due to potential threat or hazard to patients and/or the general public, an applicant shall have 5 days after notification of suspension, denial, or revocation of Accreditation, to file an appeal.
- iv. For laboratories applying for Accreditation renewal, Accreditation in the previously approved categories shall remain in effect for 30 days following revocation/suspension of Accreditation and throughout the appeal process until a decision is rendered by the Appeal Board except in cases in which the revocation/suspension is based on jeopardy to patient care or an immediate threat to public welfare.
  - a. In these latter instances, the Accreditation revocation/suspension is effective immediately and remains in effect throughout the appeal process.

### C. THIRTY DAY TIMELINE

- i. When Accreditation is denied, revoked, suspended, or limited, the form "Notification of Right to Appeal", instructions for filing an appeal, the financial obligation document, and the description of the appeal process are to be sent along with the notification of the outcome of the evaluation process.
- ii. Immediately upon receipt of Appeal documents, the Accreditation Manager or his/her designee is to verify that the materials submitted include the following:
  - a. Five (5) copies of all documents submitted in support of the appeal.
  - b. A check for the filing fee. (The current filing fee is \$1500).
  - c. Properly signed and notarized statement of financial obligation.
  - d. Five copies of an Executive Summary of the basis of the appeal
  - e. Review of the received materials must be completed by close of business of the next working day following receipt of same.
- iii. Immediately upon completion of the audit of submitted materials, the Accreditation Manager or his/her designee shall take action as follows, if all required materials have been submitted:
  - a. Notify the ARB members and the Chair of the Appeal Board
  - b. Ship copies of the Appeal documents, Executive summary, Application Packet, Inspector's checklist, Inspector's Summary Report, Commissioner's report, any pertinent documents relevant to the laboratory evaluation process, and instructions for the appeal process to the Program Director and the members of the Appeal Board. This must be completed by close of business within 2 business days following receipt of the appeal materials. Materials are to be shipped to arrive the next day.
  - c. If the materials submitted are incomplete, notify the applicant that there are deficiencies and that the necessary materials must be provided within 2 business days
    - (1) If, after such notification, the required materials are not received within the next 2 days, the appeal is considered denied.
- d. As soon as the Appeal Process is initiated, the Accreditation Manager is to begin tracking costs and is to provide log sheets to those who need to track costs they or their institution may incur.

- e. The Accreditation Manager is to arrange for a conference call to take place within 7-10 calendar days following receipt of the materials. Present on the conference call are to be: the members of the Appeal Board, the Program Director, and the Accreditation Manager acting as scribe. The Appeal Board chair should notify the Accreditation Manager, in advance, if the Program's legal counsel should be notified that it may be necessary to have him/her participate in part or all of the conference call. Further, the Appeal Board chair shall be free to contact the legal counsel, in advance, if needed.
- f. The purpose of the conference call is to determine if an appeal hearing is warranted. The criterion for deciding in favor of holding an appeal hearing is clear evidence suggesting that the decision of the ARB was not justified. The basis for this criterion is that the process of evaluation and, in particular, of reaching a decision to withhold Accreditation involves thoughtful and extensive review of data and deliberation by a large group of knowledgeable individuals and that the standards against which laboratories are measured are the minimal standards necessary to assure reliable test results. The course of the appeal process is determined by the decision about the appeal hearing as follows.
  - (a) If the Appeal Board determines to uphold the decision of the Accreditation Review Board (i.e., that a hearing is not warranted), the actions to be taken are:
    1. summarize key points identified by the Appeal Board and transmit these findings from the Appeal Board chair to the Program Director, in writing, within one business day;
    2. prepare the notification letter to be sent to the applicant;
    3. prepare an invoice of the expenses incurred, to be sent to the applicant.
  - (b) If the Appeal Board determines that a hearing is warranted, the actions to be taken are:
    1. The Accreditation Manager is to determine what dates, within the next 10 calendar days, are acceptable for a meeting of the members of the Appeal Board; what, if any, additional documents or information are needed by the appeal Board; who the Appeal Board wishes to interview during the hearing and, of those, who may be interviewed by teleconference and whose presence at the hearing is required; and two cities that are possible sites for conducting the hearing.
    2. The Appeal Board Chair is to prepare a summary of the Board's findings to be submitted to the members of the ARB. The summary is to be submitted, by email, to the Accreditation Manager, by email, within 1 business day of the conference call and forwarded, immediately, to members of the ARB. ARB members are to submit comments, by email, to the Program Director, within two business days of receipt of the email.
    3. The Accreditation Manager is to contact all parties who are to participate in the hearing and arrange the meeting for the optimal date. Travel costs for members of the applicant institution are not the responsibility of ASHI.

4. At a minimum, the hearing shall be attended by the Appeal Board members and the Accreditation Manager. At the discretion of the Appeal Board, the Program Director or the ASHI President shall also attend.
5. Prior to the meeting, the Appeal Board members are to submit to the chair, any questions they feel should be asked during the hearing. The Program Director is to provide, to the Chair a summary of the responses of the ARB to the Appeals Board's summary statement. All materials should be forwarded to the Appeal Board chair no later than two business days prior to the hearing unless the meeting date precludes meeting the 2 business day deadline. The Appeal Board Chair is to collate material received from the Program Director and the other Appeal Board members and also prepare an agenda for the hearing.
6. Prior to the hearing, the Appeal Board is to meet to determine the final agenda and strategy for the hearing. Each individual called on to testify shall answer any questions posed by the Appeal Board and shall have a maximum of 15 minutes to provide open testimony. Testimony must be limited to information about the evaluation - i.e. evidence supporting or contesting the lab's compliance with standards.
7. During the hearing, the Appeal Board shall be free to recall any witness where clarification of information is crucial to the decision-making process. The testimonies given during the hearing will be documented by a court recorder.
8. At the conclusion of the hearing the Appeal Board shall meet to determine whether the original decision will stand or be reversed. In their deliberations, the Board shall consider only facts related to the laboratory's compliance with standards and not to the nature of the evaluation process, the consequences of its decision, or the politics of the situation. The Appeal Board is to reach a final decision prior to leaving the meeting site or within one business day.
- g. Within 24 hours of the appeal hearing, the Appeal Board Chair is to prepare a statement summarizing the basis of the Board's decision. In cases in which the initial evaluation of the ARB is upheld, the statement may be as simple as that the Board found that all the deficiencies cited were in existence at the time of the evaluation or that there were deficiencies sufficient to warrant the decision of the ARB. In cases in which the ARB's decision is reversed, the statement will elucidate those citations that the Appeal Board found to be in error. This summary statement is to be communicated to the Program Director and the Accreditation Manager.
- h. Upon receipt, and prior to the expiration of the 30 day period, the Program Director is to prepare a cover letter, informing the applicant of the findings of the Appeal Board and the ARB's action to either enforce their original decision or reinstate/grant Accreditation, and send this, by certified mail or traceable courier delivery, to the applicant. In cases in which the ARB's initial decision is upheld, the Accreditation Manager is to prepare an invoice of the expenses and submit this to the applicant. Payment of the invoice is due within 60 days of receipt. In cases in which the ARB's decision is upheld, the applicant will be notified that they have a right to re-apply for Accreditation.

- i. If the decision to deny, revoke, suspend, or limit Accreditation is upheld by the Appeal Board, all appropriate deeming or contract organizations, for which the applicant has given written consent for ASHI Accreditation to be used to fulfill Accreditation or certification requirements, are to be notified during the next business day

#### D. TEN-DAY TIMELINE

- i. The 10-day Appeal Process time line is for an immediate jeopardy situation. In the event of an immediate jeopardy, action on the Accreditation status of the laboratory does not wait for full Accreditation Review Board Review. Immediate jeopardy is declared by the Inspector on the day of the inspection after consultation with the Commissioner, co-chair, program Director, or any combination of the three.
- ii. The Appeal Process under the 10-day time line shall follow the same general guidelines as for the 30-day time line. The following exceptions shall be imposed:
- iii. The applicant laboratory shall have one business day after receipt of the Appeal Board composition to show just cause to replace one member of the Appeal Board.
- iv. The applicant shall have 3 business days in which to submit the appeal documents and must forward these directly to the members of the Appeal Board.
- v. The Accreditation Manager shall have 3 business days to solicit additional input from the members of the ARB and these responses shall be sent directly to the members of the Appeal Board.
- vi. The Appeal Board shall meet on site or by teleconference within 10 days of the ARB decision to revoke Accreditation. The Appeal Board shall render its decision to uphold or reverse the decision of the ARB.

#### E. APPEAL BOARD

- i. The ARB Advisory Committee, as defined in Chapter A, shall constitute the Appeal Board with the most senior member serving as Chair of the Appeal Board. In the event there are not three individuals free of conflict of interest, the Chair of the Appeal Board shall appoint additional members, as needed, to achieve a three member board.
- ii. All members of the Appeal Board must have served on the Accreditation Review Board (or Accreditation Committee, prior to 1999) for at least 2 years and preference should be given to those who have served as Chair, Co-Chair, or Program Director.
- iii. Current members of the Accreditation Review Board may not serve on the Appeal Board. The current Program Director shall serve as an *ex officio* member of the Appeal Board.
- iv. The opinion of the Accreditation Program's legal counsel is that three members are sufficient for an impartial and objective Appeal Board and will provide a decision in every case (i.e., no "tie" votes).
- v. Upon proper showing of just cause by the applicant, a member(s) of the appeal board may be replaced.

- a. The applicant must show just cause within five days of receipt of notification of the appeal board composition.
- b. The basis of just cause will be reviewed by the Accreditation Program's attorney, when time permits, and the validity of the request will be determined by the Appeal Board.

#### F. DOCUMENTATION OF APPEAL BASIS

- i. Applicants must submit documentation to substantiate their basis for appeal with their notice to file an appeal.
- ii. Conditions that warrant an appeal include:
  - a. Bias or misrepresentation by anyone involved in review of the laboratory, i.e., the Inspector, Commissioner, or Co-Chair.
  - b. Information or data existing at the time of the review, but not made available to the Review Board.
  - c. Documentation is limited to information and data that existed at the time of the initial review and may NOT include or refer to any subsequent action or data.

#### G. APPEAL BOARD REVIEW

- i. The Appeal Board will review the applicant's documentation as well as pertinent documentation from all other relevant parties including the Inspector(s), Commissioner, and Co-Chair.
- ii. The Appeal Board will decide if the documentation warrants a reconsideration of the Review Board decision through an Appeal Hearing.
  - a. If warranted, this hearing must be held within 28 days of the filing of the appeal.
  - b. The following parties shall have the opportunity to address the Appeal Board at the hearing:
    - (1) The Director of the applicant laboratory and any other employee of the laboratory or parent institution of the laboratory;
    - (2) The Inspector(s), the Commissioner, the Co-Chair; and any other individuals deemed appropriate or necessary by the Appeal Board or the applicant.

#### H. APPEAL BOARD ACTIONS

- i. Following initial review of documentation, the Appeal Board finds that a hearing is not warranted; the decision of the Accreditation Review Board stands and becomes effective upon written notification to the applicant.
- ii. If a hearing is granted, the Appeal Board will discuss and reach a decision immediately following the hearing of all pertinent and interested parties.
- iii. If basis to reverse or modify the decision of the Review Board is found, the applicant will receive written notification of this decision and the applicant's Accreditation status will



remain in effect, for a renewal, or take effect on the date of the decision, for a new application.

#### I. APPELLANTS ACCREDITATION STATUS AND NOTIFICATION TO DEEMING AGENCIES

- i. For applicants filing an appeal for a decision affecting the renewal of their Accreditation, the Accreditation will remain in effect until the Appeal Board renders a decision;
  - a. UNLESS Accreditation was suspended or revoked because of immediate threat or hazard to patient care or the general public (see below).
- ii. The appeal process shall be completed in non-emergent situations within 30 days.
- iii. If the decision to deny, revoke, suspend or limit is upheld by the Appeal Board, all appropriate deeming or contract organizations, for which the applicant has given written consent for ASHI Accreditation to be used to fulfill Accreditation or certification requirements, will be notified of the change in Accreditation status for that laboratory during the next business day.
- iv. If the decision is to reverse the Accreditation ruling, then the laboratory's Accreditation status shall be reinstated retroactively to the date of suspension.
- v. If Accreditation was suspended due to potential threat or hazard to patients and/or the general public, an applicant shall have 5 days to file an appeal. The Appeal Board must consider the appeal and render a decision within the next five days.
- vi. If the decision is to reverse the Accreditation ruling, then the laboratory's Accreditation status shall be reinstated retroactively to the date of suspension. If the decision is upheld, notification shall be sent immediately to the appropriate organizations.

#### J. APPEAL EXPENSES AND FEES

- i. Individuals/institutions appealing the decision of the Accreditation Review Board shall be responsible for all expenses associated with the appeal process,
- ii. All appeals must be accompanied by a notice, signed by an authorized member of the applicant institution, which obligates the institution to reimburse ASHI for all expenses associated with the appeal process, in the event the initial decision of the Accreditation Review Board is upheld.
- iii. In the event the initial decision of the Review Board is upheld, a check, bank draft or money order in the amount of a specified filing fee must be submitted by the laboratory
- iv. Such expenses shall include but are not necessarily limited to:
  - a. photocopying and shipping documents;
  - b. legal fees;
  - c. communication costs;
  - d. travel expenses of members of the Appeal Board and individuals whose presence at the appeal board hearing is requested;
  - e. printing expenses;

- f. clerical/secretarial expenses;
  - g. efforts of the Accreditation Manager, Association Manager and any other member of the Society's management staff (cost to be accrued at the rate of hours spent times the sum of the hourly wage plus fringe benefits);
  - h. time contributed by the Appeal Board, Review Board, and Inspector(s) (see Accreditation Manager for current fee schedule);
  - i. all costs associated with any ad hoc inspection(s) deemed necessary by the Appeal Board.
- v. In the event the initial decision of the Review Board is reversed, a refund of 2/3 of the appeal fee will be made.

## **IX. INSTRUCTIONS FOR FILING AN APPEAL**

### **A. DESCRIPTION**

- i. When there is NOT a condition of immediate threat to patient care or danger to the general public, the Appeal Process occurs in two stages. First, the Appeal Board reviews documents submitted by the applicant and the laboratory evaluation documentation to determine if an Appeal Hearing is warranted. A hearing is warranted when there is clear evidence suggesting the decision of the Accreditation Review Board resulted from bias, misrepresentation, or unavailability of critical information. If the Appeal Board determines that a hearing is not warranted, the initial decision of the ARB is upheld and the Appeal Process ends. If the Board determines that a hearing is warranted, the process moves to a second stage in which a hearing is conducted. For purposes of the hearing, the Appeal Board may request additional documentation from any members of the ARB, the Inspector (s), or the applicant, which must be provided if the Appeal is to proceed. The ARB will meet and will conduct interviews of relevant individuals either at the meeting site or by teleconference. Subsequent to the hearing and within 30 days of the filing of the appeal, the Appeal Board will render its decision. In cases in which the ARB has assessed there to be a threat to patient care or danger to the general public, the process must be completed within 10 calendar days of the notification of the applicant. The Appeal must be submitted within 5 days and the Appeal Board will review and render a decision within 10 days. In these cases, an appeal does not stay the decision of the ARB.
- ii. All documents associated with the hearing shall remain confidential. The applicant shall receive a summary statement of the basis of the Appeal Board's decision. If the Appeal Board upholds the initial decision of the ARB, the action of the ARB will be imposed immediately and the applicant shall be billed for all costs associated with the appeal process. These costs will include but are not necessarily limited to: phone calls,

photocopying, personnel costs, shipping, and legal fees. If the Appeal Board reverses the decision of the ARB, Accreditation will be granted or renewed retroactive to the previous renewal.

- iii. Materials and testimony are to be limited to documentation of conditions existent at the time of the laboratory evaluation. No actions taken and no data generated subsequent to the evaluation are to be considered. The evaluation process itself is not to be evaluated but rather whether or not the findings of the ARB were correct and factual. The decision of the Appeal Board shall be final.
- iv. For an appeal application to be valid, it must contain all necessary documents and a check or money order to cover the filing fee. One-third of the filing fee is a non-refundable processing fee. If the Appeal Board finds against the applicant, part or all of the remaining two thirds of the filing fee will be applied to the cost of the Appeal Process. If the Appeal Board finds in favor of the applicant laboratory, two thirds of the filing fee will be returned to the applicant. If the application for an appeal is incomplete, the applicant will have 48 hours to submit the necessary materials or shall forfeit the right to an appeal

## B. MATERIALS

- i. Submit the following materials prior to the deadline for filing an appeal that was indicated on the Notice of Right to Appeal.
  - a. Five copies of documents providing evidence that the findings of the ARB were incorrect. These materials must be page numbered, bear the lab's ASHI number, and be bound together in a ring binder or other system that provides reasonable assurance of maintaining the order of the documents. The first page of the packet must be a table of contents. The front of each document must indicate the citation(s) address by the information/data contained in the document. This material must be limited to information about conditions that existed at the time of review and must not contain materials that discuss actions taken or data generated subsequent to the action of the ARB.
  - b. A check, bank draft, or money order made payable to ASHI in the amount specified in the fee schedule.
  - c. A signed agreement of financial obligation.
  - d. A written summary of no more than 2 pages in length, highlighting the bases for refuting the ARB decision.
  - e. All materials must be sent by overnight courier and must be traceable.
  - f. Send materials specified in sections a - d above, to the Accreditation Manager.
- ii. The outcome of the Appeals process will be communicated in writing to the Accreditation Manager and the Program Chair. The Accreditation Manager will notify CMS of any suspension, limitation, or revocation of Accreditation once the Appeal Process is complete and upheld by the Appeals Board.

# **Chapter C**

## **ARB Policies**

## I. CONFIDENTIALITY OF APPLICANT'S RECORDS

- A. All records, reports and correspondence concerning an applicant laboratory shall be kept in strict confidence except as required by Federal or State Law, or by specific agreement according to the signed Declaration of Intent to release information to other professional associations such as the Centers of Medicare and Medicaid Services (CMS), United Network for Organ Sharing (UNOS), the National Marrow Donor Program (NMDP) or the American Foundation for Donation and Transplantation (AFDT) – (formerly SEOPF).
- B. Upon inquiry, ASHI may release information about the Accreditation status of a laboratory but that information will be limited to the following:
  - i. Whether or not a lab is accredited;
  - ii. The areas of Accreditation;
  - iii. The date of Accreditation;
  - iv. The name of the Laboratory Director under which the laboratory was accredited;
  - v. Proficiency Test (PT) results for regulated analytes. The information on the Proficiency Testing Summary Form for regulated analytes will be provided to the requestor, with an explanation of what those results mean as appropriate to the needs of the requestor.
- C. All such inquiries must be handled by the ASHI Accreditation Office and by the Accreditation Program Director.

## II. EGREGIOUS ACTIONS REQUIRING IMMEDIATE ACTION BY ARB

- A. The following actions are considered egregious and require immediate action including notification of CMS within 10 days, for laboratories using ASHI Accreditation to satisfy CLIA certification requirements:
  - i. Falsifying data;
  - ~~ii.~~ Violations of standard precautions (blood-borne pathogens);
  - ~~iii.~~ Staff size grossly insufficient for workload;
  - ~~iv.~~ Severely deficient and inconsistent Proficiency Testing performance;
  - ~~v.~~ Working conditions that present a health or safety threat to employees\*;
  - ~~vi.~~ Scientific and/or technical incompetence;
  - ~~vii.~~ Any practice that jeopardizes patient care or has the potential to do so.

\*OSHA must also be notified of safety issues that present threat to employees

## III. SENTINEL OR IMMEDIATE JEOPARDY EVENTS

- A. Laboratories must act immediately to correct the situation and provide written notification to the accreditation office within 30 days.
- B. The Accreditation Manager will immediately notify the Executive Board of the ARB, the ASHI Executive Board of Directors, and CMS (US laboratories only).
- C. The Executive Board of the ARB will review the details of the event and determine the need for a focused inspection. Should the case be determined to warrant classification as immediate jeopardy by the Executive Board of the ARB, CMS will be notified immediately.
- D. All documents must have patient identifiers redacted (blackened out).

- E. Possible ARB Actions are covered in Chapter B, Section III.,E

#### **IV. CLINICAL ACTIVITY in RENEWAL of ACCREDITATION**

- A. A laboratory may seek renewal of Accreditation only in the areas for which there is clinical activity with the exception of "Testing or Other clinical Purposes" and "Transfusion Support" for which the laboratory uses the same methods and procedures used in other areas for which there is clinical activity.
- B. Otherwise, if no clinical activity has occurred in the past year, Accreditation will be suspended in that area until clinical activity resumes and staff competence is validated. If a laboratory ceases operations permanently, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify ASHI of this fact, in writing, within 30 calendar days.
- C. The laboratory should continue proficiency testing if they plan to resume clinical activity in the near future.
- D. Re-instatement requires
  - i. notification from the laboratory in writing that clinical activity has resumed.
  - ii. A new Accreditation letter is sent following notification of resumed clinical activity.
- E. A laboratory can maintain Accreditation for a Testing System that is not currently used by continuing to successfully participate in Proficiency Testing that uses that system.

#### **V. PERSONNEL CHANGES IN AN ACCREDITED LABORATORY**

- A. Vacancies in the Director or Technical Supervisor, Clinical Consultant and/or general supervisor positions are potentially detrimental to the continuing performance of a laboratory. Once a laboratory has been granted Accreditation, it is the responsibility of the Laboratory Director or appropriate departmental manager or chair to notify the Commissioner of changes in personnel at the level of Director or Technical Supervisor, Clinical Consultant or general supervisor.
- B. Such notification shall be in writing and should be received by the Commissioner within thirty (30) days after a change or vacancy. Failure to provide appropriate notification shall result in immediate forfeiture of Accreditation status.
  - i. Director or Technical Supervisor Vacancies
    - a. The Commissioner and ARB Manager shall be notified in writing within 30 days of termination of the Director or Technical Supervisor's appointment.
    - b. The laboratory must immediately replace with a qualified individual. A full time or an interim Director and Technical Supervisor must be identified.
    - c. Failure to have a qualified Director and Technical Supervisor during all hours of operation results in forfeiture of Accreditation.
    - d. If the vacated position was by a Director or Technical Supervisor who was also serving as General Supervisor, the laboratory Accreditation will be forfeited until both these positions are filled.
  - ii. General Supervisor Vacancies
    - a. The Commissioner and ARB Manager shall be notified within 30 days of a vacancy in the General Supervisor's position.

- b. A General Supervisor must be present on-site. The Director/Technical Supervisor may serve in this role during the time needed to recruit a new Supervisor. However, the Director must be “on-site” in order to serve as the General Supervisor.
  - c. The Director/Technical Supervisor must submit a plan for division of the supervisor’s responsibilities between the Director and senior technologists. It will be necessary for the Director to establish the ability to provide the additional time commitment necessary.
- iii. Clinical Consultant Vacancies
    - a. The Commissioner and ARB Manager shall be notified in writing within 30 days of termination of the Director’s appointment.
    - b. The laboratory must immediately replace with a qualified individual.
    - c. Failure to have a qualified Clinical Consultant results in forfeiture of Accreditation.
  - iv. All personnel changes and vacancies that may potentially affect Accreditation status shall be reviewed by the Accreditation Review Board at their laboratory review meetings and will be reported to the ASHI Board and to any agencies for which the laboratory has given ASHI the authority to provide required Accreditation information.

## **VI. PERSONNEL LICENSURE REQUIREMENTS**

- A. The following US states & territories require licensure for clinical laboratory practitioners:
  - i. California
  - ii. Florida
  - iii. Hawaii
  - iv. Louisiana
  - v. Montana
  - vi. Nevada
  - vii. New York
  - viii. North Dakota
  - ix. Rhode Island
  - x. Tennessee
  - xi. West Virginia
  - xii. Puerto Rico
- B. A copy of the appropriate licenses must be included in the application packet. It is the responsibility of the Laboratory Director to inform ASHI of any special licensing requirements.

## **VII. DOCTORAL-LEVEL POSITIONS REQUIRED BY CLIA ‘88 and ASHI**

- A. CLIA ‘88’ requires a doctoral level for three positions
  - i. Laboratory Director
  - ii. Technical Supervisor for Histocompatibility Testing
  - iii. Clinical Consultant
- B. Histocompatibility is one of the few specialty areas under Federal Regulations where a doctoral level Technical Supervisor is required. One person may fill both Director and Technical Supervisor positions in most Histocompatibility laboratories.

- C. One person may occupy all three positions, provided that person satisfies the qualifications for all three.
- D. Board certification is required for the position of Clinical Consultant. It is also required for the Laboratory Director unless he/she was serving as the Director of an ASHI accredited Laboratory on or before February 24, 2003. A Director or Clinical Consultant with an M.D. will meet this requirement if he/she is licensed to practice medicine in the State in which the laboratory is located. Directors of non-USA laboratories must be certified and continue to be certified by an appropriate professional board or other certifying agency.
- E. CMS accepts the Technical Supervisor and Clinical Consultant in Histocompatibility as equivalent for the limited Immunohematology (ABO/Rh testing) performed by facilities using ASHI Accreditation to meet CLIA requirements.
- F. The Director Training Review and Credentialing Committee is responsible for reviewing new Director and Technical Supervisor qualifications and approving them for the Areas of Accreditation and Technologies for which the laboratory is seeking Accreditation.

## VIII. APPROVED CERTIFICATION BOARDS

- A. Current Approved Certification Boards for Clinical Consultants and Directors of High Complexity Testing for USA Laboratories are as follows:
  - i. ABHI American Board of Histocompatibility and Immunogenetics
  - ii. ABMLI American Board of Medical Laboratory Immunology ([exam discontinued in 2017](#))
  - iii. ABB American Board of Bioanalysis
  - iv. ABMG American Board of Medical Genetics
  - v. ABMM American Board of Medical Microbiology
  - vi. ABCC American Board of Clinical Chemistry
  - vii. ABFT American Board of Forensic Toxicology (individuals with a Doctoral degree)
  - viii. NRCC National Registry of Certified Chemists (individuals with a Doctoral degree)

## IX. PART-TIME DIRECTORS OR TECHNICAL SUPERVISORS

- A. A part-time Director or Technical Supervisor will need to submit to the ARB a comprehensive plan of action stating how he/she will fulfill the responsibilities of the Director or Technical Supervisor and/or Clinical Consultant, detailing coverage of all of his/her laboratories, such as:
  - i. delegated responsibilities must be clearly identified.
  - ii. person(s) to whom the responsibility is delegated must be identified.
  - iii. the amount of time and frequency of on-site availability.
  - iv. mechanisms to ensure that all delegated duties are properly performed.
- B. The Director or Technical Supervisor must have regular interactions with members of the Transplant program and must be available to address issues/ problems in a timely manner.



- C. If the Part-time Director or Technical Supervisor is also the Clinical Consultant, he/she must ensure that consultation is available to the clients.
- D. The Director or Technical Supervisor is expected to be present for the ASHI on-site inspection.
- E. Unacceptable inspection outcomes may require an increased time commitment from the Director/Technical Supervisor to resolve the problems.
- F. A General Supervisor must be on-site and must meet ASHI and CLIA requirements.

## **X. CONTINUING EDUCATION REQUIREMENTS**

- A. Current ABHI certification, though not required, will be accepted as documentation of compliance with the continuing education requirement. This is verified by the Accreditation Manager.
- B. For full and part-time technical staff not currently ABHI certified, the continuing education requirements shall be relevant to the areas of Accreditation and will use real hour for the calculation. The total number of continuing education hours shall be:

- i. Directors/Technical Supervisor                      50 hours per year
- ii. Clinical Consultants                                      12 hours per year
- iii. General Supervisor                                      27 hours per year
- iv. Technologists/technicians                              12 hours per year
- v. Director in Training                                      27 hours per year (off-site CEU's)
  - a. The Director in Training may receive many "education" hours during the course of the training. However, at least 27 hours must be from seminars, workshops, lectures, etc. outside of the laboratory.

- C. A minimum of 50% of these hours must be directly related to the science and application of histocompatibility and/or immunogenetics testing.

D. If technical staff performing functions for an ASHI accredited laboratory are not involved in histocompatibility testing, then the director should ensure that such staff are competent and meet the requirements of continuing education relevant to their work areas or specific duties. DNA extraction and quantification, serum separation, sample processing, serum aliquoting do not require histocompatibility continuing education.

## **XI. NOTIFICATION OF ARB POLICY ADDITIONS & CHANGES**

- A. Notification of policy revisions/changes and new policies needs to be shared with all necessary groups/committees.
- B. After every ARB meeting, the following groups/committees may be notified of all new policies and revisions/changes made to existing policies:
  - i. QAS Committee Chair(s)
  - ii. NMDP (if applicable)
  - iii. UNOS (if applicable)

C. After every ARB meeting, the following groups/committees may be notified and asked for approval of all new policies and revisions/changes made to existing policies:

- i. CMS
- ii. ASHI Board via ARB liaison

D. After review of the policies, all appropriate groups/committees will be notified of responses for further actions when necessary.

## **XII. REVIEW and UPDATING of the ARB OPERATIONS MANUAL**

- A. All members of the ARB are encouraged to review the ARB Operations Manual annually.
- B. The Junior co-Chair is responsible for ensuring that procedures and protocols still reflect current practice.
- C. Changes to the Operations Manual (chapter C – policies) will be added as needed and approved by the full ARB. Any changes to the Operations Manual made during the year will be sent out for public comment. The public comment period will be 2-4 weeks as needed to coincide with the fall annual meeting schedule. All comments received will be reviewed and responded to by ARB executive board. The final draft of the full Operations Manual will be sent to the ASHI Board for approval. Upon ASHI Board approval the final draft will be submitted to CMS for approval.
- D. Non-substantive changes can be made with approval of the ARB (administrative protocols, typographical or syntax errors, re-wording previous policy to make it clearer, etc.)
- E. The ARB Operations Manual will be made available on the ASHI Web site. All members may find it helpful in preparing for inspections. Any comments or suggestions concerning the Operations Manual should be sent to the Accreditation Review Board Program Director.

## **XIII. REFERENCE TESTING**

- A. HLA testing may only be outsourced to another ASHI Accredited laboratory or to an ARB approved laboratory.
- B. USA laboratories may only outsource testing to a CMS certified laboratory.
- C. A copy of the current Accreditation and CMS Certificates of the reference laboratory must accompany the accreditation packet.

## **XIV. PROFICIENCY TESTING (PT) REQUIREMENTS**

- A. Laboratories must designate a PT provider for each analyte tested.
- B. Prior to the start of the PT calendar year laboratories subscribing to more than one PT survey for the same technology/method must designate the primary survey to be used for purposes of evaluating satisfactory/successful PT performance. A copy of the form to be used for designating the primary PT provider is available from the accreditation manager. A minimum of two surveys must be provided to the lab each year by the primary PT provider. (CLIA requirement).

C. When multiple laboratories are overseen by a single director, the laboratories are encouraged to subscribe to separate PT, preferably from different vendors to prevent any communication regarding the challenge. In cases where this is not possible, there should be a policy in place to preclude communication. This also applies to institutions with multiple laboratories performing HLA testing, and more than one qualified director.

D. For the purposes of PT, laboratory analytes are categorized into 3 types:

- i. CMS regulated, including
  - a. General Immunology
  - b. ABO/Rh
- ii. CMS non-regulated analytes (any not listed in ASHI Standards c.1.1 and c.1.2) with commercially available PT.
- iii. CMS non-regulated analysis with no commercially available PT

E. For CMS regulated analytes laboratories testing samples from US patients must participate in a CMS approved proficiency program. Following is a list of CMS approved Proficiency Testing Providers:

- i. ACCUTEST, INC.
- ii. AMERICAN ACADEMY OF FAMILY PHYSICIANS (AAFP)
- iii. AMERICAN ASSOCIATION OF BIOANALYSTS (AAB)
- iv. AMERICAN PROFICIENCY INSTITUTE (API)
- v. CALIFORNIA THORACIC SOCIETY (CTS)
- vi. THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP)
- vii. MEDICAL LABORATORY EVALUATION (MLE) PROGRAM
- viii. PUERTO RICO PROFICIENCY TESTING SERVICE
- ix. WSLH Proficiency Testing Program

F. For CMS non-regulated analytes the ARB approves the following Proficiency testing surveys

- i. ASHI
- ii. CAP
- iii. UCLA (if the laboratory selects the option to be graded)
- iv. ASEATTA/APHIA
- v. AFDT (SEOPF)
- vi. NMDP Blind Testing
- vii. NEQAS
- viii. International High Resolution HLA Exchange
- ix. Eurotransplant Reference Exchange
- x. EFI-approved Proficiency testing
- xi. INSTAND
- xii. Others that fulfill the following requirements: At least 2 sendouts per year and provide graded results.

G. When no formal external proficiency testing is available the following options are acceptable:

- i. Exchange of samples with another laboratory accredited by ASHI (or by a foreign equivalent organization) performing that testing.
- ii. Blind testing of reference samples with known test results.
- iii. Blind testing of clinical samples with known clearly expected test results.
- iv. Splitting samples between two technologists who are blinded to each other's test results.
- v. Having one technologist perform duplicate tests starting with an original sample that is split before any processing is started. (This should only be allowed if there is only one technologist trained to perform that particular test and the other options are not possible).

Another method for validating the test performance that provides at least equivalent confidence in the accuracy of the test method.

H. When multiple primary methods are used to test a single analyte, the lab must either subscribe to separate PT for each method or rotate PT samples from a single survey amongst various methods. For example, if a solid organ lab runs RT-PCR for recipients and SSO luminex for donors, these are both considered primary methods and as such, the lab must split the first PT challenge of the year between primary methods, RT PCR and SSO, then switch this pattern for the next PT challenge of the year. The same goes for bone marrow labs. If the lab runs SBT as primary method for confirmatory testing and runs SSO luminex for donor screening as primary method, then they have to split the PT samples as stated in the above example. If split samples are used, the lab must have a policy describing how PT challenges will be tested. If more than three primary methods are used, the lab may need to subscribe to a separate PT program to meet minimum PT requirements.

A primary method is: (1) used on a routine basis and either (2) used to report results as a standalone method or (3) when used in conjunction with another method(s) is the source of the primary reported results.

## I. PROFICIENCY TEST GRADING

- i. For US labs, a Proficiency Testing program must provide scores consistent with ASHI standards (currently C.2) in order to be considered a graded PT program. Graded proficiency testing programs are programs that report individual send-outs as Satisfactory/Unsatisfactory.
- ii. Proficiency typing results must be reported at all levels of resolution that are reported clinically (i.e. for patient specimens). Any antigen/allele that the proficiency survey grades will be evaluated
- iii. A laboratory must include samples that were not graded in the evaluation of Proficiency Testing. Samples from the 3 most recent consecutive surveys are evaluated and the correct response will be the majority ( $\geq 60\%$  consensus) response. The lab must include evidence of review of results that are not in consensus on ungraded samples. Ungraded samples include those that were intended to be graded but weren't due to non-consensus. When the

laboratory score falls in the minority (<40%) the lab must comment on its results. The commissioner will review cases on an individual basis noting any trends in the overall results submitted by the laboratory.

- iv. The ARB will review all cases of Unsuccessful PT and determine appropriate action. In all cases, additional PT submission (which may include enhanced PT- see below) will be required. If patient care is ascertained to be in immediate jeopardy, the certification will be suspended for the method under review. CMS will be notified of a suspension within 10 days in cases of immediate jeopardy.
- v. If a laboratory's certificate is suspended, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be enhanced proficiency on site, before ASHI will consider it for reinstatement for certification.
- vi. For CMS regulated analytes
  - a. PT must include 5 challenges 3 times per year.
  - b. Laboratories must submit the 3 most recent consecutive results received for each proficiency testing survey, at the time of application. In accordance with CMS, a rolling timeframe is used to determine PT performance wherein 3 consecutive PT results are assessed. The rolling time frame is continuous and does not reset annually.
  - c. Satisfactory PT performance requires a minimum of 80% concordance for each challenge (send out) of each analyte. A single miss on any specimen is considered an incorrect for phenotype/result. HLA class I and class II are evaluated separately. Failure to enroll, perform or report results for a PT event by the providers' deadline for submission is unsatisfactory and results in a score of 0%. ABO/Rh PT requires 100% concordance for each challenge (send out). Failure to attain 100% is considered an unsatisfactory performance.
  - d. Unsuccessful participation in a PT program is defined as unsatisfactory performance on 2 consecutive sendouts or unsatisfactory performance on 2 out of 3 sendouts.
  - e. The ARB Accreditation manager will monitor PT results for laboratories accredited for CMS regulated analytes by checking results reported to CMS by their approved Proficiency Testing programs every 30-45 days.
- vii. CMS non-regulated analytes,
  - a. PT must be submitted at least twice per year for all analytes
  - b. Laboratories must submit the 3 most recent consecutive results received for each proficiency testing survey, at the time of application. In accordance with CMS, a rolling timeframe is used to determine PT performance wherein 3 consecutive PT results are assessed. The rolling time frame is continuous and does not reset annually.
  - c. Satisfactory PT performance requires a minimum of 80% concordance for each challenge (send out) of each analyte. A single miss on any specimen is considered an incorrect for phenotype/result. HLA class I and class II are evaluated separately. Failure to enroll, perform or report results for a PT event by the providers' deadline for submission is unsatisfactory and results in a score of 0%.
  - d. Unsuccessful participation in a PT program is defined as unsatisfactory performance on 2 consecutive sendouts or unsatisfactory performance on 2 out of 3 sendouts.

#### J. **Corrective Action Requirements**

- i. A corrective action report must be submitted for all Proficiency Testing errors and outliers. The corrective action report is submitted in Learning Builder when the laboratory is completing their annual accreditation application. The corrective action report must include: The analyte identified as discrepant with concordant result.

- (1) The PT provider summary report. Include documentation of unsatisfactory sample or attempt for re-shipment, if applicable.
- (2) Documentation of satisfactory results on 2 prior challenges and 2 subsequent challenges, if possible.
- (3) Director's review of results and description of possible problem.
- (4) Evidence of thorough investigation, conclusions, and corrective action to prevent similar error in future. Indicate if error was due to pre-analytical, analytical, or post-analytical problems. The effectiveness of corrective actions must be evaluated by the laboratory.
- (5) Actions taken to ensure the ongoing quality and accuracy of patient test results. (Ex. Split sampling or inter-laboratory comparison, testing by alternate method, or change in reagents, procedure, etc.)
- (6) Review of reported patient results may be appropriate and necessary depending on the cause of the error (PT errors may detect reagent failures and may reflect patient testing done at the same time).

ii. The laboratory's Commissioner will review the corrective action response for completeness and determine if the response is satisfactory. If the response does not seem adequate the Commissioner will contact the laboratory as soon as possible so that the lab can resubmit their corrective action response. There is no need to contact the laboratory if the response is deemed adequate.

iii. The Commissioner will document in LearningBuilder, on the laboratory summary page, that the Proficiency Testing corrective action has been reviewed and the outcome of such review. All corrective action responses should be resolved before the ARB meets to discuss the laboratory's re-accreditation status. Any unresolved issues with the corrective action report shall be reported to the Co-chair prior to the ARB meeting.

iv. CMS Regulated Analytes.

- (1) If PT for a CMS regulated analyte is unsuccessful, enhanced proficiency testing is required.
- (2) For an initial unsuccessful PT performance, the laboratory may continue testing provided that it has a good compliance history and that the laboratory's corrective action/retraining plan indicates that there would not be immediate jeopardy to patients.
- (3) For a second instance of unsuccessful PT testing, the suspension of testing is mandatory for laboratories testing samples from U.S. patients.
- (4) Reinstatement of testing requires satisfactory performance in 2 consecutive new PT send-outs from a CMS approved vendor and would be for a minimum of 6 months unless the laboratory had already voluntarily ceased testing. Results of the enhanced proficiency testing for CMS regulated analytes will be reviewed and approved by the ARB before routine testing may be resumed.
- (5) Laboratories only testing samples from non-US patients may substitute and include local proficiency exchange programs.

| v. CMS Non-Regulated Analytes

- (1) If PT for a CMS non-regulated analyte is unsuccessful, enhanced proficiency testing is required.
- (2) Enhanced PT testing requires a number of samples equal to the number in a laboratory's designated yearly proficiency testing survey.

- (3) If the laboratory has been performing successfully in a second approved proficiency survey of the same analyte, those results may be submitted in lieu of enhanced PT (Note - this does not apply to CMS regulated analytes). The results must be from the same 12-month period as the designated PT survey and conform to all other PT requirements.
- (4) Enhanced PT may also come from blind parallel testing with another ASHI Accredited laboratory. Both parties must send their results directly and independently to the Commissioner for review without prior knowledge of the other laboratory's results. Impartiality must be maintained between the two laboratories involved with the blind sample exchange. The laboratories cannot share the same director, and the laboratory required to perform enhanced PT must be blinded and may not serve as the sending laboratory for samples.
- (5) PT results obtained since the submission of the packet may count toward the total number required for enhanced PT

**XV-ii. REQUIREMENTS FOR MOLECULAR TYPING**

- A. PT must be performed at the same level(s) of resolution as the clinical testing. Alleles reported assume the lab is utilizing the latest list of alleles as published in the appropriate WHO nomenclature (generally one year prior to application submission).
- B. Two field resolution testing should adhere to NMDP/ASHI policy.
  - i. For Single Allele Testing, the laboratory must report the presence or absence of the particular allele specified by the requisition. The laboratory must perform proficiency testing at the appropriate level of resolution when the serologic-level antigen is present or, other procedures to validate test performance as outlined in the ASHI Standards (currently C.1.1.5)
  - ii. Null Allele Discrimination - It is required by NMDP that certain null alleles be discriminated from the expressed alleles by all laboratories reporting results for the relevant loci. Refer to the NMDP/ASHI policy for specific details. These same alleles should be discriminated as applicable for other clinical applications.

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**ii-iii. AREAS of ACCREDITATION, CATEGORIES, AND SYSTEMS**

A. As previously stated, an area of accreditation is defined as the clinical service-specific activity supported by the laboratory (i.e. HSC/BM, Solid Organ, etc.).

- ASHI-defined Areas of Accreditation are:
- a. HSC/BM Transplantation: Related Donor
  - b. HSC/BM Transplantation: Unrelated Donor
  - c. Solid Organ Transplantation: Deceased Donor
  - d. Solid Organ Transplantation: Live Donor
  - e. Histocompatibility Testing for Other Clinical Purposes
  - f. Transfusion Support

B. Special Requirements for Areas of Accreditation:

i.—

a. Hematopoietic Stem Cell Transplant: Related Donor

- (1) The laboratory must provide support for a transplant program by documentation of review and interpretation of results, or by meeting the needs of the program as outlined in the letter of agreement between the laboratory and the transplant program.
- (2) If any tests are outsourced, the referring laboratory must document the review and interpretation of the results.
- (3) If any tests are outsourced, both laboratories must be accredited by ASHI or an equivalent Accrediting Organization. For laboratories that use ASHI for CLIA purposes, laboratories used for outsourced testing must also be CLIA certified.

b. Hematopoietic Stem Cell Transplant: Unrelated Donor

- (1) The laboratory must provide support for a transplant program by documentation of review and interpretation of results, or by meeting the needs of the transplant program as outlined in the letter of agreement between the laboratory and the transplant program.
- (2) Two field resolution HLA-A,B,C and DRB1 typing must be performed and reported on both the patient and potential donors.
- (3) If any tests are outsourced, the referring laboratory must document the review and interpretation of the results.
- (4) If any tests are outsourced, both laboratories must be accredited by ASHI or an equivalent Accrediting Organization. For laboratories that use ASHI for CLIA purposes, laboratories used for outsourced testing must also be CLIA certified.

c. Solid Organ Transplantation: Deceased Donor:

- (1) Laboratories that provide HLA donor typing and/or final crossmatch for deceased donors must provide 24/7 coverage.
- (2) Laboratories not providing HLA donor typing and/or final crossmatch are not eligible for deceased donor accreditation. Services may include candidate HLA typing, antibody testing, cell function testing, post-transplant monitoring, or retrospective crossmatches. If the laboratory typing is used to add candidates to the UNOS waitlist, the laboratory must document review of waitlist entry.
- (3) HLA Typing, Crossmatch Testing and HLA Antibody Testing must be performed by a laboratory accredited by ASHI or by an equivalent Accrediting Organization. For laboratories that use ASHI for CLIA purposes, laboratories used for outsourced testing must also be CLIA certified.
- (4) If any of these tests are referred to another accredited laboratory, the referring lab must document review and interpretation of results
- (5) The laboratory performing the final crossmatch must have access at the time of the crossmatch to the recipient's HLA typing and HLA antibody testing results if these tests have been performed at another laboratory.
- (6) Laboratories must provide HLA typing at the required loci described by current UNOS policy: [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf)

d. Solid Organ Transplantation: Live Donor:



- (1) Laboratories must provide HLA typing for both transplant candidates and donors.
- (2) Laboratories must have policies for regular evaluation of patient antibodies and for selection of appropriate crossmatch procedures.
- (3) HLA Typing, Crossmatch Testing and HLA Antibody Testing must be performed by a laboratory accredited by ASHI or by an equivalent Accrediting Organization.
- (4) If any of these tests are referred to another Accredited laboratory, the referring lab must document review and interpretation of results
- (5) The laboratory performing the final crossmatch must have access at the time of the crossmatch to the recipient's HLA typing and HLA antibody testing results if these tests have been performed at another laboratory.
- (6) Laboratories participating in Paired Kidney Exchanges must provide HLA typing and antibody identification at the required loci described by current UNOS/program specific policies.

e. Histocompatibility Testing for Other Clinical Purposes

f. Transfusion Support, the laboratory must

- (1) Perform HLA typing, antibody screening/identification for patients (HLA/ Platelet/ or Granulocyte antibody testing for patients)
- (2) Provide interpretive notes on results of testing
- (3) Make recommendations for selection of donors for platelet or granulocyte transfusion

C. A testing **Category** is defined as the type of testing performed in an accredited laboratory.

i. ASHI-defined Testing Categories are described as:

- a. Immunogenetics, which consists of genetic typing for immunologically-related purposes. Loci tested include, but are not limited to:
  - (1) HLA Typing
  - (2) MICA Typing
  - (3) KIR Typing
  - (4) HPA Typing
  - (5) ABO/Rh Typing and A1 Titer
- b. Crossmatching for transplant purposes
- c. Antibody Testing for immunologically-related purposes for products of the following loci
  - (1) HLA
  - (2) HPA
  - (3) MICA
- d. Other testing encompasses methods used to describe histocompatibility or immunogenetics, but are additional to the standard typing, crossmatching, and antibody testing performed in most HLA laboratories.

D. A testing **System** is defined as the actual assay system utilized in determining results in a testing Category.

i. ASHI-defined Testing Systems include, but are not limited to:

- a. Molecular Typing
- b. Serological Typing
- c. Flow Cytometry
- d. Cellular Methods
- e. Complement Dependent Cytotoxicity

E. Testing **Methods** are defined as the specific assay utilized in determining a clinical result. .

i. Testing Methods include, but are not limited to:

- a. CDC
- b. SSO
- c. SSP
- d. SBT
- e. Solid Phase Assays

F. Accreditation Table

The following table describes the relationships between Test Categories, Systems and Methods.

<b>Category</b>  (What is done)  Submitted Validation required	<b>System</b>  (Assay System)  Submitted Validation required	<b>Methods</b>  (Specific assay)  Internal Validation – labs should send the commissioner an email to notify
<b>Immunogenetics:</b> HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing, ABO-A1 Titer	Molecular Serology Flow Cytometry Next Generation Sequencing*	CDC (T and/or B) SSO SSP Sanger Sequencing Real time PCR Flow cytometric phenotyping Serology
<b>Crossmatching</b>	CDC Flow Cytometry Other	CDC (T and/or B) AHG (T and/or B) Flow (T and/or B) Solid Phase (Class I and/or II)
<b>Antibody Testing:</b> HLA, HPA, MICA, AT1R	Antibody Detection 1. CDC 2. Solid Phase 3.	CDC (T and/or B) AHG (T and/or B) ELISA (Class I and/or II) Flow (Class I and/or II)

	Antibody Identification 1. CDC 2. Solid Phase 3.	Microarray (Class I and/or II)
<b>Other Testing</b>	Molecular Immunology Flow Cytometry Cellular Chimerism/Engraftment Monitoring	STR VNTR Flow-Immunophenotyping Immune Cell Function/MLC/PLT SNP Testing Soluble Biomarker Testing

*\*novel, emerging technologies such as NGS may require validation submitted at the discretion of the ARB.*

**XVII. ADDING NEW AREAS of ACCREDITATION OUT of CYCLE**

- A. Established laboratories may add new Areas of Accreditation out of their normal inspection cycle.
- B. If an application is for an Area of Accreditation for which the Director or Technical Supervisor has not been previously approved, a Director or Technical Supervisor Portfolio will be required. The Director or Technical Supervisor should supply the documentation of training and expertise along with case files for review. The Chair of the Director Training Review committee can be contacted for further clarification, if needed.
- C. The Laboratory must submit Validation Packets for all new Testing Categories and Systems to the ARB Commissioner. See detailed sections below regarding requirements for Validation of Categories and Systems and Test Data Submission.
- D. Upon approval of the Director or Technical Supervisor Training, Test Data Submission, and/or Validation Packet, the Accreditation Manager will arrange for a “focused inspection” for the addition of a new Area in the next available cycle. . The laboratory will bear the cost associated with the focused inspection for the addition of a new Area of Accreditation.
- E. Following approval of the ARB an updated certificate and/or letter, using the same expiration date as the original certificate will be issued. The new Area of Accreditation will be added to the certificate and/or letter with an effective date of approval for the new Area of Accreditation noted.

**XVIII. DATA SUBMISSION REQUIREMENTS FOR NEW LABS OR CHANGES TO AREAS OF ACCREDITATION, CATEGORIES, AND SYSTEMS**

The commissioner must thoroughly review the accreditation material for a new lab or an established lab adding a new category of testing. The review will include validation packets for each category and/or system. Case studies should demonstrate how tests are performed in situations unique to the laboratory, patient, or sample (e.g. DNA from blood versus buccal; lymphocytes from blood versus

spleen). These represent the minimum acceptable data for assessing tests used in histocompatibility testing and interpretation. Definition of relevant terms:

**Case Study:** Histocompatibility assessment for specific recipient and donors should include worksheets, test results, troubleshooting, and final report with interpretive comments. Cases include each type of patient and sample being tested, and should be chosen to demonstrate the laboratory's ability to accurately type, troubleshoot, interpret, and correlate results with other testing information.

**Parallel Testing:** Testing of the same material on comparable platforms (with respect to sensitivity/resolution). Well characterized or reference materials are an ideal source of sample.

**Blind Parallel Testing:** Similar to proficiency testing where testing lab does not know result obtained on the split sample. To satisfy this data requirement, the lab may use graded PT, or can arrange to have shared samples provided to another laboratory that performs the category/system to be evaluated. Results from testing at each laboratory must be submitted INDEPENDENTLY to the commissioner. Shared samples must not be from PT until after the reporting deadline is past. Samples may not be shared between two labs that share the same director. Acceptable performance is 80% or greater concordance.

**New Director of established laboratory:** Appropriate credentials and experience must be approved by the DTRC for AREAS for which approval is sought. Materials that are provided to the DTRC for assessment may also be used to establish and validate new test categories, systems, and methods. A focused inspection may be required if the change is outside the on-site review cycle.

**New Laboratory:**

1. The laboratory director must provide a summary of the laboratory services to be provided. It must describe the areas of accreditation sought, the categories of testing to be provided, which systems will be used, and a complete list of methods. A testing protocol (e.g. draft joint agreement) and QA program must also be submitted.
2. Validation packets for each system must be submitted.
3. Five (5) case studies for each **AREA or CATEGORY** of accreditation
4. Case studies **MUST** contain representative data from all of the **SYSTEMS** and **METHODS** used in the lab. Patient data must be redacted. For laboratories that have not begun clinical testing case studies may be artificial using samples from the validation to demonstrate how interpretation and reporting will be performed.

For example: Established director of a new lab seeks to include HSC/BM unrelated donor. S/he must provide a list of HLA typing categories and systems to be used in the lab (HLA typing: Molecular: SBT; KIR typing: Molecular: SSO; Antibody testing: solid phase: microarray). Material must include

validation of each system, case reports with supporting worksheets and interpretation, including appropriate resolution typing of the recipient and donors.

**A. Accredited Laboratory:**

1. Addition of new **AREA** of accreditation:
  - a. Provide a summary of the services (categories) to be provided.
  - b. Describe the systems to be used and
  - c. Provide a complete list and validation packets of systems.
  - d. Provide the testing protocol or joint agreement.
  - e. Provide detail of quality assurance program relevant to the category and test systems.
  - f. A focused inspection will be performed in the next available cycle. The laboratory will bear the cost of the inspection if it is outside of its normal on-site review.
  
2. Addition of new **CATEGORY** of accreditation:
  - a. Provide summary of CATEGORIES to be added.
  - b. Describe the systems to be used and
  - c. Provide complete list and validation packets of systems.
  - d. Provide detail of QA program relevant to the category and systems to be added.
  - e. For the category of "Other testing" 5 case studies must also be submitted so that the commissioner has a full understanding of testing that is often tailored to specific program requirements.
  - f. Focused inspection is not required, but validation must be reviewed by commissioner and the ARB.
  
3. Addition of a new **TEST SYSTEM**:
  - a. Submit protocol for use of new TEST SYSTEM.
  - b. Submit validation packet for all new tests within the system (e.g. adding Molecular typing by any method). Note: parallel testing must be performed using a system of equivalent resolution of sensitivity.
  - c. Submit quality assurance plan appropriate to the testing.
  - d. Focused inspection is not required, but validation must be approved by the commissioner and co-chair.
  
4. Addition of a new **METHOD** (within approved SYSTEM):
  - a. Perform validation, and have material available for inspector. The commissioner must be notified so that the inspector can be advised of new method.

## **XIX. VALIDATION/VERIFICATION OF NEW SYSTEMS OR METHODS**

FDA approved testing systems require verification to ensure that the test performs according to established specifications. Lab developed testing (LDT) requires validation to demonstrate that the

performance characteristics and clinical efficacy are appropriate for the intended use of the test. Although there are essential differences many of the tasks are the same, and since many of the tests performed in H&I labs are IVD or LDT, the standards for **validation** are specified.

Appropriate assessment of laboratory testing systems and methods is essential for the high complexity lab. Validation provides the director with an understanding of the strengths, weaknesses, and limitations of testing performed in the laboratory. It is also the foundation for the accreditation process. Provision of thorough validation and verification materials to the commissioner and the ARB will expedite the approval process. Appendix I provides a one page step-by-step guideline to material that must be included in an acceptable validation.

ALL test methods, systems, and categories MUST be validated. Validation of the broader CATEGORIES and SYSTEMS must be submitted to the commissioner. When approved by the commissioner and co-chair, the addition will be made to the accreditation letter. Additions or change in a specific assay method must also be validated, but the material can be maintained in the lab for review with the inspector. The laboratory is permitted to perform patient testing prior to receiving official approval for methods validations. Submission requirements:

1. Summary and interpretation of validation. This document is signed by the director or technical supervisor and summarizes the steps undertaken to validate the test.
2. The testing protocol describes the application or purpose of the test. The appropriate joint agreement would be an appropriate document.
3. The SOP provides the step-by step procedure that is reviewed and signed by the director.
4. Performance specifications summarize the accuracy, precision, sensitivity and specificity, range of results, normal values and limitations of the assay. Multiple sources exist for guidance on the calculation of these parameters.
5. Quality control procedures relevant to the technology used and quality assurance measures appropriate to the system.
6. Equipment calibration data for any instruments used in the testing system.
7. Completed training checklist(s) of tasks required for technical staff to demonstrate proficiency, and documentation of competency of all personnel who will be performing the test, and of those reviewing test results.
8. A minimum of 20 parallel tests, at least 10 of which are blinded (described above). Graded proficiency testing may be used to satisfy this requirement. Parallel tests must be performed using a system or method of equivalent sensitivity or resolution (but must be a system already approved in the lab if not blinded). Worksheets must be provided. Samples chosen for parallel testing should demonstrate a variety of potential results (e.g. different antigens or antibody specificities and strengths).
9. For kits include a copy of the manufacturer's instructions for use.
10. Documentation of enrollment in a PT program, or description of how PT is to be performed.
11. ALL patient data MUST be redacted.

Useful links:

<http://www.westgard.com/method-validation-tools-2.htm>

<http://www.fda.gov/ScienceResearch/FieldScience/ucm171877.htm>

## **XX. APPROACH for ACCREDITATION for NEW METHODS**

- A. As new methods or new tests emerge, or the ARB adds new testing systems, and laboratories seek accreditation, it is the responsibility of ASHI to determine if it is within the purview of testing for Immunogenetics and Transplantation. If so, we will determine if we have the appropriate standards and expertise to be able to inspect for accreditation of laboratories for each new method/technology.
- B. An *ad hoc* committee will be formed (and chaired by an ARB member) to address the issue of accreditation for each new testing category or system.
  - i. The committee will consist of the following:
    - a. ARB member(s)
    - b. QAS committee member(s)
    - c. Person(s) with expertise in the method/technology or testing category
  - ii. the *ad hoc* committee will advise the ARB of the need for the following:
    - a. Inspector Training module
    - b. New standards if present standards are not sufficient (QAS)
    - c. Appropriate forms of PT or equivalent

# Appendices



APPENDIX I  
**VALIDATION GUIDELINE**

Laboratory Name: \_\_\_\_\_

ASHI # \_\_\_\_\_ CLIA # \_\_\_\_\_ UNOS # \_\_\_\_\_

Director/Technical Supervisor: \_\_\_\_\_

Commissioner: \_\_\_\_\_ Date of Review: \_\_\_\_\_

**New Addition:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

For all directors, is the new category or system part of your original DTRC portfolio? If not, the director must demonstrate participation in the laboratory's category or system validation process.

**Validation Checklist**

**For new category or system, the following documents must be submitted to your commissioner for review.**

**For new method of previously approved system, the following documents must be available for the inspection but not submitted to your commissioner.**

- \_\_\_\_\_ Summary and Interpretation of Validation - signed by Director or Technical Supervisor
- \_\_\_\_\_ Testing protocol – how test is to be used; purpose of test
- \_\_\_\_\_ Step-by-step procedure
- \_\_\_\_\_ Performance Specifications – summary of accuracy, precision, sensitivity, specificity, range of results, normal values, limitations of assay, as appropriate
- \_\_\_\_\_ QC procedures and QA monitoring
- \_\_\_\_\_ Equipment Calibration data
- \_\_\_\_\_ Training checklist
- \_\_\_\_\_ Competence documentation for those trained to perform test
- \_\_\_\_\_ Enrolled in PT program

Parallel Testing – for new System Minimum of 20 tests; 10 of which must be blinded. Graded PT samples may be used to meet the blinded sample requirement. See section XXI (above) for minimum number of tests required for addition of new Testing Categories.

**Acceptable performance is 80% or greater concordance.**

- \_\_\_\_\_ Parallel Testing – for new Method, may be with previously approved method; Include worksheets if not blinded parallel study; Minimum of 20 tests.

\_\_\_ Validation approved

\_\_\_ Additional data requested

\_\_\_\_\_  
Commissioner

\_\_\_\_\_  
Co-Chair

Useful links:

<http://www.westgard.com/method-validation-tools-2.htm>

<http://www.fda.gov/ScienceResearch/FieldScience/ucm171877.htm>

<b>Category</b> (What is done) Submitted Validation required	<b>System</b> (Assay System) Submitted Validation required	<b>Methods</b> (Specific assay) Internal Validation – labs should send the commissioner an email to notify
<b>Immunogenetics:</b> HLA Typing, MICA Typing, KIR Typing, HPA Typing, ABO/Rh Typing, ABO-A1 Titer	Molecular Serology Flow Cytometry Next Generation Sequencing*	CDC (T and/or B) SSO SSP Sanger Sequencing Real time PCR Flow cytometric phenotyping Serology
<b>Crossmatching</b>	Complement Dependent Cytotoxicity Flow Cytometry Other	CDC (T and/or B) AHG (T and/or B) Flow (T and/or B) Solid Phase (Class I and/or II)
<b>Antibody Testing:</b> HLA, HPA, , MICA, AT1R	Antibody Detection 1. CDC 2. Solid Phase 3. Other  Antibody Identification 4. CDC 5. Solid Phase 6. Other	CDC (T and/or B) AHG (T and/or B) ELISA (Class I and/or II) Flow (Class I and/or II) Microarray (Class I and/or II)
<b>Other Testing</b>	Molecular Immunology Flow Cytometry Cellular Chimerism/Engraftment Monitoring	STR VNTR Flow-Immunophenotyping Immune Cell Function/MLC/PLT SNP Testing Soluble Biomarker Testing

\*novel, emerging technologies such as NGS may require validation submitted at the discretion of the ARB.

**Appendix II**  
**Accreditation Timeline**

<b>Cycle 1</b> 1A = Odd Years; 1B = Even Years*		<b>Cycle 2</b> 2A = Odd Years; 2B = Even Years*		<b>Cycle 3</b> 3A = Odd Years; 3B = Even Years*	
<b>Date Completed</b>	<b>Step in Cycle</b>	<b>Date Completed</b>	<b>Step in Cycle</b>	<b>Date Completed</b>	<b>Step in Cycle</b>
1 January	Application link sent to laboratory	1 May	Application link sent to laboratory	1 September	Application link sent to laboratory
1 March	Application deadline	1 July	Application deadline	1 November	Application deadline
15 March	All applications sent to Commissioners	15 July	All applications sent to Commissioners	15 November	All applications sent to Commissioners
1 March	Packet review done by Commissioners**	1 September	Packet review done by Commissioners**	1 January	Packet review done by Commissioners**
15 April	Inspections begin Prev defec to insp.	15 August	Inspections begin Prev defec to insp.	15 December	Inspections begin Prev defec to insp.
15 June	Inspections completed	15 October	Inspections completed	15 February	Inspections completed
15 June	Interim Report summaries completed	15 October	Interim Report summaries completed	15 February	Interim Report summaries completed
1 July	Lab responses due	1 November	Lab responses due	1 March	Lab responses due
15 July	Onsite Application summaries completed	15 November	Onsite Application summaries completed	15 March	Onsite Application summaries completed
August	Meeting Month	December	Meeting Month	April	Meeting Month
20 August	Letters & certificates edited & reviewed by commissioners & co-chairs	20 December	Letters & certificates edited & reviewed by commissioners & co-chairs	20 April	Letters & certificates edited & reviewed by commissioners & co-chairs
25 August	All letters/ certificates mailed to labs	24 December	All letters/ certificates mailed to labs	25 April	All letters/ certificates mailed to labs
1 September	Date accreditation begins	1 January	Date accreditation begins	1 May	Date accreditation begins

\*Refers to expiration dates; i.e., labs with expiration dates in odd years (05, 07, 09) are in the A cycles (1A, 2A, 3A).

\*\*Refers to packet review with the exception of labs being inspected before April 15, August 15, and October 15. Those (onsite) packets should be reviewed earlier to relay information to inspector before inspection date.

**Appendix III**

**Complaint Grievance Form**

V2.1.22.2016

**This form must be used for documentation and follow-up of all complaints/grievances made against an ASHI accredited laboratory. See ARB operations manual for complete instructions on complaint investigation.**

**Complaint/Grievance Received From:**

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- ASHI Executive Board: \_\_\_\_\_
- ASHI Board Member(s): \_\_\_\_\_
- ARB Executive Board Members: \_\_\_\_\_
- ARB Board Member(s): \_\_\_\_\_
- Ombudsperson: \_\_\_\_\_
- CMS/CLIA: \_\_\_\_\_
- Other: \_\_\_\_\_

Received By: \_\_\_\_\_ Date: \_\_\_\_\_

ARB Program Director Notified (Date): \_\_\_\_\_

**Description of Complaint/Grievance:**

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ARB Executive Board Review (Date): \_\_\_\_\_

Further Action Indicated:  Yes /  No

CMS needs to be notified:  Yes /  No

**Supporting Description Complaint/Grievance Documentation:**

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Attachments / Data File Names: \_\_\_\_\_

**Complaint/Grievance Action Plan:**

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Action Plan sent to the ASHI Executive Board (Date): \_\_\_\_\_

Action Plan sent to the CMS (Contact Person / Date): \_\_\_\_\_

**Complaint/Grievance Investigation/Outcome Summary:**

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Summary sent to the ASHI Executive Board (Date): \_\_\_\_\_

Summary sent to the CMS (Contact Person / Date): \_\_\_\_\_

Complainant notification (Date): \_\_\_\_\_

Attachments / Data File Names: \_\_\_\_\_

**Inspection after Complaint Investigation:**

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*The outcome of the complaint investigation and effectiveness of any corrective actions will be assessed at the next onsite inspection of the laboratory. If necessary, the inspector will be made aware of the complaint and be instructed to examine the laboratory's records verifying the effectiveness of the corrective action. The findings related to the complaint will be included in the complaint tracking document (see appendix III) and forwarded to CMS and the ASHI Executive Board as the final step. Should there be no concerns related to the original complaint the complaint investigation will be considered closed.*

Summary sent to the ASHI Executive Board (Date): \_\_\_\_\_

Summary sent to the CMS (Contact Person / Date): \_\_\_\_\_

**Comments:**

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**Appendix IV**

### New Commissioner Review

Name: \_\_\_\_\_ Review Cycle/Year: \_\_\_\_\_

Duties:		Comments:
I. Pre-Inspection: Packet Review		
A. Communicates to the inspector any previous deficiencies and laboratory response to deficiencies in order to ensure that corrective actions have been effective	<u>YES</u> <u>NO</u>	
B. Communicates any concerns to inspector prior to the inspection	<u>YES</u> <u>NO</u>	
C. Enters the summary report in a timely manner for interim laboratories	<u>YES</u> <u>NO</u>	
D. Communicates with the laboratory when follow-up information/documentation if needed	<u>YES</u> <u>NO</u>	
II. Inspection:		
A. Available for standard interpretation, questions and/or concerns day of the inspection	<u>YES</u> <u>NO</u>	
III. Post-Inspection:		
A. Reviews inspector report within a week to review deficiencies cited	<u>YES</u> <u>NO</u>	
• Questions on any deficiencies are followed-up with both the inspector, laboratory and co-chair when appropriate	<u>YES</u> <u>NO</u>	
• When considering removing a deficiency contacted both the inspector and laboratory	<u>YES</u> <u>NO</u>	
B. Sends a signed copy of deficiency report back to the laboratory	<u>YES</u> <u>NO</u>	
C. Reviews and approves responses to deficiencies	<u>YES</u> <u>NO</u>	
D. Communicates when follow-up information/documentation if needed	<u>YES</u> <u>NO</u>	
E. Prepares "Summary Report" for review by co-Chair within a timely manner	<u>YES</u> <u>NO</u>	
F. Review final letter/certificate for accuracy, completeness and consistency	<u>YES</u> <u>NO</u>	
G. Demonstrates working knowledge of ARB Operations Manual	<u>YES</u> <u>NO</u>	

IV. ARB Meeting		
A. Prepared for presentation of laboratory summary review	<u>YES</u> <u>NO</u>	

Additional Comments:

I have completed the above duties and I feel competent with all that is required with this position.

Commissioner: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By:

Co-Chair: \_\_\_\_\_

Date: \_\_\_\_\_

Program Manager: \_\_\_\_\_

Date: \_\_\_\_\_

Need Inspector Input: Items I.A , I.B, II.A, III.A

Need Laboratory Input: Items I.D, III.A, III.B, III.C,., III.E



Appendix V

*SCOPE OF AUDIT*  
 FOCUSED INSPECTION FOR NEW DIRECTOR/CHANGE OF DIRECTOR/AD HOC INSPECTIONS  
 v2.9.25.2016

Laboratory: \_\_\_\_\_ ASHI No.: \_\_\_\_\_ CLIA

No.: \_\_\_\_\_ Page \_\_\_ of \_\_\_

Topic	Section	Requirement	Yes	NO	Observations
Position	N/A	(title)  Lab Director  Technical Supervisor  Clinical Consultant  Positions held at other laboratories: (5 labs maximum. If more than 2 are NY licensed labs, a waiver from NY is required)			Informational    If not the clinical consultant, who serves in the role:  _____  List other labs and positions:  _____  _____  (use the other side if required)
On-site Schedule	3.2.2.2	How often on site? On-site commensurate with workload (TS)  Is a log kept of hours on/off-site and activities? (Optional)  Evidence of active involvement in lab?	N/A	N/A	_____  If the director does not keep a log of hours on site and activities, is there a written plan for coverage.  List observations showing involvement:



				Degrees, Board Certification Licensed in state, if required Clinical consultant? Must be board certified 2 years full time training (Post-doc, combined AP/CP residency) <u>and</u> 2 years full time training experience directing/supervising ASHI accredited HLA lab.
Responsibilities	E.2.2	Director responsible for the overall operation and administration of the laboratory. Technical supervisor (TS) responsible for the technical and scientific oversight of the lab. The clinical consultant is responsible for providing consultation on the appropriateness of testing ordered and interpretation of test results to the clinical staff.		All three roles may be fulfilled by the same person
	E.2.2.3 E.3.2.3.1	Is the director involved in the selection and oversight of all test systems to provide quality lab services for all aspects of test performance. Appropriate for application?		Describe:  (If test systems are selected by someone other than the director, are they appropriate for the application?)
	E.2.2.4	Does the director ensure that the physical plant and environmental conditions are appropriate for the testing and protect employees from physical, chemical and biological hazards?		<u>Lab tour</u> : Note use of PPE; Presence of fire extinguishers , MSDS and eye wash devices; evacuation instructions; biohazard waste handling including sharps; clutter, trip hazards and storage of materials. <u>List any issues</u> :
	E.2.2.6 E.3.2.3.2	Is there evidence of the role of the director in validation/verification to		Describe:

		ensure that methods are adequate to determine the accuracy, precision and other pertinent performance characteristics?			
	E.2.2.7	Is there evidence of the role of the director in competency testing to ensure that the testing personnel are performing the test methods as required for accurate and reliable results?			Describe:  (Look at records of training and competency evaluation)
	E.2.2.8 E.3.2.3.3	Is the director involved in PT to ensure that: <ul style="list-style-type: none"> <li>• The lab is enrolled in an ASHI approved PT for each test the lab performs</li> <li>• PT samples are tested as required in section C of the Standards. Attestation statement signed by director</li> <li>• Results are on or before the deadlines set by the PT provider</li> <li>• PT graded reports are received and reviewed by the director to evaluate the labs performance and identify problems that need corrective action.</li> <li>• An approved CA plan is followed when any PT results is found to unsuccessful or unsatisfactory.</li> </ul>			Describe:  (Examine PT records that were forwarded to you by the commissioner for active review by the director/TS before submission, on receipt of graded summaries and on corrective actions is needed)
	E.2.2.9	What is this director's role in developing and maintaining the QA activities of the lab? <ul style="list-style-type: none"> <li>• QA policies and procedures</li> <li>• Review of records</li> <li>• Corrective actions</li> <li>• Document control</li> <li>• Investigation/remedial actions for errors and complaints</li> <li>• Follow up of corrective action plans</li> </ul>			Describe:  (Review the lab's written QA plan and SOPs and review records for director's signature, especially corrective actions.)

	E.2.2.10- .11 E.3.2.3.4- .6	<p>Is there evidence of the director's role in monitoring and maintaining of acceptable levels of analytical performance (QC)</p> <ul style="list-style-type: none"> <li>• QC policies and procedures</li> <li>• Establish and maintain acceptable levels of performance from specimen receipt to test reporting.</li> <li>• Review of QC records in a timely manner</li> <li>• Resolve technical problems</li> <li>• Prompt appropriate corrective actions in the event of test system failures.</li> <li>• Results reported only when test systems are working properly</li> </ul>			Describe:
	E.2.2.12	<p>Is the director involved in ensuring that reports of test results include pertinent information required for interpretation (see D.6.2) and that they are timely and accurate?</p> <p>Prior to release, final reports must be reviewed and approved by the director, TS or general supervisor</p>			<p>Is a copy of the report template reviewed and approved by the director, even if this is electronic?</p> <p>Is there evidence that all final reports are reviewed and signed by the director, TS or an individual who meets the qualifications for general supervisor in a timely manner?</p> <p>Observations:</p> <p>Reports signed?</p> <p>TAT?</p>
	E.2.2.13	<p>Does the director ensure that consultation is available to the lab's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions?</p>			<p>Describe:</p> <p>(Ask about a case in which the director consulted with the clinical staff)</p>
	E.2.2.14	<p>Does the director ensure that a</p>			Supervisor or individual

		general supervisor provides on-site supervision of high complexity test performance in accordance with ASHI Standards.		who meets the standards for general supervisor on-site during regular working hours of the lab? 24/7 if the lab operates 24/7.
	E.2.2.15	<p>Is there evidence that the director provides appropriate consultation and supervision to ensure accurate testing and reporting of test results for all aspects of services provided by the lab.</p> <p>Does the director ensure that the lab employs a sufficient number of laboratory personnel with the appropriate qualifications (see E.5 and E.6)</p>		<p>Are all complaints and errors investigated, root causes determined and corrective actions implemented? (check for repeated client complaints or technical errors) Y _____ No _____</p> <p>Are there a sufficient number of technologists to perform both routine and stat testing? (check for staff turnover or high absenteeism)</p>
	E.2.2.16- .17 E.3.2.3.7- .8	<p>Is there evidence of the role of the director in training and competency testing of all testing personnel prior to testing patient specimens. (Director, TS or designee)</p> <ul style="list-style-type: none"> <li>• Identify training needs</li> <li>• Assess education and experience</li> <li>• Maintain records of education and experience for each employee</li> <li>• Provide and document training appropriate for complexity of testing</li> <li>• Evaluate and document competency</li> <li>• Develop training and competency SOPs and forms</li> </ul>		Describe:
	E.2.2.18	Does the director ensure that an approved procedures manual is		Describe:

		<p>available to all testing personnel.</p> <ul style="list-style-type: none"> <li>• Approved by director, TS (signed and dated) prior to use</li> <li>• Reviewed at least every other year by the director and TS. Reviewed and signed within 6 months for new directors</li> <li>• Any revision that changes the way tests are performed or reported must be signed by the CLIA designated director.</li> <li>• Copies of the obsolete manuals are maintained.</li> </ul>			(If the director has been employed in the lab for more than 6 months, the SOPs should have been reviewed and approved by the director.)
	E.2.2.19	<p>Has the lab director provided job descriptions for each consultant, supervisor and person performing any phase of testing (pre-analytical, analytical, post-analytical)?</p> <ul style="list-style-type: none"> <li>• Procedures authorized to perform</li> <li>• Supervision required</li> <li>• Delineates the supervisory or director review required prior to reporting test results.</li> </ul>			<p>Describe:</p> <p>(Check that the job descriptions have sufficient detail and that they are signed by the employee )</p>
	E.2.2.20 E.3.2.3.9	<p>Is there evidence that the director ensures that each member of the technical staff participates in CE relevant to his/her area of responsibility at least to the level required by ARB. If employees perform other testing, CE activities should be relevant to those activities also.</p>			Describe:
		<p>Is there evidence of active involvement in corrective action of any previous deficiencies cited on inspections?</p>			(The list of previous deficiencies should have been sent to you by the commissioner prior to the inspection)

Appendix VI

**Repeat Deficiency Report Form**  
(Note: please date and initial all entries)  
v1.1.22.2016

ASHI Lab # \_\_\_\_\_ Commissioner: \_\_\_\_\_ Co-Chair: \_\_\_\_\_

Standard # \_\_\_\_\_

Description: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Previous Corrective  
Action: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Current Corrective  
Action: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

ARB Conference Call Required (yes/no). Provide summary if yes.  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

CMS Notification Required (yes/no) \_\_\_\_\_

Date Form Sent to Accreditation Office: \_\_\_\_\_



Appendix VII

**Commissioner Inspection Report Form**

*Upload into LearningBuilder upon Completion*

v1.1.22.2016

Date of inspection:	
Inspector name and contact info:	
Date inspector contacted with concerns and prior deficiencies (insert text):	
Laboratory name and contact:	
Inspection review date:	
Commissioner identified issues (list on summary report):	
Additional comments from inspector (copied from correspondence including date may be listed in the remaining issues box):	
Date corrective action received:	
Date corrective action approved:	
Is additional corrective required; requires contingency?:	
Date follow-up received:	

**SUMMARY OF STEPS – The ASHI Inspection**

1. Lab notified of inspector and sent the blackout form by AM
2. Commissioner notified of inspection date by AM
3. Commissioner reviews packet and sends email to inspector (at least 2 weeks prior to inspection)
4. Inspection
5. Commissioner reviews inspection summary and notifies lab (within 1 week of inspection). The Co-chair notified if commissioner and inspector disagree on citation, prior to the lab notification. If Co-chair and commissioner disagree, the co-chair may take the issue to the exec board for discussion. Deficiencies should not be held for full board decision unless no consensus is reached or the standard/observed practice is not clear as it does not provide enough time for labs to follow-up prior to expiration of their accreditation.
6. Lab returns corrective actions (<=30 days from inspection)
7. Commissioner reviews/accepts CA (<35 days from inspection)Notifies lab immediately if CA is not acceptable.
8. Co-chair review (<40 days from inspection) and any contingencies noted:
9. ARB review and vote (at meeting or email if contingency) **\*\*Contingencies should be reserved for items that will take resolve (enhanced PT, space, staffing, etc).**
10. Letters to co-chair/commissioners week after meeting
11. Return date established by AM.

Appendix VIII

**NGS Validation Form**

**Minimum Guidelines for Validation of NGS for HLA**

Upon careful consideration, the ASHI ARB has deemed that HLA typing using Next Generation Sequencing (NGS) represents a new assay system; hence laboratories that intend to add NGS technology are required to submit a Validation Packet to their ARB Commissioner. In keeping with the increased complexity of both technical and bioinformatics processes associated with NGS-HLA testing, ARB has developed guidance for minimum requirements for laboratories to use as they prepare for validation. All laboratories submitting validations must continue to follow the Validation Checklist that is published as Appendix I of the ARB Operations Manual (abbreviated version appended to this document). In addition labs are advised to account for and as applicable submit materials outlined below:

**For labs using commercially available kits for NGS:**

**Parallel Testing:**

Validation should be performed based upon the specific parameters that are relevant to the platform used. Since the availability of validation data from outside sources influences the extent to which a laboratory must independently validate the method, the laboratories that use a commercially available kit should:

1. Ensure the validation includes all sample types (e.g., blood, buccal swab) the lab routinely uses for clinical testing.
2. Ensure that the performance characteristics that are generally required for all validations (e.g., specificity, reproducibility) are established. Additionally, the laboratory must validate metrics that ensure high quality results specific to NGS. Examples that are consistently used include average coverage and read depth.
3. Ensure that the validation includes testing for the common variants. For HLA typing, this would require testing the HLA types that the lab frequently encounters. Testing heterozygous and homozygous types should be considered.
4. Ensure the data management system is included in validation. This includes file format and provisions for managing the data files that will accumulate over time.
5. Ensure the validation includes sufficient number of samples and no less than 50 samples for all loci. More importantly, the laboratory should validate the range of number of samples routinely run in each run for the given lab. For example, if a lab routinely runs 10-20 samples on each run, the lab should validate the lower and higher end of their sample number range on a run to ensure comparable endpoints.
6. Ensure to validate reproducibility (e.g., inter-assay, intra-assay, and inter-technologist). This can be accomplished with 3 samples tested at least 3 times. For example, inter-assay validation would require testing at least 3 samples in 3 different assay runs. The endpoints for comparison would include typing assignments as well as quality metrics.
7. Ensure that appropriate criteria for acceptance of sequencing runs are determined. This may be accomplished by defaulting to the acceptable factors and parameters set by each manufacturer.
8. The laboratory must have a provision for new data, such as intron sequences and novel alleles.

**Blind Parallel Testing:** After the validation is completed, the laboratory is prepared to demonstrate proficiency by blind testing of samples. A minimum of 20 blind samples are necessary to fulfill the

requirement. Samples may not be shared between two labs that share the same director. Acceptable performance is 80% or greater of the blind samples concordant at all tested loci at least in the 1st and 2<sup>nd</sup> fields. The blind samples may have been sequenced by NGS or Sanger's method or their high resolution result has been obtained by other methods such as SSO and SSP.

**Quality testing:** ASHI standards located at D.5.2.11 provide important metric driven elements that must be included.

- 1) D.5.2.11.1 Sufficient representation of all pertinent allelic specificities of the locus tested in order to evaluate possible allele dropouts. Alleles with consistently poor representation in, sequencing data (drop-out) must be addressed by alternative methods for detection.
- 2) D.5.2.11.2 Document and validate the process/method for preparing the enriched sample for sequencing, including **compliance with relevant vendor specifications.**
- 3) D.5.2.11.2 When barcodes are incorporated after target enrichment, fidelity of the barcoding method to identify a particular sample needs to be monitored (e.g. by rotating control samples with different barcode sequences).
- 4) D.5.2.11.4 Define and document acceptable analytic performance criteria for the sequencing run incorporating vendor specifications.
  - a. base quality per read position
  - b. average read length
  - c. average coverage
  - d. uniformity of coverage across the length of the targeted region
- 5) D.5.2.11.4 Instrument performance measures must include data from internal control samples and/or vendor supplied quality control material.
- 6) D.5.2.11.8 Independently validate software programs used to generate genotyping information from next generation sequencing data. Ensure that the genotyping algorithms are appropriate for the sequencing strategy used and the error modalities (e.g., homopolymer errors, substitutions) presented by different sequencing chemistries.

A focused inspection is not required, but validation must be approved by the commissioner and co-chair.

**For labs developing own reagent for NGS:**

New testing systems require validation to demonstrate that the performance characteristics and clinical efficacy are appropriate for the intended use of the test. Appropriate assessment of laboratory testing systems is essential for the high complexity lab. Validation provides the director with an understanding of the strengths, weaknesses, and limitations of testing performed in the laboratory. It is also the foundation for the accreditation process. As such, it is expected from a lab that is developing their own reagents to run sufficient number of samples to optimize their protocol.

**Reference:**

Volume 76, Issue 12 of Human Immunology, edited by D. Monos and M. Maier is dedicated to Single-Molecule DNA Sequencing.