

## ASHI ACCREDITATION PROGRAM POLICIES

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### GENERAL INFORMATION

All Policies will be assigned a policy number that will reflect the category of the Policy (R - review; A - administration; O - operational) and a number that indicates the policy number and the year in which it was adopted. When a Policy is revised, a suffix is to be appended that will be the letter M (modified) and the number of the revision and year of the change. E.g., a review policy initially adopted in 1998 and then amended later that year and then, again, in 1999 would have a number such as R-7-98-M-2-99. The description of the Policy is to include the policy name, number, date approved or revised, the rationale (if appropriate), and a complete description of the policy itself. The Operations Manual main body should have only the most current version of a Policy. The rationale of revised Policies should be the rationale for the revision. All previous versions of a policy should be retained in a separate file. This will prevent repeating mistakes as well as facilitate resurrecting worthwhile policies that were inappropriately discontinued. A copy of discontinued policies should be retained in the file and should note the date and rationale for the action.

It would be worthwhile to identify keywords in Policies and develop and maintain an index. A Policy Manual is to be maintained as an appendix to the Accreditation Operations Manual. Maintenance of the Policy Manual is the responsibility of the junior-most chair. Part or all of some policies may be incorporated into the body of the Operations Manual as appropriate. Maintenance of the Operations Manual and review of the Policy Manual is the responsibility of the Program Director.

### Summary of Numbering System

Initial policies have a three part alphanumeric designation:

- letter to designate the category: review (R), administration (A), operational (O)
- policy number
- year of adoption

example: R-02-99

Revised policies acquire a three part suffix: M-##-## where the first set of numbers is the number of the revision and the second set is the year they occurred.

**POLICY NAME:** Definition of Possible Evaluation Outcomes  
**POLICY NO.:** R-01-99, M-1-04  
**DATE APPROVED:** 01-28-99, 9-21-04

**RATIONALE:**

There needs to be sufficient flexibility to accommodate varying degrees of compliance with Standards and Regulations as well as those situations that pose a threat to patients or others. The possible evaluation outcomes defined are the same as those used by CMS and achieve the goal defined above.

**POLICY**

The possible outcomes of the evaluation process will be:

**Grant or Renew Accreditation**

May be outright or contingent on follow-up action by lab. Conditions under which this may occur:

1. Lab is in compliance with all relevant Standards, Regulations, requirements (grant Accreditation outright; may be accompanied by recommendations).
2. Lab has deficiencies in compliance with one or more Standards and:
  - a. the deficiencies, collectively, do not represent a threat to patient care or a hazard to the general public (this includes lab personnel);
  - b. 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 (how and when improvements will occur).*

**Deny or Revoke Accreditation –the Accreditation Office notifies CMS within 30 days**

The deficiencies, collectively, represent a threat to patient care and/or hazard to the general public that the lab is unwilling to or incapable of correcting immediately.

OR

There are substantial deficiencies and the deficiencies cannot be corrected in a reasonable time.

**Limit Accreditation**

Accreditation is granted in some but not all areas for which the lab has applied.

Occurs when:

1. deficiencies sufficient to deny Accreditation are limited to certain Areas of Accreditation;
- OR
2. there are insufficient data for evaluating a certain category.

**Suspend Accreditation – the Accreditation Office notifies CMS within 30 days**

May be in one or more categories.

Used when the operation of the laboratory poses a threat to patient care and/or a hazard to the general public and when there is evidence that the laboratory is capable and willing to correct the problem(s) in a reasonable time. (Notification within 10 days if imminent jeopardy).

This condition requires rapid action by the inspector, commissioner, and chair because of obligations to CMS for labs using ASHI Accreditation as evidence of compliance with CLIA certification requirements. Should be applied to all labs, for uniformity.

**POLICY NAME:** Information to Provide to Inspector  
**POLICY NO.:** R-02-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Part of the evaluation of an Accredited lab is an assessment of the implementation and efficacy of action taken to correct previous deficiencies. Inspectors must have adequate information to make this determination.

**POLICY**

The Commissioner is to provide the following to the Inspector

1. a list of previous citations - the last Commissioner and Inspector's Summary Reports plus other problems noted;
2. information about issues that needed clarification or were of concern to Commissioner in the application packet.

**POLICY NAME:** Guidelines for Presentation of Evaluation Summary to ARB  
**POLICY NO.:** R-03-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Guidelines will enhance the consistency of the presentations

**POLICY**

The primary review shall include:

1. a brief history of the lab: initial dates of Accreditation in each category, years of experience of key personnel, deficiencies cited in current inspection and whether any are repeats from previous inspections, number of ABHI certified personnel;
2. current deficiencies;
3. lab's response to current deficiencies;
4. Commissioner's recommendation for action (cite precedence if applicable).

**POLICY NAME: Egregious Actions Requiring Immediate Action**  
**POLICY NO.: R-04-99**  
**DATE APPROVED: 01-28-99**

**RATIONALE**

Identification of actions considered egregious provides consistency in following this requirement and allow the laboratories to be informed.

**POLICY**

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:

1. data falsification;
2. violations of standard precautions (blood borne pathogens);
3. staff size grossly insufficient for workload;
4. severely deficient and inconsistent PT performance;
5. working conditions that present a health or safety threat to employees (reported to OSHA\*);
6. scientific and/or technical incompetence;
7. any practice that jeopardizes patient care.

\*OSHA will be notified of any safety or health issues found in laboratories.

**POLICY NAME:** Inspection Requirement Following Lab Relocation  
**POLICY NO.:** R-06-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

It is necessary to determine that laboratory facilities have adequate space, lighting, and ventilation and comply with local, State, and Federal safety regulations. For laboratories performing tests for deceased donor transplants, the new facilities must be capable of supporting 24 hour, 7 day a week coverage. Compliance with these requirements can only be assessed by an on-site inspection.

**POLICY**

On-site inspections shall be mandatory for labs that have relocated, even if the new location is within the same building. The inspection shall occur after a reasonable time (generally 3-5 months after the move), shall be focused on an inspection of the facilities, and shall utilize a checklist adapted for this purpose.

Refer to Policy O-19-05 for waiving re-location inspections.

**POLICY NAME:** Review of the Labs of the Accreditation Program Director & Chairs  
**POLICY NO.:** R-07-99  
**DATE APPROVED:** 04-15-99

**RATIONALE**

With a review board, rather than an individual, making final decisions about evaluations, there is no value in having the reviews of any of the ARB member labs done differently than any other lab.

**POLICY**

The review process as described in the Policy Manual, in which a primary and secondary review are performed by the Commissioner and co-Chair, respectively, and a final decision made by the ARB, shall be applied to all laboratories, including those of the members of the ARB. ARB members shall excuse themselves from the room during the Board's discussion of their review.

**POLICY NAME:** Continuing Education Requirements  
**POLICY NO.:** R-08-99, M-1-02, M-2-04  
**DATE APPROVED:** 04-23-99, 10-18-02; 08-06-04

**RATIONALE**

Continuing education requirements should support maintenance of competency of full and part time laboratory personnel and should not create an unacceptable burden on the laboratory or the individual. Wherever possible, criteria for various requirements should take into consideration policies established by others with experience/expertise in the area.

**POLICY**

ABHI certification is not a requirement; however, evidence of recertification\* will be accepted as documentation of compliance with the continuing education requirement.

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:

- 50 contact hours per year for Directors and Technical Supervisors
- 12 contact hours per year for Clinical Consultants
- 27 contact hours per year for Supervisors\*
- 12 contact hours per year for technologists/technicians
- 27 (outside of their training curriculum)\*\* contact hours per year for Directors in Training

\*Supervisors who are not CHS must have 27 hrs/yr

\*\*The Director in training may receive many “educational” hours during the course of training. However, at least 27 hours must be from seminars, workshops, lectures, etc. outside the training curriculum.

**POLICY NAME:** Test Validation Submission Requirements  
**POLICY NO.:** R-09-99, M-1-02, M-2-02, M-3-08  
**DATE APPROVED:** 04-23-99, 04-05-02, 10-18-02, 08-02-08

#### **RATIONALE**

The Accreditation Program must assure that laboratories meet all requirements for instituting a new clinical assay.

#### **POLICY**

The following materials must be submitted to the Commissioner for review prior to initiating a new clinical assay:

1. Summary of the internal validation data and interpretation of data
2. The step-by-step procedure;
3. The protocol for use of the procedure;
4. The program for personnel training;
5. Documentation of the competency of personnel who will be performing the test and reviewing the test results;
6. Performance specifications to include accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics;
7. Quality control procedures;
8. Calibration data for necessary equipment
9. Quality assurance data;
10. External blinded\*, parallel validation tests:
  - a) Specimens from an ASHI accredited laboratory (under the direction of a different individual(s)) or,
  - b) Well-characterized blinded reference materials (commercial panels, etc.) or,
  - c) A complete set (one year) of PT, or
  - d) A combination of a, b, and c (if c is partial)

\*NOTE: results from the reference laboratory and the validating laboratory must be reported independently to the commissioner.

11. The laboratory must be enrolled in a PT program

**For reference, see ASHI application instructions, refer to the ASHI ARB website, or refer to the CLIA State Operating Manual CFR493.1213.**

**POLICY NAME:**       **Benchmarks for Review of High Volume Laboratories**  
**POLICY NO.:**       **R-10-99, M-1-06**  
**DATE APPROVED:**   **08-5-99, 08-04-06**

### **RATIONALE**

While all laboratories must be held to the same standards, laboratories that have extremely high or low volume workloads experience different problems and obstacles in achieving and maintaining the desired level of quality. It may be more difficult to identify problems in high volume laboratories because of the large staff size and large numbers of test results produced. Benchmarks that focus on problems that are exacerbated by high work volumes would help reviewers recognize problem areas in such labs.

### **POLICY**

The following are benchmarks to be used in the inspection of high volume labs. This list should be amended as new information and experience dictates. Working definition of high volume is  $\geq 50,000$  tests per year.

1. Existence and use of formal routes of communication to assure reliable and time transmission of information within and outside the lab.
2. Adequate space free of clutter and hazards.
3. Written agreements with clients re. services to be provided and the specifics of each.
4. Tracking mechanisms for (including documentation of the use of these mechanisms and evidence of corrective action):
  - client inquiries
  - complaints and responses
  - errors and corrective actions
  - test requisitions
  - specimens
  - turn-around times
5. Methods appropriate for the work volume.
6. Appropriate QC for all automated procedures and equipment.
7. Procedure and protocol manuals that are complete, up-to-date, and readily accessible.
8. Mechanism for validating reports
9. Appropriate, organized training programs and documentation of personnel competency and periodic evaluation.
10. Well-defined and documented inventory, storage, and QC of reagents.
11. At least once per year, each individual must test an unknown for each clinical test that he/she performs.
12. Documented review of QA problems with testing personnel.

**POLICY NAME:** Review of Director Portfolios/Qualifications  
**POLICY NO.:** R-11-99, M-1-02  
**DATE APPROVED:** 08-5-99, 04-05-02

### **RATIONALE**

Review of Director portfolios/qualifications is a time consuming responsibility that is an integral part of the Accreditation process for individuals not previously qualified as a Director in one or more Areas of Histocompatibility and Immunogenetics. The co-Chairs and Commissioners have performed this function in the past but the volume of work and the increasing number of such applications threatens to bog down the laboratory evaluation process and delay the evaluation of labs involving these Directors. The Accreditation Program also reviews Director Training Programs and therefore, already has a group of individuals who are familiar with the requirements for a Director/Technical Supervisor.

### **POLICY**

The Director Training Review and Credentialing Subcommittee will perform the initial review of Director portfolios/qualifications as follows:

One member of the Subcommittee will perform the review within 30 days of receipt of the portfolio at the ASHI Accreditation Office. The reviewer will send a summary to the three Chairs addressing three areas:

1. the extent to which the portfolio was complete;
2. evidence of expertise in the appropriate areas;
3. weaknesses and concerns

For those portfolios judged acceptable and following receipt of the written summary, the Chairs will have 1 week to contact the applicant to arrange a oral interview to be conducted by a minimum of 3 people to include as follows:

1. At least 2 members of the Directors Training Review and Credentialing Subcommittee, including the reviewer(s).
2. One Co-chair of the ARB.

The Accreditation Manager will transcribe comments concerning the interview. In the case of an established Director/Technical Supervisor, that is adding a category(ies) or Areas(s) of Accreditation, the oral interview may be waived.

Instruction and forms for this process are to be included in the Accreditation Operations Manual. There will be a fee assessed for the review.

Criteria for membership on the subcommittee:

- ASHI member
- not on the ASHI Board of the ASHI Foundation
- an approved director
- sign a confidentiality agreement and a conflict of interest disclosure statement.

Collectively, the Subcommittee shall represent expertise in all the Areas of Accreditation.

**POLICY NAME:** Accreditation Certificate Cover Letter  
**POLICY NO.:** R-12-99  
**DATE APPROVED:** 10-19-99

**RATIONALE**

It is necessary to document what Technologies have been reviewed and approved for each lab. The ASHI Accreditation Certificate includes the Area of Accreditation but cannot accommodate the many Technologies that may be in use.

**POLICY**

Each ASHI Accreditation Certificate will be accompanied by a cover letter that details the Technologies approved for the approved Areas of Accreditation.

The ASHI database will include both the Area of Accreditation and the Technologies for submission to CMS.

**POLICY NAME:** ABO and/or Rh Typing  
**POLICY NO.:** R-13-99, M-1-04, M-2-07, M-3-08, M-4-08  
**DATE APPROVED:** 10-19-99, 09-21-04, 12-01-07, 01-08-08, 05-20-08

## **RATIONALE**

Prior to 1999, laboratories that tested in the two-subspecialty Areas of Histocompatibility and ABO/Rh typing had to be evaluated by two organizations. Evaluation in the subspecialty of ABO/Rh typing, by ASHI, would reduce the number of inspections imposed on these labs. For these labs, ASHI will perform evaluation in the area of ABO/Rh typing.

## **POLICY**

As of 1999, labs can now be evaluated for ABO / Rh typing as part of their ASHI reviews.

Labs testing samples from US patients must participate in a CMS approved Proficiency program for ABO/ Rh.

Satisfactory PT for ABO/Rh requires 100% agreement with consensus results for each shipment and failure to attain 100% is considered an unsatisfactory performance. Corrective actions must be undertaken for any unsatisfactory performance and the effectiveness of such corrective actions must be evaluated by the laboratory.

Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance using a rolling time frame. The ARB Accreditation office will monitor PT results for laboratories accredited for ABO typing by checking results reported to CMS by their approved ABO Proficiency Testing programs on a quarterly basis

If ABO/Rh is unsuccessful, enhanced proficiency testing is required. Refer to Policy O-13-01. 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. For a second instance of unsuccessful ABO PT testing, the suspension of testing is mandatory for laboratories testing samples from U.S. patients, requires satisfactory performance in 2 consecutive new PT send-outs from CMS approved vendors and would be for a minimum of 6 months unless the laboratory had already voluntarily ceased testing. To expedite compliance with this requirement, laboratories may subscribe to two different proficiency testing programs. Results of the enhanced proficiency testing in ABO/Rh will be reviewed and approved by the ARB before routine testing may be resumed

Laboratories only testing samples from non US patients may substitute and include local proficiency exchange programs.

**POLICY NAME:** Proficiency Testing Corrective Action  
**POLICY NO.:** R-14-99, M-1-02  
**DATE APPROVED:** 11-24-99, 04-05-02

### **RATIONALE**

Guidelines have been requested for required documentation when Proficiency Testing corrective action is needed.

### **POLICY**

In the re-accreditation instructions to applicants section J. – External PT Results:

Satisfactory PT performance requires at least an 80% success rate for each challenge (send out) of each analyte.

Therefore, unsatisfactory performance is getting below an 80% score for a challenge (send out) of each analyte. Unsatisfactory performance in two consecutive or in two out of three challenges constitutes unsuccessful performance and requires enhanced proficiency testing.

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%. Laboratories must designate one PT provider for each analyte tested. Refer to Policy # O-13-1 for Enhanced Proficiency Testing requirements.

We are requesting along with the PT summary, and copies of all PT results, documentation of corrective action for each PT error.

A corrective action investigation and report for these errors must include:

1. The analyte identified as discrepant, unsatisfactory or unsuccessful. Submit the scored/graded report(s) from the PT program.
2. Your CLIA number.
3. The PT provider. Include documentation of the laboratories' attempt to obtain additional sample or reshipment, if needed or appropriate.
4. Documentation of the results of the PT events for the 3 prior challenges.
5. Evidence of satisfactory PT results on the subsequent testing event.
6. Director's review of the QC results for the method/analyte at the time of the unsatisfactory or unsuccessful PT event.
7. Evidence of thorough investigation, conclusions, as well as any and all remedial follow up actions taken by the laboratory to correct the root cause of the problem once identified. Include changes in policy and/or procedures where applicable. Indicate whether the error was in the pre-analytical, analytical, or post-analytical phase of testing.
8. All interim actions taken to assure the ongoing quality and accuracy of patient test results. For instance, split sampling or inter-laboratory comparison, or testing by alternate method or change in reagents or procedure.
9. A look back at reported patient results may be appropriate and necessary depending on the cause of the error.

**POLICY NAME:** Inspections by Members of the ARB  
**POLICY NO.:** R-15-99, M-1-02, M-2-03, M-3-07  
**DATE APPROVED:** 12-9-99, 04-05-02, 10-26-03, 03-30-07

### **RATIONALE**

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.

### **POLICY**

#### **USE of ARB Members as INSPECTORS**

1. New Commissioners are strongly discouraged from serving as an Inspector during the first 2-year term.
2. 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.
3. If any member of the Board serves as an inspector, they are to recuse themselves from the ARB vote for that laboratory.
4. Inspector training requirements will be met by active service on the Accreditation Review Board.
5. Co-Chairs cannot inspect laboratories in their 4 regions.

#### **INSPECTORS for INTERNATIONAL LABORATORIES (outside continental North America)**

1. 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.
2. 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.
3. 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.
4. 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.

**POLICY NAME: Inspection Requirements Following Change in Lab Director/Technical Supervisor**

**POLICY NO.: R-16-00, M-1-02**

**DATE APPROVED: 8-5-00, 04-05-02**

**RATIONALE**

CFR 493.15 requires that the Accrediting Organization receive notice of change in lab Director or Technical Supervisor within 30 days. A change in Director or Technical Supervisor can greatly impact the lab's operation. An on-site inspection is required to re-evaluate the lab.

**POLICY**

An on-site inspection shall be mandatory for labs that have a change of lab Director or Technical Supervisor. The inspection shall occur after a reasonable time (generally 3-6 months after the change). Generally, the inspection should involve a single day by a single Inspector. The Inspector's Checklist – Change in Director or Technical Supervisor will be used which focuses on those items that directly involve the Director or Technical Supervisor (e.g. procedure manual signed by new Director or Technical Supervisor, etc.). The Inspector will be instructed to include an evaluation of the new lab Director's or Technical Supervisor's role in the lab in relation to the responsibilities outlined in the Standards and guidelines.

In cases where a qualified Director is relocating to a laboratory where an established Director is remaining in service (i.e. as a co-Director), the on-site inspection may be waived if the qualifications of the new Director are not substantially different from the Areas of Accreditation of that laboratory.

In cases of temporary/interim Directors while a formal search for a permanent Director is in progress, an inspection will occur after a reasonable time (generally 3-6 months). This inspection can be rescheduled if a permanent Director is retained prior to the inspection date.

See Policy O-18-05 for waiving change of Director inspections.

**POLICY NAME:** CLIA Certification Requirement for Labs doing HLA Typing for the NMDP Donor Registry  
**POLICY NO.:** R-17-00  
**DATE APPROVED:** 08-5-00

**RATIONALE**

Some labs are performing HLA typing of NMDP donors for the NMDP donor registry. In a few labs, this is the only testing considered in the specialty of Histocompatibility testing. CMS has determined that HLA typing of NMDP donors for the donor registry is a test that must meet the conditions set forth in the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

**POLICY**

HLA typing of donors for inclusion in the NMDP donor registry must be evaluated as a Histocompatibility test. A lab doing only HLA typing of donors for inclusion in the NMDP donor registry must meet the lab requirements of CLIA. Therefore, they must have a CLIA number.

**POLICY NAME:** Internal Proficiency Quality Control (Monthly Unknown) Guidelines  
**POLICY NO.:** R-18-00, M-1-03  
**DATE APPROVED:** 08-05-00, 10-26-03

#### **RATIONALE**

For histocompatibility-testing individuals performing an array of different tests, periodic assessment of an individual's testing reproducibility is only required to involve a single unknown. However, each calendar year must include an unknown periodic assessment of each of the different tests performed by each of the testing individuals.

#### **POLICY**

Each histocompatibility-testing individual must perform a periodic internal proficiency quality control/unknown and, for each test authorized to be performed by a histocompatibility-testing individual, at least one unknown must be tested each year. External proficiency samples can be used as part of the internal proficiency quality control. Internal Proficiency can also be designed to evaluate tech-to-tech variations in scoring, reproducibility, or interpretation.

#### **EXAMPLE:**

At year's end, a technologist authorized to perform serological HLA typing, molecular typing and flow cytometry crossmatching must have at least one serologic typing proficiency, at least one molecular typing proficiency and at least one flow cytometry proficiency. Records of performance evaluation must be maintained and reviewed at least monthly.

**NOTE:** ASHI Standards dropped the requirement for monthly unknowns. Competency in each area of testing must be evaluated on an annual basis.

**POLICY NAME:** Evaluation of Proficiency Testing  
**POLICY NO.:** R-19-00, M-1-03, M-2-06, M-3-07, M-4-08  
**DATE APPROVED:** 08-05-00, 10-26-03, 08-04-06, 03-30-07, 08-02-08

#### **RATIONALE**

To ensure the lab is performing proficiency as appropriate for the technologies used in the lab.

#### **POLICY**

Proficiency testing must be submitted at least twice per year for all methods used as “stand alone\*” methods in the laboratory.

In relation to Proficiency Testing for HLA Typing, Proficiency typing results must be reported at all levels of resolution that are reported clinically. Any antigen/allele that the proficiency survey grades will be evaluated. A single miss on any locus is considered an incorrect phenotype/result. HLA class I and class II are evaluated separately.

In relation to Proficiency Testing for any clinical test, a laboratory may choose to include samples that were not graded in the evaluation of Proficiency Testing, when the number of graded samples is very small. If non-graded samples are included, the laboratory must use “all” ungraded as well as graded samples for that survey to include the 3 most recent consecutive surveys. The correct response will be the “majority\*\*” response. The commissioner will review cases on an individual basis noting any trends in the overall results submitted by the laboratory.

\*Stand alone method: the only method used to determine a clinical result reported for any assay.

\*\*Majority: defined as ≥60% consensus

**POLICY NAME:** Accreditation Requires Clinical Activity  
**POLICY NO.:** R-21-00, M-1-03, M-2-05  
**DATE APPROVED:** 08-05-00, 10-26-03, 08-06-05

#### **RATIONALE**

Although a lab may do proficiency and blind testing for an Area of Accreditation, without a history of clinical testing, performance cannot be evaluated completely.

#### **POLICY**

A lab can only retain an Area of Accreditation for which there is clinical activity with the exception of "Testing for 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.

When/if no activity has occurred in the past year, Accreditation will be suspended in that Area until activity resumes and staff competence is validated. Reinstatement requires notification from the laboratory in writing that activity has resumed.

A laboratory can maintain Accreditation for a Technology that is not currently used by continuing to successfully participate in Proficiency Testing that uses that Technology.

**POLICY NAME:** Determination of DNA Typing Resolution  
**POLICY NO.:** R-22-01, M-1-04, M-2-05, M-3-06, M-4-08  
**DATE APPROVED:** 08-10-01, 04-04-04, 08-06-05, 12-29-06, 04-05-08

**RATIONALE**

Labs are performing DNA Class I and/or Class II typing at different levels of resolution. The approved level(s) of DNA typing resolution is included in the Accreditation letter accompanying the ASHI Certificate of Accreditation. Determining the appropriate level(s) of resolution may not be obvious from the application. To ensure consistency, guidelines for determining the level(s) of resolution were developed.

**POLICY**

Validation and external proficiency testing 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).

DNA typing low resolution will be granted if serologic (antigen level) resolution is reported, predominantly.

DNA typing high resolution will be granted if single alleles or clusters of alleles (as defined below) are predominantly reported.

Laboratories must achieve a high resolution typing for at least 80% of the alleles typed and reported for one year’s proficiency testing submitted in order to be considered to be performing high resolution DNA typing. See ARB Policy R-24 for reduced proficiency sample testing.

Laboratories performing high resolution DNA typing must report single alleles. With the exception of selected null alleles (see policy R-37-07), the lab does not need to resolve the differences between alleles for those groups of HLA class I alleles that have identical sequence in exons 2 and 3 and those groups of HLA class II alleles that have identical sequence in exon 2 and differ outside these exons, as designated in the currently observed IMGT/HLA database release and found on the list of Common & Well Documented Alleles\*. The lab does need to resolve selected or “frequently found” null alleles found on the list of Common & Well Documented Alleles\* with a frequency rate greater than 1 in 1000. See policy R-37-07. Clinical practice may dictate a laboratory’s means of identification of these “frequently found” null alleles by utilizing more than one technique such as supplemental serologic typing or nucleotide sequencing of exon 4.

High Resolution results for a locus must include only one unambiguously assigned possible genotype, or **MULTIPLE** ambiguous genotypes in which only one possible genotype includes TWO alleles on the list of **Common and Well Documented Alleles (CWD)\***.

Possible Combinations	Examples	Results
CWD1, CWD2, or rare 1, rare 2	B*3501, B*4601 or B*3562, B*4608	Acceptable
CWD1, CWD2, or CWD3, CWD4	B*3501, B*4901 or B*5001, B*5301	NOT Acceptable
CWD1, CWD2g1, or CWD1, CWD3g1	B*3501, B*0705 or B*3501, B*0706**	Acceptable
CWD1, CWD2, or CWD1 rare	B*3501, B*4601 or B*3501, B*4608	NOT Acceptable
CWD1, CWD1 or CWD1, rare	B*3501, B*3501 or B*3501,	NOT Acceptable

	B*3562	
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\*\*B\*0705 and B\*0706 differ outside exons 2 and 3 and do not need to be resolved although they are both on the list of Common Alleles. The group B\*0705/0706 is common in Asians and well documented in Caucasians and Africans.

**\*Reference: *Report of the ASHI ad hoc Committee for the Identification of Common and Well Documented Alleles.***

**POLICY NAME:** Lot Validation for Commercial Molecular Typing Kits  
**POLICY NO.:** R-23-01, M-1-03  
**DATE APPROVED:** 04-05-02, 10-26-03

#### **RATIONALE**

Kit QC (validation) for molecular typing kits is not specified in the ASHI Standards or Inspector Guidelines. The minimum number of DNA specimens to be run for QC has not been specified. Commercial molecular typing kits are considered equivalent to serological trays from a quality control perspective. The QC of molecular typing kits should approximate the QC required for serological trays.

#### **POLICY**

##### **New Lot validation for Commercial Molecular Typing Kits**

Parallel tests with reference DNA specimens or spiking (positive panel) must be tested on new lots of commercial molecular typing kits. The actual number of parallel samples tested is determined by the Director for the size of the kit and frequency of use. The samples chosen for parallel testing should include:

- As many different alleles as possible for the number of samples tested.
- Alleles that have demonstrated weak amplification with previous lots of the same kit.
- Alleles that test primer/probe sets that have changed from the previous lot.
- Expected positives and negatives.
- The results of the QC check and the Date in Use must be recorded.

Performance of the trays must be monitored continuously.

##### **Quality Control for New Shipments of Molecular Typing Kits**

- The laboratory must ensure that all components of the typing kits are working properly. This can be accomplished by:
  - Testing with a reference DNA and assessing quality of reactions and accuracy of result  
OR
  - Testing with a non-critical patient sample and assessing quality of reactions and ability to give a clear interpretation of result.
  - The results of the QC check and the Date in Use must be recorded.
- **Performance of the trays must be monitored continuously**

**POLICY NAME:** HLA Molecular Typing class I and class II  
Proficiency Testing Requirements  
**POLICY NO.:** R-24-01, M-1-03, M-2-05, M-3-06  
**DATE APPROVED:** 04-05-02, 10-26-03, 08-06-05, 08-04-06

### **RATIONALE**

Many laboratories are requesting Accreditation in HLA class I and/or class II low and/or high resolution molecular typing for multiple methods. Some of the PT exchanges test a large number of samples per year and it may be cost prohibitive to perform all methods on all samples. There is also the consideration that testing all samples with all methods may not mimic patient testing. For these reasons, it may be permissible for a laboratory to perform PT on a reduced number of samples according to the criteria listed below, noting that Federal Regulations (493.1236) require PT challenges to occur at least twice per calendar year.

### **POLICY**

Laboratories may choose to test a reduced number of PT samples for HLA class I and class II low or high resolution molecular typing under the following conditions:

- The laboratory must have a written policy that describes how the PT will be used to assess performance of each of the methods used in the laboratory. This policy must be established prior to testing of PT samples. All PT testing must be submitted according to the pre-established schedule of testing.
- The lab must designate the PT provider(s);
- The lab must participate in at least two separate send-outs of a PT survey for each method and each locus;
- The lab must test a minimum of 8 samples (or 100% if <8 provider samples) per year for each method and each locus at the resolution used for clinical samples.
- The laboratory must include their PT testing policy with the PT summary report when submitting the ASHI re-accreditation packet whenever they are submitting less than the full year's worth of results for a method.

**POLICY NAME:** Director/Technical Supervisor Approval for New Testing Categories/Technologies/Methods  
**POLICY NO.:** R-25-02, M-1-03, M-2-08, M-3-08  
**DATE APPROVED:** 04-05-02, 10-26-03, 04-05-08, 08-02-08

### **RATIONALE**

Testing categories use different technologies and methods. There are many new methods which fall under the five separate technologies being validated and implemented in Histocompatibility Laboratories. Many technologies are related in methodology. As such, the expertise required to implement these Technologies is related.

### **POLICY**

1. New Directors/Technical Supervisors must have their credentials, training, and experience reviewed by the Directors Training Review and Credentialing Committee (DTRC) for each Areas of Accreditation for which they are seeking approval. This would include CV, Board Certifications, training documentation, and portfolios of case studies.
2. Portfolios will be required and will be reviewed by the DTRC for any Director/Technical Supervisor who wishes to add an Areas of Accreditation for which s/he has not been previously approved. This also applies to Directors/Technical Supervisors who move to an existing lab that performs testing in an Areas of Accreditation for which s/he has not been previously approved.

#### **Areas of Accreditation are:**

HSC/BM Transplantation: Related Donor  
HSC/BM Transplantation: Unrelated Donor  
Solid Organ Transplantation: Deceased Donor  
Solid Organ Transplantation: Live Donor  
Relationship Testing  
Histocompatibility Testing for Other Clinical Purposes  
Transfusion Support

3. When the laboratory introduces a new testing category/technology and/or method into the lab, validation studies must be performed and copies sent to the Commissioner for review. Upon approval of the validation, the laboratory and the Director/Technical Supervisor will be approved for the testing category/technology and/or method. If it is a new technology or testing category for the laboratory, the commissioner and co-chair will review the validation; an ad-hoc inspection may be required if the validation package indicates areas of concern that can only be resolved by direct observation.
4. If a Director/Technical Supervisor moves to a laboratory performing methods for which s/he has not yet been approved, in a technology or testing category for which s/he is approved, s/he must provide the Commissioner with Documentation of Expertise. This must include documentation of training (either on-the-bench training or workshop attendance, etc. and review of at least 20 Cases with interpretation of results. If the method involved is under a technology or testing category for which the Director does not have previous approval, then documentation will be reviewed by the ARB.

5. If a new method is contained within a technology or testing category for which a Director/Technical Supervisor has prior approval, only validation studies are necessary.
6. If a method is under more than one technology or testing category, the Director/Technical Supervisor must be approved for all the technologies or testing categories involved in the laboratory's testing protocol.

**Methods under each Technology**

<b>Technologies:</b>	<b>Testing Categories:</b>	<b>Methods included under Technology:</b>
Serology/Solid Phase	HLA Typing Crossmatching HLA Antibody Screen/ID Relationship Testing	Cytotoxicity, ELISA, Microarray
Molecular- Polymorphism Analysis	HLA Typing Relationship Testing	SSO, rSSO, SSP, RFLP
SBT / Fragment Analysis	HLA Typing Chimerism/Engraftment Relationship Testing	Sequencing, STR, VNTR,
Flow Cytometry	HLA Typing Crossmatching HLA Antibody Screen/ID Immunophenotyping	Methods for Quantitation, Direct Labeling, Indirect Labeling, Internal Labeling, External Labeling
Cellular	Cellular Assays	MLC, PLT, CTL, Mitogen or Antigen stimulation, and Immune Cell Function (ex. e.g., by measuring thymidine incorporation or ATP production)
ABO/Rh		ABO grouping, Rh typing, anti-A1 titers

**\*Microarray includes Bead Technology**

**POLICY NAME:** Transfusion Support Accreditation  
**POLICY NO.:** R-26-02, M-1-04  
**DATE APPROVED:** 04-05-2002, 9-21-04

### **RATIONALE**

Laboratories often request Accreditation in the Area of Transfusion Support on the application packet. Often these laboratories are HLA typing patients and/or transfusion donors but not providing interpretation related specifically to the non-rbc cellular transfusion treatment of the patient.

### **POLICY**

Effective 1/1/2002:

In order to be accredited for Histocompatibility related Transfusion Support:

- Laboratories must provide interpretative notes along with the HLA typing and HLA antibody screening results from patients and donors, which reflect the effect of non-rbc (platelet, granulocyte) transfusions on the patients' care.
- Laboratories only HLA typing transfusion donors do not qualify for Accreditation in this Area.
- There are no minimum numbers of cases per year required.
- Laboratories must be compliant with all relevant ASHI Standards.

### **Note to CMS:**

This applies only to histocompatibility testing (HLA typing and HLA antibody testing) relative to assistance in the selection of HLA compatible transfusions of platelet products or granulocyte products.

Recipients of multiple transfusions of platelets and granulocytes often develop HLA antibodies that result in difficulties in obtaining compatible donor material. Transfusion of units whose HLA matches specific HLA antibody present results in no increase in cell count following the transfusion (referred to as "refractory").

Blood banks/transfusion services often interact with histocompatibility labs to type the recipient and test for HLA antibody when the expected benefit is not apparent. They use this information to select the potential donors that would be HLA compatible.

This Area of Accreditation is limited to laboratories that do more than simply perform HLA typing on recipients. This is intended for laboratories that do extensive testing or are actively involved in the donor selection. Most often this occurs in HLA laboratories associated with Blood Banks.

**POLICY NAME:** Water Quality  
**POLICY NO.:** R-27-02, M-1-04  
**DATE APPROVED:** 08-08-2002, 12-03-04

**RATIONALE**

Laboratories must document the quality of the water used for reagents and in test systems. The frequency and extent may vary according to the quality of the source water.

**POLICY**

Bottled 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.

**POLICY NAME:** Deficiencies overruled by ARB  
**POLICY NO.:** R-29-03  
**DATE APPROVED:** 10-26-2003

**RATIONALE**

An inspector may occasionally cite a laboratory for a deficiency that is subsequently overruled by the ARB. Since the previous deficiencies are sent to the Inspector at the next cycle, it is important that these deficiencies be removed from the report so that the lab is not written up for a “repeat deficiency” at the next inspection.

**POLICY**

If a deficiency cited by the Inspector is overruled by the ARB during the review process, the deficiency must be removed from the final report. The laboratory and Inspector will be notified of the ARB’s decision in a letter, if applicable.

**POLICY NAME:** Plan of Action from Directors of Multiple Labs

**POLICY NO.:** R-30-04, M-01-06  
**DATE APPROVED:** 04-02-04, 12-01-06

### **RATIONALE**

When a Director provides less than full time on-site coverage in a laboratory, he/she needs to submit to the ARB a plan of action stating how he/she intends to meet the needs and responsibilities for the role of Director and/or Technical Supervisor and/or Clinical Consultant. If responsibilities are delegated, these need to be clearly identified, including to whom they are delegated and how the tasks will be monitored.

### **POLICY**

When a Director changes the number of laboratories for which he/she is responsible, the ARB will request a written Plan of Action identifying how the roles of Director and Technical Supervisor will be fulfilled, as well as a comprehensive plan, detailing the coverage of all of his/her laboratories.

This Plan of Action needs to identify the amount of time and frequency of on-site availability and identify any tasks that will be delegated to others as well as a mechanism to evaluate that the delegated tasks are properly handled.

The Director must have regular interactions with the staff and the transplant programs and must be available to address issues, problems or concerns in a timely manner. Evidence of off-site interactions and on-site visits must be available.

If the part-time Director also serves as the Clinical Consultant, he/she must ensure that consultation is available to the clients. Access to the Clinical Consultant is critical when there is a time-sensitive issue. This function may not be delegated to the General Supervisor.

The Laboratory Director is expected to be available during inspections.

**POLICY NAME:** Out of Cycle Processing of Laboratory Reviews  
**POLICY NO.:** R-31-04, M-1-06, M-2-08  
**DATE APPROVED:** 08-06-04, 12-01-06, 04-05-08

**RATIONALE**

In circumstances where a focused inspection or Director portfolio submission is required, laboratories may request an out of cycle review process.

**POLICY**

The Commissioner will handle the review with the Co-Chair. If both are in agreement that the request is appropriate and the materials submitted are complete, a focused inspection and/or director portfolio review will be scheduled and reviewed at the next ARB meeting. In rare instances, the Accreditation Office will call for a full Board review of the on-line report and will call for electronic vote on the laboratory application.

**POLICY NAME:** Solid Organ Transplantation: Deceased Donor Accreditation  
**POLICY NO.:** R-32-04, M-1-05  
**DATE APPROVED:** 12-03-2004

## **RATIONALE**

The current standard of care for solid organ transplantation requires assessment of risk for rejection. This assessment requires HLA Typing and evaluation of the extent of sensitization by HLA Antibody Screening and Crossmatching. Accreditation for Deceased Donor transplant also requires 24-hour on-call coverage. The “equivalent accrediting organization” phrase was added in order to give us some flexibility with the foreign labs. This would allow us the option for them to use EFI labs, if approved by the ARB on a case-by-case basis.

## **POLICY**

In order to be accredited for Solid Organ Transplantation: Deceased Donor:

- The laboratory must provide 24-hour on call coverage for deceased donor workups and be the laboratory of record for the final crossmatch with the recipient.
- HLA Typing, HLA Crossmatch Testing and HLA Antibody Screening must be performed by a laboratory Accredited by ASHI or by an equivalent accrediting organization.
- If any of these tests are referred to another Accredited laboratory, the referring lab must document review and interpretation of results
- 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.
- Laboratories must be compliant with all relevant ASHI Standards.

**POLICY NAME:** Solid Organ Transplantation: Live Donor Accreditation  
**POLICY NO.:** R-33-04, M-1-05  
**DATE APPROVED:** 12-03-2004

## **RATIONALE**

The current standard of care for solid organ transplantation requires assessment of risk for rejection. This assessment requires HLA Typing and evaluation of the extent of sensitization by HLA Antibody Screening and Crossmatching. The “equivalent accrediting organization” phrase was added in order to give us some flexibility with the foreign labs. This would allow us the option for them to use EFI labs, if approved by the ARB on a case-by-case basis.

## **POLICY**

In order to be accredited for Solid Organ Transplantation: Live Donor:

- Laboratories must provide HLA typing for both transplant candidates and donors.
- Laboratories must have policies for regular evaluation of patient antibodies and for selection of appropriate crossmatch procedures.
- HLA Typing, HLA Crossmatch Testing and HLA Antibody Screening must be performed by a laboratory Accredited by ASHI or by an equivalent accrediting organization.
- If any of these tests are referred to another Accredited laboratory, the referring lab must document review and interpretation of results.
- 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.
- Laboratories must be compliant with all relevant ASHI Standards.

**POLICY NAME:** Proficiency Testing Requirements for Antibody Testing by Multiple Methods  
**POLICY NO.:** R-34-04  
**DATE APPROVED:** 12-03-2004

### **RATIONALE**

Many laboratories are requesting Accreditation for multiple different methods for HLA antibody screening and/or antibody identification for class I and/or class II HLA antibodies. Current PT surveys for class I and class II antibodies may contain a minimum of 12 samples. In some cases, there is not enough sample volume to perform testing for all methods used in the laboratory, especially since the same sera are also used for crossmatch testing. Federal Regulations (493.1236) require PT challenges to occur at least twice per calendar year.

### **POLICY**

Laboratories may choose to test a reduced number of PT samples for each method for HLA class I and class II Antibody Screening under the following conditions:

- The laboratory must have a written policy that describes how the PT will be used to assess the performance of each of the methods used in the laboratory.
- The lab must designate the PT provider(s)
- This policy must be established prior to testing of PT samples.
- All PT testing must be submitted according to the pre-established schedule of testing.
- The lab must participate in at least two separate send-outs of a PT survey for each method and for each HLA class (I, II) of antibodies
- The lab must test a minimum of 8 samples per year (or 100% of samples if PT provides <8) for each method and for each HLA class (I, II) of antibodies
- The laboratory must include its PT testing policy with the PT summary report when submitting the ASHI re-accreditation packet whenever it is submitting less than the full year's worth of results for a method or antibody class.

**The laboratory must either compare the results of different methods using the same PT samples or compare the results using other samples at least twice a year.**

**POLICY NAME:** Alternatives to Formal External Proficiency Testing  
**POLICY NO.:** R-35-06  
**DATE APPROVED:** 08-04-06

## **RATIONALE**

Laboratories performing tests clinically for which formal external proficiency testing is not available must evaluate test accuracy at least twice per year. The following options may be used as alternatives to formal external Proficiency Testing.

## **POLICY**

The following options are acceptable when no formal external Proficiency Testing is available:

1. Exchange of samples with another laboratory accredited by ASHI (or by an equivalent organization) for performing that testing.
2. Blind testing of reference samples with known test results.
3. Blind testing of clinical samples with known clearly expected test results.
4. Splitting samples between two technologists who are blinded as to each other's test results.
5. Having one technologist perform duplicate tests starting with an original sample that is split before any processing is started. (This should only be allowed when there is only one technologist trained to perform that particular test and the other options are not possible.)
6. Another method for validating the test performance that provides at least equivalent confidence in the accuracy of the test method.

**POLICY NAME:** Proficiency Testing Accepted by ASHI  
**POLICY NO.:** R-36-06, M-1-08  
**DATE APPROVED:** 08-04-06, 04-05-08

## **RATIONALE**

The ARB needs to recognize vendors supplying PT materials. ASHI Standards require that graded PT be used for any analyte for which it is available

## **POLICY**

The ARB approves the following Proficiency Testing surveys for analytes not regulated by CMS:

1. ASHI
2. CAP
3. ASEATTA
4. New York State
5. AFDT (SEOPF)
6. NMDP Blind Testing
7. UCLA International DNA Exchange
8. EuroTransplant Reference Exchange
9. EFI EPT Approved PT
10. INSTAND
11. German Society for Parentage Testing
12. International Society of Forensic Genetics ISFG
13. ISFG Spanish-Portuguese Working Group Paternity Testing Survey
14. Others that fulfill the following requirements:
  - a. At least 2 sendouts per year
  - b. Graded results

ABO is a regulated analyte. Labs governed by CMS must participate in a CMS approved survey for ABO/Rh typing.

**POLICY NAME:** Null Allele Discrimination  
**POLICY NO.:** R-37-07, M-1-08, M-2-08  
**DATE APPROVED:** 03-31-07, 05-20-08

## **RATIONALE**

Molecular typing can lead a laboratory to incorrectly assign an antigen (serologic equivalent) as being expressed when it is truly a null allele.

## **POLICY**

It is strongly recommended that the following frequently encountered null alleles be discriminated from the expressed alleles by all laboratories reporting results for the relevant loci

- A\*2409N – should be distinguished from A\*2402 when A\*24 is found in association with B\*40 or B\*27, even though the difference is located in exon 4.
- B\*5111N – should be distinguished from B\*5101 when B\*51 is found in association with A\*0201, Cw\*15 and DRB1\*0402, even though the difference is located in exon 4.
- Cw\*0409N – should be distinguished from the expressed allele Cw\*0401 when B\*4403 is present (B\*44 in association with Cw\*04) – these differ only by a deletion of one nucleotide in Exon 7.
- DRB5\*0108N – should be distinguished from the expressed allele DRB5\*0102 when DRB5 is found in association with DRB1\*1502
- DRB4\*0103N – should be distinguished from expressed DRB4 alleles when DRB4 is found in association with DRB1\*0701 and DQB1\*0303 (DQ9) (DRB1\*07 in association with DQB1\*03)

**POLICY NAME:** Requirements for the Clinical Consultant  
**POLICY NO:** R-38-08, M-1-08  
**DATE APPROVED:** 04-05-08, 08-01-08

## **RATIONALE**

The clinical consultant is considered to be one of the key personnel in the laboratory. Appropriate documentation is required to demonstrate that the clinical consultant fulfills all the requirements according to ASHI standards.

## **POLICY**

1. The laboratory must have a qualified clinical consultant at all times.
2. The ARB must be notified when a change occurs in the clinical consultant position within 30 days of a change. The following supporting documentation must be provided:
  - Board Certification for US laboratory clinical consultants or Board Certification or equivalent for non-US laboratory clinical consultants
  - Documentation of experience relevant to the laboratory's areas of accreditation (such as fellowship training, post-doctoral training, or publications in histocompatibility or transplantation)
  - CV
  - CE documentation for all applicable areas of accreditation
  - A university transcript or degree must be available if requested by an onsite inspector.. For graduates of non-US universities, verification of equivalency of the university transcript must be available if requested by an onsite inspector.
3. All of the above listed documentation must be available for all current Clinical Consultants
4. A change in clinical consultant may potentially affect accreditation status. Qualifications shall be reviewed by the commissioner and sent to the ARB for approval. Approved changes shall be reported to any agencies for which the laboratory has given ASHI the authority to provide required accreditation information.

**POLICY NAME:** Requirements for the General Supervisor  
**POLICY NO:** R-39-08, M-1-08  
**DATE APPROVED:** 04-05-08, 08-01-08

## **RATIONALE**

The general supervisor is considered to be one of the key personnel in the laboratory. Appropriate documentation is required to demonstrate that the supervisor fulfills all the requirements according to ASHI standards.

## **POLICY**

The laboratory must have a qualified general supervisor at all times.

1. The ARB must be notified when a change occurs in the general supervisor position within 30 days of such change.
2. The following supporting documentation must be provided for new general supervisors to confirm laboratory training and experience for the individual:
  - ABHI Certification (CHT or CHS) or other professional certifications if available
  - State license, if required
  - Documentation of histocompatibility experience (such as personnel records, CHS or letter from the director(s) in whose laboratory training occurred)
  - CV
  - CE documentation for all applicable areas of accreditation
  - A university transcript or degree must be available if requested by an onsite inspector. For graduates of non-US universities, verification of equivalency of the university transcript must be available if requested by an onsite inspector
3. A change in general supervisor may potentially affect accreditation status. Qualifications shall be reviewed by the commissioner and sent to the ARB for approval. Approved changes shall be reported to any agencies for which the laboratory has given ASHI the authority to provide required accreditation information

**POLICY NAME:** Plan of Action for Changes Involving a Change of  
Director's Time Commitment  
**POLICY NO.:** R-40-08  
**DATE APPROVED:** 04-05-08

### **RATIONALE**

When a Director's time commitment at a laboratory changes, he/she must submit to the ARB a plan of action stating how he/she intends to meet the needs and responsibilities for the role of Director and/or Technical Supervisor and/or Clinical Consultant. If responsibilities are delegated, these need to be clearly identified, including to whom they are delegated and how the tasks will be monitored.

### **POLICY**

1. The ARB must be notified when a change in a director's time commitment occurs within 30 days of such change.
2. When a Director's time commitment changes from full time to part time, the ARB will request a written plan of action identifying how the roles of Director and Technical Supervisor will be fulfilled, as well as a comprehensive plan detailing the coverage.
3. This plan of action needs to identify the amount of time and frequency of on-site availability and identify any tasks that will be delegated to others as well as a mechanism to evaluate that the delegated tasks are properly handled.
4. The Director must have regular interactions with the staff and the transplant programs and must be available to address issues, problems or concerns in a timely manner. Documentation of off-site interactions and on-site visits must be available.
5. If the part-time Director also serves as the Clinical Consultant, he/she must ensure that consultation is available to the clients. Access to the Clinical Consultant is critical when there is a time-sensitive issue. This function may not be delegated to the General Supervisor.

**POLICY NAME:** ARB Response to Repeat Deficiencies in the next On-site or Interim cycle  
**POLICY NO.:** R-41-08, M-1-08  
**DATE APPROVED:** 05-20-08, 08-01-08

Rationale: 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.

Policy: If a 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:

1. The Commissioner will verify that there indeed is a repeat deficiency by contacting the Inspector and/or contacting the Laboratory Director, as appropriate.
2. If it is verified that there is a repeat deficiency, the Commissioner will make a preliminary assessment of the seriousness of the deficiency in relation to its potential to affect patient care and/or its nature as one of the 4 deficiencies considered to be Mandatory Deficiencies by CMS in the case of labs testing samples from US patients. These Mandatory Deficiencies are:
  - i. Failure to fill a "key" laboratory personnel position (Director, Technical Supervisor, Clinical Consultant or General Supervisor) with a qualified individual for any time period.
  - ii. Failure to enroll in Proficiency Testing (or equivalent) for any approved test system.
  - iii. Exchange of information or samples with another laboratory involved in reporting Proficiency Testing results.
  - iv. Failure to successfully participate in Proficiency Testing  
NOTE: 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.
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:

- i. 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 ABO PT testing, the suspension of testing is mandatory for laboratories testing samples from U.S. patients and would be for a minimum of 6 months. Reinstatement of testing requires satisfactory performance in 2 consecutive new PT send-outs from CMS approved vendors.
- ii. A scheduled or unannounced ad-hoc laboratory inspection
- iii. A recommendation that the laboratory seek expert advice from a particular ASHI member and then submit a new corrective action plan
- iv. A request for submission of a request for and approval of a new plan for corrective action with review of the effectiveness of the plan within 6 months of approval.

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.

**POLICY NAME:** Requirements for Technical Personnel  
**POLICY NO:** R-42-08, M-1-08  
**DATE APPROVED:** 05-20-08, 08-01-08

## **RATIONALE**

All laboratory technical personnel must meet CMS qualification requirements. Appropriate documentation is required to demonstrate that technologists fulfill all the requirements according to ASHI standards.

## **POLICY**

1. The laboratory will provide a list of all technical staff members, including new staff members, with every annual re-accreditation application
2. The following supporting documentation must be available for review for members of the technical staff during each on-site inspection:
  - ABHI Certification (CHT or CHS) or other professional certifications if available
  - State license, if required
  - Documentation of training and annual competency assessment for each test method performed (for new members of the technical staff, competency assessment must be documented twice in the first year of employment)
  - CE documentation for all applicable areas of accreditation
  - A university transcript or degree must be available if requested by an onsite inspector.. For graduates of non-US universities, verification of equivalency of the university transcript must be available if requested by an onsite inspector.

**POLICY NAME:** Single Allele Testing in Absence of DNA High-Resolution Accreditation  
**POLICY NO:** R-43-10  
**DATE APPROVED:** 04-10-10

## **RATIONALE**

This policy provides clarification of requirements for single allele pharmacogenetic or disease association testing.

## **POLICY**

The laboratory must report the presence or absence of the particular allele specified by the requisition. If not approved for DNA typing high resolution, the laboratory must have approval for the low-resolution level typing of the method (e.g. SSO, SSP, etc) and validation for each HLA allele they wish to report. The laboratory must perform proficiency testing at high-resolution level 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)

**POLICY NAME: Relevant Content of Continuing Education**  
**POLICY NO: R-44-10**  
**DATE APPROVED: 04-10-10**

## **RATIONALE**

ASHI standards require that technical staff participate in continuing education relevant to the areas of responsibility in histocompatibility and/or immunogenetics testing at least to the level of the minimum requirements outlined by the ASHI Accreditation Review Board. This policy modifies section XIII, D, 2 of the ARB Operations Manual

## **POLICY**

**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 minimum number of continuing education hours shall be:**

- Directors/Technical Supervisor: 50 hours per year
- Clinical Consultants: 12 hours per year
- General Supervisor: 27 hours per year
- Technologists/technicians: 12 hours per year

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

**POLICY NAME: Proficiency Testing Designation**  
**POLICY NO: R-45-10**  
**DATE APPROVED: 04-10-10**

## **RATIONALE**

Per current ARB policy, laboratories may subscribe to more than one PT survey for the same technology/method but must designate a single PT provider for each technology/method tested. A requirement that this designation be submitted to the ARB at the start of each calendar year will assist the accreditation commissioner in his/her review of the PT submitted in the accreditation application.

## **POLICY**

At the start of each calendar year, all laboratories must fill out the Designation of Primary PT Provider form and submit to the accreditation manager who will forward to the ARB. A primary PT provider will be designated for each technology/method used in the laboratory. If the laboratory chooses to test a reduced number of samples for antibody testing or molecular typing, they must follow the protocols in the ARB Operations Manual.

**POLICY NAME:** Definition of Graded Proficiency Testing  
**POLICY NO:** R-46-10  
**DATE APPROVED:** 04-10-10

## **RATIONALE**

ASHI standards require laboratories to participate in graded proficiency testing programs, when available. This policy clarifies the definition of “graded”.

## **POLICY**

For US labs, a PT program must provide scores consistent with standard 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.

**POLICY NAME: Communication to CMS of ARB imposed sanctions, revocation or withdrawal of accreditation, and associated appeals**

**POLICY NO.: R-47-10**

**DATE APPROVED: 07-21-10**

**RATIONALE:**

For laboratories utilizing ASHI for CLIA and for other deeming entities, there needs to be a process for communication of actions taken by the ARB as a result of laboratory review.

**POLICY**

The ARB must annually report to CMS any of the following actions which occur in laboratories using ASHI for CLIA:

1. A list of laboratories in which “alternative” sanctions have been imposed showing –
  - The effective date of the sanctions,
  - The reasons for imposing the sanction,
  - The corrective action taken by the laboratory, and
  - If the laboratory has achieved compliance, the verified date of compliance;
2. A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation; and
3. All appeals and reconsideration decisions.

This information will be communicated to CMS or other deeming entities by the PD and/or Accreditation Manager at least annually or, when necessary, after the ARB Meeting where the actions are approved by the ARB. An annual summary will also be provided to CMS.

**POLICY NAME:** Employment Conflict of Interest for Inspectors and ARB Members  
**POLICY NO.:** O-01-99, M-1-03  
**DATE APPROVED:** 08-5-98, 10-26-03

**RATIONALE**

No member of the ARB should be involved in activities that are or appear to involve a conflict of interest or with their position in the Accreditation Program.

**POLICY**

No Inspector or member of the ARB may solicit or accept business or job opportunities from any laboratory for which they are currently providing ARB review services (e.g.. There may be no conflict of interest by any persons directly involved in the inspection process).

Any conflict of interest or potential conflict of interest should be reported to the Program Director and noted in the individual's profile.

**POLICY NAME:** ASHI Membership Requirement for ARB  
**POLICY NO.:** O-02-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Appointment on the ARB involves a mutual commitment and recognition between the individual and the Society.

**POLICY**

ARB and Appeals Board members must be members of ASHI.

**POLICY NAME:** Non-Review Responsibilities of Chairs  
**POLICY NO.:** O-03-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Responsibilities of the Chairs should familiarize them with the overall perspective of the Program's operations.

**POLICY**

Responsibilities of chairs:

Junior-most Chair: maintain Policy Manual

Middle chair: organize ITWS

Senior chair: become familiar with responsibilities of and fill in for Program Director.

**POLICY NAME:** Accreditation Advisory Committee  
**POLICY NO.:** O-04-99, M-1-02, M-2-03  
**DATE APPROVED:** 01-28-99, 12-06-02, 10-26-03

#### **RATIONALE**

The Advisory Committee should serve in support of the ARB and should have expertise in the responsibilities and operations of the Accreditation Program

#### **POLICY**

The composition of the Accreditation Advisory Committee will be the last 3 ARB Program Directors.

All members shall be past Chairs or Program Directors.

The Committee may have additional members to meet special needs.

- The senior-most member shall serve as Chair.
- The Advisory Committee shall serve as the Appeal Board.

If the departing Program Director cannot fulfill the role of service on the Appeals Board, the most senior Commissioner rotating off the Accreditation Review Board will be asked to assume those duties.

Members of the Advisory Committee may be invited to ARB business meetings, excluding participation in laboratory review.

Advisory Board Members may attend ARB business meeting but attendance is not required; travel expenses will be covered by ASHI only when attendance is required.

Advisory Board Members will receive current ARB manuals, minutes, and other information relevant to staying knowledgeable about the Program

**POLICY NAME:** Inspector Training Requirements  
**POLICY NO.:** O-05-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

All inspectors shall be familiar with the new review system.

**POLICY**

All Inspectors must go through an inspector-training workshop within two years of implementation of the new system and prior to performing an inspection under the new system.

**POLICY NAME:** Inspector Training Requirements  
**POLICY NO.:** O-06-99, M-1-99, M-2-02, M-3-02  
**DATE APPROVED:** 08-5-99, 04-05-02, 08-8-02

### **RATIONALE**

ASHI must assure that Inspector competency is maintained. This is an absolute necessity for maintaining a meaningful evaluation process and is mandated by our agreement with CMS.

Issues regarding the assignment of Inspectors have arisen, including:

- Difficulty finding inspectors for certain laboratories
- Some Inspectors performing multiple inspections per year
- Insufficient Inspectors for some inspection cycles
- Expenses involved in travel costs

### **POLICY**

All Inspectors must go through formal Inspector Training. After attending a full day training workshop, they must perform a minimum of one on-site inspection with a qualified Inspector. The trainee and trainer must both submit an evaluation of the process on the appropriate evaluation forms for each inspection performed to the ARB Inspector Training Chair. When the Inspector Training Chair concurs that the Inspector trainee is qualified based on the evaluations s/he will submit the approval in writing to the ARB Accreditation Manager, including areas of expertise. A certificate will be issued to the new Inspector and the database updated to reflect the new Inspector status and areas of expertise.

When the roster of labs to be inspected is circulated, there will be a column to check if an Inspector is available to perform inspections that cycle. Specific labs may be checked as a preference; however, they may not be accommodated. The actual site selections will be made with considerations regarding travel cost and any specific needs of the laboratory.

In order for an Inspector to remain in active status, he/she must

1. be available to perform a minimum of 1 inspection each year and actually perform a minimum of 1 inspection every 2 years. There will be one right of refusal.
2. attend a minimum of one Inspector's Workshop (1/2 day) every other year.

**POLICY NAME:** Duties and Responsibilities of Ombudspersons  
**POLICY NO.:** O-07-99  
**DATE APPROVED:** 01-28-99

### **RATIONALE**

To enhance the efficacy and credibility of the Accreditation Program there needs to be a means by which applicants can address complaints or suggestions. Such information can be directed to the members of the ARB. However, applicants may have the incorrect impression that any negative comment could jeopardize their Accreditation or would fall on deaf ears. It is also difficult to be totally objective about criticism. Therefore, a sounding board comprised of individuals who are well versed in the Accreditation process from having served as a Commissioner or Chair but who are sufficiently removed to be seen as objective, would provide a very useful function.

### **POLICY**

The program shall have Ombudspersons that serve as an alternative venue for applicants and members to submit suggestions and complaints.

#### Qualifications

A past Commissioner, Chair, or Program Director who has been off the ARB for at least one year.

#### Responsibilities and Privileges

1. serves as a diplomat for the Accreditation Program and is to be receptive to all suggestions, complaints, inquiries, etc.
2. takes the following action on information received:
  - A. communicates suggestions to the Program Director
  - B. investigates complaints about general practices to determine if they involve an incident or are a perception;
  - C. investigates complaints about specific incidents to determine an accurate account as possible;
  - D. reports complaints and findings to the PD or, if the complaint involves the PD, to the senior co-Chair who will issue a written response summarizing action taken; if anonymity is desired, the PD's report may be sent to the Ombudsperson for follow up with the complainant;
  - E. the Ombudspersons are to provide the PD with a brief summary of activities for inclusion in the annual report to ASHI Board of Directors.
3. may attend ARB Business Meeting but attendance is not required; travel expenses to be covered by ASHI only when attendance is required.
4. to receive current ARB manuals, minutes, and other information relevant to staying knowledgeable about the Program

**POLICY NAME:** Selection of Inspectors for Labs Outside N. America  
**POLICY NO.:** O-08-99, M-1-00, M-2-00, M-3-03, M-4-04  
**DATE APPROVED:** 08-5-00; 10-26-03; 08-06-04

### **RATIONALE**

Reorganization and modernization of the ASHI Accreditation Program, in 1999, was directed, in part to democratizing the process and to enhancing consistency in the review process. Part of this effort was a disbandment of geographic regions to normalize the workload among the Board members. This may place some commissioners at a disadvantage in dealing with foreign labs. Further, Accreditation of those laboratories is not simply an evaluation process but also a representation of the entire Society. Inspectors for these labs must be capable of representing all aspects of ASHI in the best possible light and must have some knowledge of ASHI's history and be recognized experts in the field. Further, selection of the inspectors must take into account any politically sensitive issues.

Modification: Occasionally, inspections have not been obtainable under the above restrictions. Other inspectors that have not been a commissioner but are very experienced inspectors have been available. Current Chairs and Commissioners may be appropriate for some inspections.

### **POLICY**

1. 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.
2. Inspections for International Laboratories should be first offered to a past member of the ARB or an ARB member who has served at least three years.
3. 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.
4. 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.
5. Selection of Inspectors for laboratories outside of N. America may be done one cycle earlier to obtain lower airfares.

**POLICY NAME:** Schedule for Inspector Training Workshops  
**POLICY NO.:** O-09-99, M-1-02  
**DATE APPROVED:** 08-4-99, 04-05-02

**RATIONALE:**

It is necessary to have an ongoing training program to maintain an adequate pool of inspectors and to update them on changes in technology, regulations, and protocols. These goals can be achieved by conducting two types of workshops: full day training workshops for new inspectors or those who have not performed inspections in the recent past, and half-day updates to keep active, trained inspectors up-to-date. Conducting these workshops in conjunction with meetings that are attended by qualified or potential inspectors serves to minimize cost. [Note: While the One Lambda Technical WS may be an ideal venue and an ITWS conducted at the 1999 WS was extremely well attended and received, ASHI Board of Directors banned holding ITWS in conjunction with a commercial program. If this prohibition is removed, this venue should also be considered.]

**POLICY:**

Generally, there will be a minimum of a full-day training workshop at the Annual ASHI meeting. However, it is important that trainees who have attended a full-day workshop complete their on-site training segment in a timely manner in order to become full-fledged Inspectors. If there is a significant delay in the number of trainees who have not had this opportunity within the year of their initial workshop, then the full day workshop at the Annual meeting may be waived until there is not a backlog. Half-day workshops will always be held at the Annual meeting. However, there must be a pre-registration of at least 10 participants; otherwise, the workshop will be cancelled. Special requests for additional workshops will be reviewed and approved by the ARB Executive Board.

Regional meeting workshops discontinued once on-line training is available.

**POLICY NAME:** Reports to ASHI Board of Directors  
**POLICY NO.:** O-10-99  
**DATE APPROVED:** 08-5-99

### **RATIONALE**

ASHI Board of Directors requested that the Program's reports include benchmarks by which the Board can evaluate the ARB's performance.

### **POLICY**

Items to include for all reports to the Board of Directors

1. number of reviews performed since last report, categorized by on-site, renewal, or ad hoc
2. appeals in progress
3. complaints received and action taken
4. meetings/teleconferences with other organizations
5. policy changes
6. workshops, articles, website hits, etc.
7. items on list of materials requiring Board review

Items to include in report to the Board once a year

1. summary of fulfillment of obligations to other organizations (e.g., validation surveys, data submission, renewal applications, reports, etc.). (given at ASHI annual meeting)
2. changes in ARB (ASHI Annual Meeting)
3. approval of new ARB Program Director (mid-term meeting)
4. validation survey outcomes
5. summary of Accredited labs, by category
6. budget

**POLICY NAME:** Review of Federal Register  
**POLICY NO.:** O-11-99  
**DATE APPROVED:** 08-5-99

**RATIONALE**

The Accreditation Program must be aware of the latest changes in Federal Regulations implementing CLIA.

**POLICY**

The Accreditation Program Director will be responsible for checking the Federal Regulations for changes, at least quarterly.

**POLICY NAME:** Inspection expenses for Labs Creating Special Circumstances  
**POLICY NO.:** O-12-00  
**DATE APPROVED:** 08-05-00

**RATIONALE**

In some cases, inspection expenses for special circumstances have been clearly caused by the lab and usually exceed the annual Accreditation fee, resulting in a financial loss to ASHI.

**POLICY**

Inspection expenses in excess of the biennial Accreditation fees will be charged to the lab when the expenses are clearly the result of special circumstances caused by the lab. The lab will be notified that they will be responsible for the additional expenses in excess of the biennial Accreditation fees.

**POLICY NAME:** Enhanced Proficiency Testing Requirements  
**POLICY NO.:** O-13-01, M-1-02, M-2-04, M-3-04, M-4-06, M-5-07, M-6-08, M-7-08  
**DATE APPROVED:** 05-07-01, 04-05-02, 09-21-04, 11-01-04, 08-06-06, 12-01-07,  
01-08-08, 05-20-08

#### **RATIONALE**

Enhanced Proficiency Testing requirements are the same as the requirements for a new method approval.

#### **POLICY**

Laboratories will be required to submit enhanced proficiency testing results when 2 out of 3 consecutive proficiency testing challenges are unsatisfactory. (See policies R-13-99 and R-14-99.)

For ABO typing, enhanced Proficiency Testing for labs testing samples from U.S. patients must involve 2 different send-outs from CMS approved vendors although 2 different vendors can be used.

For other analytes, enhanced Proficiency Testing requirements are equal to the number of samples in the laboratory's designated yearly proficiency testing survey or 8 samples, whichever is less and the lab may use blinded, parallel testing with another ASHI Accredited laboratory or equivalent (check with the laboratory's Commissioner). Impartiality must be maintained between the two laboratories involved with the blind sample exchange e.g. the laboratories cannot share the same director. If the laboratory has been performing successfully in a second approved Proficiency survey (refer to ARB policy R-36-06) or other formal sample exchange of the same analyte, those results may be submitted to satisfy the requirement for Enhanced Proficiency Testing. These results must cover the same 12-month period as the designated Proficiency Testing survey and conform to all other proficiency testing requirements.

A laboratory required to submit enhanced PT may also be required to submit subsequent PT summaries as they become available for the next one year period.

**POLICY NAME:** Adding/Updating Areas of Accreditation Out of Cycle  
**POLICY NO.:** O-14-02  
**DATE APPROVED:** 04-05-02

### **RATIONALE**

Rapidly changing technologies available to Histocompatibility Laboratories are necessitating that laboratories add new Areas of Accreditation and Technologies out of their normal review cycle. The review process should accommodate these additions where possible.

### **POLICY**

Laboratories may add new categories/methods out of their normal inspection cycle. The Laboratory must contact their Commissioner to begin the process. The laboratory must submit a Validation Packet. The Accreditation Manager will process the packet according to the pre-set routine of the next available cycle. The laboratory will bear the cost associated with arranging the appropriate inspection, if necessary, and the cost of the application process.

Following the 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 Areas of Accreditation noted.

**POLICY NAME:** Re-Issue of Accreditation Certificate After Change of Director  
**POLICY NO.:** O-15-02  
**DATE APPROVED:** 10-18-02

#### **RATIONALE**

During the course of a laboratory's Accreditation cycle, the directorship may change. There may be an interim period where the laboratory Certificate does not indicate the current Director.

#### **POLICY**

In consultation with Jamie Perdigao, ASHI counsel, the existing certificate may remain in the laboratory until such time that the focused change in Director inspection is completed and the new Director is approved by the ARB. At that time a new Certificate can be issued.

**POLICY NAME: Issuing Previous Deficiencies to Inspectors**  
**POLICY NO.: O-16-02**  
**DATE APPROVED: 10-18-02**

**RATIONALE**

As part of the conditions for deemed status with CLIA, ASHI Inspectors must inspect laboratories for previous documented deficiencies.

**POLICY**

Commissioners must supply Inspectors with a copy of the signed Deficiency Report that was left at the laboratory during the previous inspection. If there were no deficiencies noted, the Commissioner must note that in the Summary Report.

**POLICY NAME:** Criteria for Waiving Change of Director Inspections  
**POLICY NO.:** O-18-05, M-1-06, M-2-08  
**DATE APPROVED:** 08-05-05, 08-04-06, 08-02-08

## **RATIONAL**

There are circumstances when it is evident that a Director who has previous HLA Director experience does not require an on-site review of his/her competence to direct clinical testing at a different laboratory.

## **POLICY**

An ad-hoc change of Director inspection can be waived when the following criteria are met:

- Director is currently responsible for no more than 2 laboratories
- Director must have previous experience as an approved ASHI Director in the Areas of Accreditation & Technologies for which the new lab is accredited.
- No Director involvement problems existed at the previous labs
- Lab has successfully completed one send-out of PT (as it becomes available) in each test category under the new Director.
- Documentation of review of laboratory protocols, procedures, and QA program
  - Send coversheet with signature(s) OR a letter listing procedures, protocols, and QA program with evidence of review
- Show evidence of resolution of pre-existing issues, deficiencies, and contingencies in new laboratory,
- Technical staff experience is adequate;
- No change in General Supervisor within 1 year
- A written plan for coverage if Director position is part time (See R-30)
- A written plan for delegation of Director responsibilities

Documentation must be submitted to the Commissioner within 6 months of initial notification of the change of Director.

Approval of the full ARB is required.

**POLICY NAME:** Criteria for Waiving Relocation Inspections  
**POLICY NO.:** O-19-05, M-1-08  
**DATE APPROVED:** 08-05-00, 08-01-08

## **RATIONAL**

There are circumstances when it is evident that the relocation of a laboratory does not require an on-site review of its ability to continue to perform clinical testing competently.

## **POLICY**

A re-location inspection can be waived when the following criteria are met:

- Documentation that the new lab square footage is comparable or better than the old lab square footage
- Photographs of the new space can be provided
- A plan for handling of Protected Health Information (PHI) is provided
- A hazardous waste storage/disposal plan is provided
- A description of refrigerator/freezer alarm system is provided
- A plan for assessment of or documentation of relocated equipment function at the new location
  
- The new Floor Plan demonstrates:
  - Adequacy of space
  - The location of safety equipment
  - Fire exit routes
  - The location of wet lab areas
  - Office space/paperwork areas
  - Placement of equipment
  - Traffic Flow
  - The location of pre-amp and post-amp areas
  - Room temperature charts

Documentation must be submitted to the Commissioner within 3 months of relocation.

Approval of the full ARB is required

**POLICY NAME:** ARB Responsibilities in Approval of New Directors  
**POLICY NO.:** O-20-06  
**DATE APPROVED:** 08-04-06

## **RATIONALE**

To ensure that new Directors meet all ASHI Standards and ARB requirements:

## **POLICY**

The letter of the approval for new Directors will be signed by the DTRC Chair and the ARB Program Director.

Training documentation including logs and case analyses must be kept in the lab for a minimum of 2 years and may be reviewed during the next onsite inspection.

**POLICY NAME:** Approval of Laboratories and/or Directors for New Technologies  
**POLICY NO.:** O-21-06, M-1-08  
**DATE APPROVED:** 08-04-06, 04-05-08

## **RATIONALE**

As the ARB reviews the validation packets for new Technologies, they will also determine Director qualifications for the new Technology.

## **POLICY**

ASHI Directors adding a new Technology will be approved by the ARB:

1. If the Director was involved in the validation of a new Technology, then the validation packet submitted to the Commissioner is sufficient documentation of training and review.
2. If the Director moves to a laboratory that is Accredited for a Technology for which he/she was not previously approved, the Director must submit a log of case reviews to the Commissioner. This should be completed prior to a focused inspection for change of Director. The number of cases is equal to the required amount of cases per testing category on the validation checklist.

Technologies are:

Serology/Solid Phase  
DNA Typing  
Sequencing/Fragment Analysis  
Flow Cytometry  
Cellular

3. Ad hoc inspections for new technologies may be required if:
  - a. the new technology is new for both the lab and director. (except ABO)
  - b. The validation package indicates areas of concern that can only be resolved by direct observation

**POLICY NAME:** Announced Inspections with Only Two Weeks Notice  
**POLICY NO.:** O-22-06  
**DATE APPROVED:** 12-01-06

## **RATIONALE**

In compliance with CMS guidelines and the Government Accountability Office (GAO) report on CLIA, ASHI must perform announced inspections with only two weeks notice for US laboratories. We are allowed to give no more than two weeks notice for the date of routine (re-application/onsite) inspections.

## **POLICY**

At the beginning of each cycle (after receipt of the packet) the Accreditation Manager will send each laboratory Director a calendar to record no more than 10 blackout dates. Once the Inspector is approved, they are 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, they are to immediately notify the Accreditation Manager. No more than 2 weeks prior to the inspection date, the Accreditation Manager will notify the laboratory (Director & General Supervisor) by email and phone, of the exact inspection date.

Only the Accreditation Manager and the laboratory's Commissioner will be notified of the inspection date initially.

**POLICY NAME:** Co-chair and Commissioner approval of pass-through laboratories  
**POLICY NO.:** O-23-07  
**DATE APPROVED:** 08-05-07

## **RATIONALE**

Co-chair and Commissioner approval is necessary for interim laboratories to be included on the pre-ARB Meeting conference call pass-through list.

## **POLICY**

Co-chairs must be present on the conference call or have provided prior approval for laboratories to be included on pass-through list. Commissioners may give prior approval of laboratories to the appropriate Co-Chair.

**POLICY NAME:** Approach for Accreditation for New Methods, Technologies, or Testing Categories  
**POLICY NO.:** O-24-07, M-1-08  
**DATE APPROVED:** 12-01-07, 08-01-08

## **RATIONALE**

As new methods/technologies emerge, or the ARB adds new testing categories, 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.

## **POLICY**

An Ad Hoc committee needs to be formed (and chaired by an ARB member) to address the issue of accreditation for each new method/technology or testing category.

The committee will consist of the following:

- ARB member(s )
- QAS committee member(s)
- Person(s) with expertise in the method/technology or testing category

The Ad Hoc Committee will advise the ARB of the need for the following:

- Inspector Training module
- New standards if present standards are not sufficient (QAS)
- Appropriate forms of PT or equivalent

**POLICY NAME:** Procedure for Investigation of Complaints/Grievances against a Laboratory  
**POLICY NO.:** O-25-08  
**DATE APPROVED:** 04-05-08

## **RATIONALE**

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.

## **POLICY**

Complaints may be received by the ASHI Executive Office, ARB Members, or ASHI Board Members.

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. 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.

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 (announced or unannounced)

If an inspection is warranted, inspectors will be chosen by the ARB Executive Board.

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.

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.

The full ARB will be notified about the outcome of the investigation at the next ARB meeting, as appropriate.

**POLICY NAME:** New Commissioner Transition Timeline  
**POLICY NO.:** O-26-08  
**DATE APPROVED:** 09-23-08

**RATIONALE:**

The ARB welcomes new commissioners each year at ASHI’s annual meeting. The table below was developed in order to assist the incoming and outgoing ARB members with the transition of files and other information,

**POLICY**

The table below will give a general timeline of events in regards to incoming and outgoing ARB members:

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
October 15	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

**Notes:**

- Cycle 2 is the most important cycle during the transition. Files for this cycle should be copied and sent first, as the new Commissioner will be presenting the summaries at the December ARB meeting.
- Cycle 1 labs are not affected/active through this transition.

**POLICY NAME: ARB-CMS Interactions**  
**POLICY NO: O-27-08**  
**DATE APPROVED: 09-23-08**

## **RATIONALE**

Since the ASHI ARB 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 ARB activities are primarily involved in the communication process.

## **POLICY**

1. 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)
- The ARB Accreditation Manager (permanent position)

2. CMS sponsors a “Partners meeting” twice a year 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). These meetings are held in the spring (usually in April) and in the fall (usually in September). To ensure continuity in communication with the ASHI ARB, the following ARB key members will attend these meetings as follows:

- The ARB Accreditation Manager and the Current ARB Program Director will attend the spring CMS Partners Meeting (registration paid by CMS, other expenses, at CMS government rates, are included in the ASHI ARB budget)
- The current ARB Program Director and the Senior ARB Co-Chair who will become the next ARB Program Director) will attend the fall CMS Partners Meeting expenses, with hotel costs at CMS government rates, are included in the ASHI ARB budget)

3. 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)

- 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.

- 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.

4. 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.

5. 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:

- Requests for CMS approval of new ARB policies following each ARB meeting after approved by the ARB and the ASHI Executive Board
- 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).
- Requests for CMS clarification of CMS regulations in relation to specific ASHI Standards and Guidelines
- 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
- 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

Submission of applications for renewal of CMS deemed status or additions to specialties for CMS deemed status, as applicable.



**POLICY NAME:** Notification of Possible Insurance Claim  
**POLICY NO.:** A-01-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

A responsibility of the ASHI Executive Director is to interface with organizations contracted by ASHI for various services.

**POLICY**

The ASHI Executive Director is responsible for notifying the insurance company when there is threat of an action against the Society.

**POLICY NAME:** Administrative Fee for Appeal  
**POLICY NO.:** A-02-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

The Appeal Process requires extra work by the Administrative Staff, contribution of time from the Appeal Board members, expenditure for clerical functions (mailing, phone calls, fax, etc), and possible legal fees. Administrative costs should not be borne by either the Society or laboratories that are compliant with Standards. Further, there should be a disincentive to filing an Appeal frivolously, for nuisance purposes, or to obstruct the review process.

**POLICY**

There will be a standard fee assessed for filing an appeal. That amount should include a non-refundable portion to cover administrative expenses associated with initiating the Appeal process and an additional amount sufficient to offset the initial processing costs. The additional amount shall be reimbursed if the Appeal Board finds in favor of the appellant.

**POLICY NAME:** Annual Business Meeting of ARB  
**POLICY NO.:** A-03-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Ombudspersons must be adequately informed about the Policies and practices of the ARB.

**POLICY**

Ombudspersons shall receive summaries of ARB meetings excluding any confidential information. They shall be invited to attend the Board's Annual Business Meeting, which will occur during the ASHI Annual Meeting.

**POLICY NAME:** Maintenance of Manuals and Forms  
**POLICY NO.:** A-04-99  
**DATE APPROVED:** 01-28-99

**RATIONALE**

Copies of all manuals and forms must be available for distribution. These should be maintained in a central location, readily accessible to the Accreditation Manager.

**POLICY**

The ASHI Accreditation Office is responsible for the physical maintenance of all Accreditation Manuals and forms and providing relevant individuals, including all ARB members, Advisory Committee Members, and Ombudspersons with the most recent versions of each.

**POLICY NAME:** Expenses for International Inspections  
**POLICY NO.:** A-06-99, M-01-07  
**DATE APPROVED:** 04-23-99, 03-30-07

**RATIONALE**

The cost of international travel (outside of North America) 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.

**POLICY**

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.

Airfare costs that exceed the annual Accreditation fee may be billed to the laboratory upon discussion with the Accreditation Manager.

**POLICY NAME:** Expenses for *Ad Hoc* Inspections  
**POLICY NO.:** A-07-99  
**DATE APPROVED:** 04-23-99

#### **RATIONALE**

Ad hoc inspections are performed under the following circumstances:

1. the laboratory wishes to add an Area of Accreditation outside its normal cycle;
2. there are performance issues that warrant on-site monitoring;
3. there have been significant changes in the laboratory (e.g. relocation) that warrant an on-site inspection.

The expense of these *ad hoc* inspections should not be borne by all laboratories through a general increase in Accreditation fees.

#### **POLICY**

All expenses for an ad hoc inspection are to be charged to the laboratory. There will be an additional processing fee charged to the laboratory.

**POLICY NAME:** Gifts for Exemplary Inspectors  
**POLICY NO.:** A-08-99, M-1-02  
**DATE APPROVED:** 08-5-99, 08-08-02

**RATIONALE**

Positive incentives are important to maintaining an adequate pool of inspectors.

**POLICY**

All Inspectors will receive certificates of appreciation each year at the annual meeting. Inspectors performing 10 cumulative inspections will also receive a gift.

**POLICY NAME:** Fee for Review of Director Portfolio  
**POLICY NO.:** A-09-99, M-1-02  
**DATE APPROVED:** 08-5-99, 08-08-02

**RATIONALE**

Costs associated with review of Director's Portfolios should not be borne by all applicants.

**POLICY**

The fee for review of Director's Portfolios will be \$150 per category of Accreditation to a maximum of \$700 for qualifications to direct a full service laboratory.

**POLICY NAME:** Record Retention  
**POLICY NO.:** A-10-99, M-1-02, M-2-04, M-3-07  
**DATE APPROVED:** 10-19-99, 04-05-02, 12-03-04, 08-05-07

## RATIONALE

As long as the Accreditation Office maintains a complete copy of all documentation for each lab, the Commissioners need to retain only specific documents on file and for transfer to the subsequent Commissioner. The co-Chairs need to retain only complete files relating to the current cycle and specific documents relating to each laboratory for transfer to the subsequent co-Chair

## POLICY

The Accreditation Office must receive and maintain a copy of all lab Accreditation, new test validation and Director portfolio documentation for a minimum of 5 years. Files for a minimum of two years will be maintained on-site with the Accreditation Manager.

The Commissioner should 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 Test Validation Checklists.

The co-Chair should 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. Summary Reports, Accreditation Letters and Certificates
2. Deficiency Reports
3. Relevant Correspondence concerning Individual Laboratories with Commissioners (paper and/or electronic)
4. Validation Checklists

Both Commissioners and 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.

After each cycle: Commissioners should send signed copies of deficiency reports, corrective actions, signed exit interview forms and other important correspondence; and, any out of cycle new test validation materials to the Accreditation office.

At the end of the two-year retention period, non-critical materials that identify particular laboratories must be shredded or destroyed in a manner compliant with HIPPA.

**POLICY NAME:** Inspector's Copy of Lab's Documentation  
**POLICY NO.:** A-11-99, M-1-02  
**DATE APPROVED:** 12-9-99, 08-08-02

**RATIONALE**

To help ensure continued confidentiality, the Inspector should not retain any of the lab's documentation.

**POLICY**

Inspectors must leave their copy of the laboratory's Application Packet with the laboratory at the end of the inspection, unless it is required for further review by the Inspector post-inspection. In which case, the Application and all other inspection documentation must be submitted to the Commissioner.

**POLICY NAME:** Issuing an Updated ASHI Certificate  
**POLICY NO.:** A-12-00  
**DATE APPROVED:** 08-05-00

**RATIONALE**

A lab may request an updated ASHI Certificate or require that an updated Certificate be issued due to a change in information on the certificate. Although an updated certificate may be warranted, the lab should not be in possession of multiple certificates with overlapping Accreditation periods.

**POLICY**

When warranted, an updated Certificate will be prepared and released to the lab upon receipt of the original Certificate by the ASHI Accreditation Office.

**POLICY NAME: Accreditation Application Due Date**  
**POLICY NO.: A-13-00**  
**DATE APPROVED: 08-05-00**

**RATIONALE**

The Accreditation Application due date for Cycle 1 is March 1.  
The Accreditation Application due date for Cycle 2 is July 1.  
The Accreditation Application due date for Cycle 3 is November 1.

These due dates may be a weekend day, holiday or day that the ASHI Accreditation Office is closed precluding receipt of the applications until the next business day. Requiring that the applications be received before the due date would unfairly shorten the time the lab has for preparation and delivery of their application.

**POLICY**

When the Accreditation Application due date is a weekend, holiday or day that the office is closed, the due date will be adjusted to the next business day. The due date is interpreted as the date of receipt of the Accreditation Application in the ASHI Accreditation Office.

**POLICY NAME:** Penalty Fee for Late Applications  
**POLICY NO.:** A-15-00, M-1-03, M-2-04  
**DATE APPROVED:** 12-06-00, 10-26-03, 9-21-04

**RATIONALE**

Late packets delay the inspection/approval process.

**POLICY**

If a laboratory does not submit their packet by the deadline, the Accreditation Manager will contact the laboratory and notify them that the Packet is late. 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 their ASHI Accreditation will expire for a minimum of four months. CMS will be notified by the ASHI Accreditation office that the laboratory Accreditation has lapsed. A lapse in Accreditation will require outsourcing of testing until the Accreditation is reinstated. 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.

**POLICY NAME:** Director Training Review and Credentialing Committee Reports  
**POLICY NO.:** A-16-02  
**DATE APPROVED:** 04-05-02

**RATIONALE**

Many Directors require portfolio reviews prior to adding new areas/methods of Accreditation. The status of these reviews is critical to the determination of Accreditation for the laboratory.

**POLICY**

The Chair of the DTRC Committee will provide a written update prior to the scheduled quarterly meeting of the ARB that will include a list of pending, in progress and approved Director reviews since the last report.

**POLICY NAME:** Laboratory Review Contingency Lists  
**POLICY NO.:** A-17-02, M-1-03  
**DATE APPROVED:** 10-18-02, 10-26-03

**RATIONALE**

During the laboratory reviews at the Accreditation Review Board meetings, the ongoing Accreditation of a laboratory is contingent on certain issues or requirements that the laboratory must comply. It is important to track these contingencies to assure laboratory compliance.

**POLICY**

The Accreditation Manager will compile a contingency list during the review of laboratory application packets. The list will contain issues with which laboratories must comply to maintain their Accreditation status, e.g. submission of PT to the Commissioner. The list will be distributed to all Board members after the meeting.

1. Commissioners must report at next ARB meeting on progress of labs with contingencies. The laboratories that have met the requirements of the contingencies will be removed from the list.
2. The Board will determine appropriate action for labs that have not met the requirements of their contingencies.

**POLICY NAME:** Director Training Portfolio Reviews by Commissioners  
**POLICY NO.:** A-18-02  
**DATE APPROVED:** 12-06-02

**RATIONALE**

Commissioners who are Directors with certification in appropriate Areas of Accreditation and test methodology may be helpful in the review of newly submitted portfolios

**POLICY**

With approval by the Chair of the Director Training Review and Credentialing Committee, it is acceptable for a Commissioner, who is a laboratory Director and ABHI certified, to review portfolios submitted to the DTRC for review.

**POLICY NAME:** Expenses for Inspections of Laboratories in North America  
**POLICY NO.:** A-20-07  
**DATE APPROVED:** 08-05-07

## **RATIONALE**

Costs for inspecting laboratories in North America are expected to be within reasonable boundaries in order to not exceed the accreditation inspection fees.

## **POLICY**

Airfare should be arranged at least 21 days in advance in order to receive maximal discounts. Airfares exceeding pre-set ASHI/ARB allowances are subject to Executive ARB and accreditation manager approval.

One day inspections usually will have only one night reimbursed but may have up to two night's accommodations reimbursed in rare circumstances when outbound travel cannot be arranged.

Two day inspections usually will have only two nights reimbursed but may be reimbursed for three night's accommodations in rare circumstances when outbound travel cannot be arranged. Any variance from this needs Executive ARB and accreditation manager approval. Weekend stays will not be reimbursed unless approved by the Executive ARB and accreditation office.

Please refer to the ASHI Travel Policy for specific details on reimbursement.

**POLICY NAME:** Notification of ARB Policy Additions and Changes  
**POLICY NO.:** A-21-07  
**DATE APPROVED:** 12-01-07

## **RATIONALE**

Notification of policy revisions/changes and new policies needs to be shared with all necessary groups/committees.

## **POLICY**

After every ARB meeting, the following groups/committees will be notified of all new policies and revisions/changes made to existing policies:

- QAS Committee Chair(s)
- NMDP (if applicable)
- UNOS (if applicable)

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

- CMS
- ASHI Board via ARB liaison

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

**POLICY NAME:** Policies  
**POLICY NO.:** A-22-09  
**DATE APPROVED:** 04-03-09

## **RATIONALE**

The ASHI ARB Operations Manual is the guideline for the organization and functioning of the ASHI Accreditation Program. It is updated by the ASHI ARB and approved by the Centers for Medicare and Medicaid Services on an annual basis. However, circumstances and situations arise during the course of the intervening year in the accreditation process that mandate a consistent guide for all members of the ASHI community between annual updating and CMS review of the Operations Manual. Policies adopted by the ARB during the course of the year will be the mechanism for such guidance until the operations manual can be adjusted accordingly. This policy amends the ARB Operations Manual Section XXXIX (REVIEW and UPDATING of the ARB OPERATIONS MANUAL).

## **POLICY**

Policies:

- a) Policies are maintained by the Junior Co-chair for the ARB.
- b) Policies arise from decisions made at ARB meetings. New policies will be presented to the full ARB for discussion and approval. Subsequent review and approval by the ASHI Board of Directors and CMS is required prior to implementation.
- c) Policies will be incorporated into the Operations Manual during the annual update.
- d) Policies shall have a rationale which includes, if applicable, which section of the Operations Manual is affected.
- e) All policies that have not been incorporated into the ARB Operations Manual shall be null and void once the revised Operations Manual is approved by CMS. However, if CMS approval has not been attained by January 1<sup>st</sup>, non-incorporated policies shall expire on that date.
- f) The ASHI Accreditation Manager shall keep track of all policies and their individual status.

**POLICY NAME:** Inspector Training Coordinator/Immediate-Past Program Director  
**POLICY NO.:** A-23-09  
**DATE APPROVED:** 04-03-09

## **RATIONALE**

The inspector training coordinator has been the immediate-past Program Director of the ARB. This has never been officially spelled out or adopted by the ASHI ARB and Board of Directors. This policy amends Section I of the Personnel Section of the ARB Operations Manual.

## **POLICY**

### **I. INSPECTOR TRAINING COORDINATOR**

#### **1. Appointment and Term**

- a. Selected based on past service as Program Director for the period immediately preceding appointment.
- b. Appointment contingent upon ASHI Board approval
- c. Term is for one (1) year but, if necessary, may be extended upon approval by both the ASHI ARB and Board of Directors.

#### **2. Qualifications**

- a. Has provided outstanding service as ARB Program Director
- b. Able and willing to commit the time necessary to fulfill responsibilities and to represent ASHI in a positive light
- c. An ASHI member

#### **3. Responsibilities**

- a. Oversees the training and performance review of ASHI inspectors.
- b. Provides commentary regarding performance of each inspector based on the results of the laboratory's post-inspection questionnaire.
- c. Plans and organizes Inspector Training workshops.
- d. Works with ARB Manager and ASHI staff as needed in planning workshop.
- e. 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.

- f. Reviews Inspector Evaluation Forms and New Inspector Trainee Forms.
- g. Recommends approval of new Inspectors.
- h. Determines if second inspection as trainee is needed.
- i. Provides a report to the Accreditation Review Board.
- j. The Inspector Training Coordinator is a member of the ARB Executive committee but shall have no vote. May be requested to perform *ad hoc* duties for the ARB and/or the ARB Executive committee.
- k. Will forward concerns arising from an inspection to the commissioner.
- l. Serve as liaison to the DTRC

**POLICY NAME:** Implementation Date of New Standards  
**POLICY NO.:** A-24-09  
**DATE APPROVED:** 04-03-09

## **RATIONALE**

To clear up confusion about the effective date of revisions and additions to the ASHI Standards and when more stringent standards will be enforced. This policy amends the ARB Operations Manual Section VIII (General Guidelines and Time Lines for the Accreditation Process).

## **POLICY**

Any changes to the ASHI standards must be approved by the Centers for Medicare and Medicaid Services (CMS) because ASHI has deemed status under the Clinical Laboratory Improvement Amendments with CMS.

ASHI will submit new or revised Standards to CMS for review by December 1<sup>st</sup> of each year. Once approved by CMS, new or revised standards will be effective on January 1<sup>st</sup> of the year following their submission to CMS. If the new or revised standards have not been approved by CMS by January 1<sup>st</sup>, the new or revised standards will become effective once notice of CMS approval has been received by ASHI. Cycle 1 laboratories will be the first labs inspected with the new or revised standards approved by CMS.

For standards that are considered to be more stringent than previous standards, ASHI-accredited laboratories will have one year after the new standard's effective date to be compliant with the new standard. After the one year compliance period, the new more-stringent standards will be enforced by the ARB. When changes are requested by an organization for which ASHI has deemed status, compliance with the changed standards will be enforced by the ARB on the date required by the respective organization, if applicable.

Standards which are less stringent than previous standards are effective immediately.

**POLICY NAME: Hematopoietic Stem Cell Transplantation**  
**POLICY NO: A-25-09**  
**DATE APPROVED: 12-04-09**

## **RATIONALE**

This policy ensures consistency in requirements for all areas of accreditation. This policy amends the ARB Operations Manual Section XXXI.B Special Requirements for Areas of Accreditation

### **Policy (added to section)**

#### **1. Hematopoietic Stem Cell Transplant: Related Donor**

- 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.
- If any tests are outsourced, the referring laboratory must document review and interpretation of the results.
- If any tests are outsourced, both laboratories must be accredited by ASHI or an equivalent Accrediting Organization.

#### **2. Hematopoietic Stem Cell Transplantation: Unrelated Donor**

- 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.
- If any tests are outsourced, the referring laboratory must document review and interpretation of the results.
- If any tests are outsourced, both laboratories must be accredited by ASHI or an equivalent Accrediting Organization.

**POLICY NAME:** ARB Document Control  
**POLICY NO.:** A-26-10  
**DATE APPROVED:** 12-03-10

## **RATIONALE**

The ARB works with many documents that are updated on a regular basis, including the application packets, Standards & Guidance, Operations Manual and policies. Because these documents are edited on a regular basis, and have to go through multiple levels of review and approval, it is not uncommon to have multiple drafts and versions of a single document. This policy was created to organize this process and avoid confusion for the ARB.

## **POLICY**

Any document revision process will be directed by the accreditation manager. The following steps will be taken for document control:

1. Document is developed or revised and approved by the ARB (or received from the appropriate committee)
2. Document is sent out for public comment if applicable
3. Document is sent to the ASHI Board for approval
4. Document is sent to CMS for approval
5. Document is labeled as final with the approval date
6. Document is sent to the ARB for their final records
7. Document is posted online on the ASHI website
8. Previous versions of the document are stored in archived files and labeled as past documents

**POLICY NAME:** PT Report 160  
**POLICY NO.:** A-27-10  
**DATE APPROVED:** 12-03-10

## **RATIONALE**

CMS requires the ARB to monitor PT results for regulated analytes on a regular basis. This monitoring is done through the "Report 160" generated through the OSCAR CMS database system.

## **POLICY**

The accreditation manager is responsible for the following process:

1. Run the CLIA Report 160 once a month, as close to the 1<sup>st</sup> of each month as possible.
2. Initially review the results of each report, sign and date reports.
3. Send reports for a second review to the current "Program Director" (PD). Reports are to be signed, dated by the PD upon completion of review and sent back to the accreditation manager.

**NOTE:** Any required follow-up/corrections to a report will be communicated back to the accreditation manager for appropriate actions.

4. Electronic copies as well as a hard copy of signed reports will be maintained by the accreditation manager.
5. Update the "PT Report 160" tracking sheet.
6. Notify the laboratory's commissioner and co-chair if concordance falls below 100%.
7. Update the ARB executive board on a quarterly basis with report outcomes.

**POLICY NAME: CMS Online Systems – ASPEN & CASPER**  
**POLICY NO.: A-28-10**  
**DATE APPROVED: 12-03-10**

## **RATIONALE**

Per the agreement with CMS, ASHI is required to update all CLIA lab information electronically in the online CMS databases (ASPEN and CASPER.) This information includes but is not limited to subspecialty information, test volume within those subspecialties, and last inspection/survey date. In CASPER, it is required that reports 97, 98, and 99 are run on a regular basis.

## **POLICY**

The accreditation manager is responsible for the following process in ASPEN:

1. Log into ASPEN/CASPER as needed but no less than once a month
2. Laboratory information will be updated as required in ASPEN (including laboratory demographic info, test volume, and inspection date.)
3. When a new subspecialty is added, all ASHI labs that meet the requirements will be updated appropriately with test volumes included.
4. Send reports for a second review to the current “Program Director” (PD). Reports are to be signed, dated by the PD upon completion of review and sent back to the accreditation manager.
5. Electronic copies as well as a hard copy of signed reports will be maintained by the accreditation manager.
6. Update the ARB executive board on a quarterly basis with report outcomes.

The accreditation manager is responsible for the following process in CASPER:

1. Run report 97 (CLIA Terminated Labs) monthly through CASPER and initially review the results of each report, sign and date.
2. Run report 98 (CLIA Unmatched Labs) monthly through CASPER and initially review the results of each report, sign and date.
3. Run report 99 (CLIA Matched Labs) monthly through CASPER and initially review the results of each report, sign and date.
4. Send reports for a second review to the current “Program Director” (PD). Reports are to be signed, dated by the PD upon completion of review and sent back to the accreditation manager.
5. Electronic copies as well as a hard copy of signed reports will be maintained by the accreditation manager.
6. Update the “CASPER Report 97/98/99” tracking sheet.
7. Changes between current and previous reports will be verified and updated in the CMS database.
8. Update the ARB executive board on a quarterly basis with report outcomes.

**NOTE:** Any required follow-up/corrections to a report will be communicated back to the accreditation manager for appropriate actions.