

ASHI ACCREDITATION PROGRAM POLICIES

Last Updated: 2.18.2011

File: ARBPoliciesList 2182011

POLICY NO.	POLICY NAME:	Location
Review Policies		
R-01-99, M-1-04	Definition of Possible Evaluation Outcomes	Ops: Section XXI; p. 51
R-02-99	Information to Provide to Inspector	Ops: Section XII-A; p. 36
R-03-99	Guidelines for Presentation of Evaluation Summary to ARB	Ops: Section III-C; p. 13
R-04-99	Egregious Actions Requiring Immediate Action	Ops: Section XXIII; p. 53
R-05-99	Requirement for Case File Submission	Packet Instructions
R-06-99	Inspection Requirement Following Lab Relocation	Ops: Section IX; p. 30
R-07-99	Review of the Labs of the Accreditation Program Director & Chairs	Retired
R-08-99, M-1-02, M-2-04	Continuing Education Requirements	Ops: Section XII-D; p. 37
R-09-99, M-1-02, M-2-02, M-3-08	Test Validation Submission Requirements	Ops: Section XXXI; p. 58, 60; Section XXXII; p. 66; Section XXXIV; p. 69
R-10-99, M-1-06	Benchmarks for Review of High Volume Laboratories	Ops: Section XIV; p. 48
R-11-99, M-1-02	Review of Director Portfolios/Qualifications	Ops: Section XXXIII; p. 67
R-12-99	Accreditation Certificate Cover Letter	Ops: Section XXII; p. 53
R-13-99, M-1-04, M-2-07, M-3-08, M-4-08	ABO and/or Rh Typing	Ops: Section XII-D; p. 39, 43
R-14-99, M-1-02	Proficiency Testing Corrective Action	Ops: Section XII-D; p. 42
R-15-99, M-1-02, M-2-03, M-2-07, M-3-07	Inspections by Members of the ARB	Ops: Section XI-B; p. 34
R-16-00, M-1-02	Inspection Requirements Following Change in Lab Director or Technical Supervisor	Ops: Section IX; p. 31
R-17-00	CLIA Certification Requirement for Labs doing HLA Typing for the NMDP Donor Registry	Ops: Section XIII; p. 47
R-18-00	Internal Proficiency Quality Control (Monthly Unknown) Guidelines	Ops: Section XII-E; p. 45
R-19-00, M-1-03, M-2-06, M-3-07, M-4-08	Level of Proficiency Testing and Clinical Technology	Ops: Section XII-D; p. 39
R-20-00	Adding SBT in a Lab with High Resolution DNA Expertise	Retired
R-21-00, M-1-03	Accreditation Requires Clinical Activity	Ops: Section XXV; p. 54
R-22-01, M-1-04, M-2-05, M-3-06, M-4-08	Determination of DNA Typing Resolution	Ops: Section XII-D; p. 40
R-23-01, M-1-03	Lot Validation for Commercial Molecular Typing Kits	Ops: Section XII-E; p. 46
R-24-01, M-1-03, M-2-05, M-3-06	HLA High Resolution Molecular Typing class I and class II Proficiency Testing Requirements	Ops: Section XII-D; p. 41
R-25-02, M-1-03, M-2-08, M-3-08	Director/Technical Supervisor Approval for New Areas of Accreditation and/or Technologies	Ops: Section XXXI; p. 58
R-26-02, M-1-04	Transfusion Support Accreditation	Ops: Section XXXI-B; p. 59
R-27-02	Bottled Water Quality	Ops: Section XII-E; p. 46

ASHI ACCREDITATION PROGRAM POLICIES

Last Updated: 2.18.2011

File: ARBPoliciesList 2182011

POLICY NO.	POLICY NAME:	Location
R-28- retired		
R-29-03	Deficiencies Overruled by ARB	Ops: Section XIX-B; p. 50
R-30-04	Plan of Action from New Directors of Multiple Labs or Part-time Directors	Ops: Section XXX; p. 57
R-31-04, M-1-08	Out of Cycle Processing of Laboratory Reviews	Ops: Section XXXV; p. 70
R-32-04, M-1-05	Solid Organ Transplantation: Deceased Donor Accreditation	Ops: Section XXXI-B; p. 58
R-33-04, M-1-05	Solid Organ Transplantation: Live Donor Accreditation	Ops: Section XXXI-B; p. 59
R-34-04	Proficiency Testing Requirements for Antibody Testing by Multiple Methods	Ops: Section XII-D; p. 41
R-35-06	Alternatives to Formal External Proficiency Testing	Ops: Section XII-D; p. 44
R-36-06, M-1-08	Proficiency Testing Accepted by ASHI	Ops: Section XII-D; p. 43
R-37-07, M-1-08	Null Allele Discrimination	Ops: Section Xii-D; p. 40
R-38-08, M-1-08	Requirements for Change of the Clinical Consultant (pending ASHI Board/CMS approval)	Ops: Section XXVI-A; p. 55
R-39-08, M-1-08	Requirements for Change of the General Supervisor (pending ASHI Board/CMS approval)	Ops: Section XXVI-A; p. 55
R-40-08	Plan of Action for Changes Involving a Change of Director's Time Commitment	Ops: Section XXVI-B; p. 55
R-41-08, M-1-08	ARB Response to Repeat Deficiencies in the next On-site or Interim cycle	Section XX-B P. 52
R-42-08, M-1-08	Requirements for Technical Personnel	Ops: Section XIII-D; p. 42
R-43-10	Single Allele Testing in Absence of DNA High-Resolution Accreditation	Ops: Section XIII-D; p. 42
R-44-10	Relevant Content of Continuing Education	Ops: Section XIII-D; p. 38
R-45-10	Proficiency Testing Designation	Ops. Section XIII-D; p. 39
R-46-10	Definition of Graded Proficiency Testing	Ops. Section XIII-D; p 45
R-47-10	Communication to CMS of ARB imposed sanctions, revocation or withdrawal of accreditation, and associated appeals	
R-xx-xx		
Operational Policies		
O-01-99, M-1-03	Employment Conflict of Interest for ARB Members	Ops: Section II; p. 8
O-02-99	ASHI Membership Requirement for ARB	Ops: Section III; p. 8
O-03-99	Non-Review Responsibilities of Chairs	Retired
O-04-99, M-1-02, M-2-03	Accreditation Advisory Committee	Ops: Section III-F; p. 19
O-05-99	Inspector Training Requirements	Retired
O-06-99, M-1-99, M-2-02, M-3-02	Inspector Training Requirements	Ops: Section IV-B; p. 22
O-07-99	Duties and Responsibilities of Ombudspersons	Ops: Section III-F; p. 20
O-08-99, M-1-00, M-2-00, M-3-03, M-4-04	Selection of Inspectors for Labs Outside N. America	Ops: Section XI-C; p. 35

ASHI ACCREDITATION PROGRAM POLICIES

Last Updated: 2.18.2011

File: ARBPoliciesList 2182011

POLICY NO.	POLICY NAME:	Location
O-09-99, M-1-02	Schedule for Inspector Training Workshops	Retired
O-10-99	Reports to Council	Ops: Section III-A; p. 9
O-11-99	Review of Federal Register	Ops: Section III-A; p. 10
O-12-00	Inspection expenses for Labs Creating Special Circumstances	Ops: Section IX; p. 30
O-13-01, M-1-02, M-2-04, M-3-04, M-4-06, M-5-07, M-6-08, M-7-08	Enhanced proficiency testing requirements	Ops: Section XII-D; p. 42
O-14-02	Adding/Updating Areas of Accreditation Out of Cycle	Ops: Section XXXV; p. 70
O-15-02	Re-Issue of Accreditation Certificate After Change of Director	Ops: Section X-C; p. 33
O-16-02	Issuing Previous Deficiencies to Inspectors	Ops: Section I; P. 7; Section III-C; p. 13; Section XII-C; p. 37
O-17-03, M-1-03	Laboratory Review of Contingency List	Ops: Section XX-A; p. 50
O-18-05, M-1-06, M-2-08	Criteria for Waiving Change of Director Inspections	Ops: Section IX; p. 31
O-19-05, M-1-08	Criteria for Waiving Relocation Inspections	Ops: Section IX; p. 30
O-20-06	ARB Responsibilities in Approval of New Directors	Ops: Section XXXII-A; p. 66
O-21-06, M-1-08	Approval of Directors for New Technologies	Ops: Section XXXI-D; p. 60
O-22-06	Announced Inspections with only Two Weeks Notice	Ops: Section VIII-A; p. 26, Section XII-A; p. 35
O-23-07	Co-chair and Commissioner Approval of pass-through laboratories	Ops: Section V; p. 24
O-24-07, M-1-08	Approach for Accreditation for New Methods/Technology	Sec XXXVII; p 71 in revised version
O-25-08	Procedure for Investigation of Complaints/Grievances Against a Laboratory	Ops: Section X; p. 35
O-26-08	New Commissioner Transition Timeline	Ops: Section III-C; p. 14
O-27-08	ARB-CMS Interactions	Ops: Section VI; p. 26
O-28-10	Expiration of Accreditation and Certificate Dates	
O-xx-xx		
Administrative Policies		
A-01-99	Notification of Possible Insurance Claim	Ops: Section III-F; p. 20
A-02-99	Administrative Fee for Appeal	Ops: Section XXXVIII-H; p. 74
A-03-99	Annual Business Meeting of ARB- Ombudsmen	Ops: Section III-G; p. 20
A-04-99	Maintenance of Manuals and Forms	Ops: Section III-E; p. 19
A-05-99	Inspector Reimbursement Guidelines	Instructions for Inspectors
A-06-99, M-1-07	Expenses for International Inspections	Ops: Section XII-C; p. 38
A-07-99	Expenses for <i>Ad Hoc</i> Inspections	Ops: Section IX; p. 30
A-08-99, M-1-02	Gifts for Exemplary Inspectors	Retired
A-09-99, M-1-02	Fee for Review of Director Portfolio	Ops: Section XXXIII-3; p. 69
A-10-99, M-1-02,	Record Retention	Ops: Section III-E; p. 18

ASHI ACCREDITATION PROGRAM POLICIES

Last Updated: 2.18.2011

File: ARBPoliciesList 2182011

POLICY NO.	POLICY NAME:	Location
M-2-04, M-3-07		
A-11-99, M-1-02	Inspector's Copy of Lab's Documentation	Ops: Section XVIII; p. 49
A-12-00	Issuing an Updated ASHI Certificate	Ops: Section X-C; p. 33
A-13-00, M-1-04	Accreditation Application Due Date	Ops: Section VIII-D; p. 29
A-14-00	Announcement of Inspection as required by JCAHO	Ops: p. 21
A-15-00, M-1-03	Penalty fee for late applications	Ops: Section VIII-D; p. 30
A-16-02	Director Training Review Committee Reports	Ops: Section III-H; p. 21
A-17-02, M-1-03	Laboratory Review Contingency Lists	Ops: Section XXI-B; p. 52
A-18-02	Director Training Portfolio Reviews by Commissioners	Retired
A-19-04	ARB Handling of Reported Sentinel Events	Ops: Section XXVI; p. 54
A-20-07	Expenses for Inspections of Laboratories in North America	Ops: Section XII-C; p. 38
A-21-07	Notification of ARB Policy Additions and Changes	Sec XL p. 79 in revised version
A-22-09	Policies	
A-23-09	Inspector Training Coordinator/Immediate-Past Program Director	
A-24-09	Implementation Date of New Standards	
A-25-09	Hematopoietic Stem Cell Transplantation	
A-26-10	ARB Document Control	
A-27-10	PT Report 160	
A-28-10	CMS Online Systems – ASPEN & CASPER	
A-xx-xx		