

ACCREDITATION PROCESS DESCRIPTION

Information contained within this section of the AIM addresses the accreditation process of the following activities:

- Blood Banks and Transfusion Services
- Cellular Therapy (Clinical, HPC, Cord, Somatic Cells)
- Donor Centers and Donor Testing Laboratories
- Immunohematology Reference Laboratories (IRL)
- Molecular Testing (MT)
- Relationship Testing Laboratories (RT)
- Perioperative Services

| Action Step | Who | Documents |
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| <p>1. 7 months before the accreditation expiration date, generate and send pre-populated FDVRs and renewal notification email to the accreditation contact on record -within 2 weeks.</p> | <p>AABB National Office Assessment Coordinators</p> | <ul style="list-style-type: none"> • Prepopulated FDVR <p>Renewal forms on AABB website</p> <ol style="list-style-type: none"> 1. Accreditation process checklist 2. Planning Information form 3. Data Form for Additional Activities 4. Locations Table (if applicable) 5. CLIA forms (if applicable) 6. CLIA Personnel Verification form (if applicable) 7. Annual Statistics Table 8. Contact Information form 9. Florida forms (if applicable) 10. Pre assessment materials <ul style="list-style-type: none"> ➤ Current organizational chart ➤ Brief description of quality plan ➤ Master list of documents ➤ List of internal and external assessments ➤ Last AABB assessment summary report including signature page ➤ List of proficiency testing performed ➤ IRL cases (if applicable) ➤ RT cases (if applicable) |
| <p>2. Update demographic information and activities on FDVR. Complete all applicable renewal forms and pre assessment materials and send them electronically to accreditation@aabb.org or by</p> | <p>Facility</p> | <ul style="list-style-type: none"> • Prepopulated FDVR <p>Renewal forms on AABB website</p> <ol style="list-style-type: none"> 1. Accreditation process checklist 2. Planning Information form 3. Data Form for Additional Activities 4. Locations Table (if applicable) 5. CLIA forms (if applicable) |

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| <p>fax to 301-657-0957 within 14 days.</p> | | <ol style="list-style-type: none"> 6. CLIA Personnel Verification form (if applicable) 7. Annual Statistics Table 8. Contact Information form 9. Florida forms (if applicable) 10. Pre assessment materials <ul style="list-style-type: none"> ➤ Current organizational chart ➤ Brief description of quality plan ➤ Master list of documents ➤ List of internal and external assessments ➤ Last AABB assessment summary report including signature page ➤ List of proficiency testing performed ➤ IRL cases (if applicable) ➤ RT cases (if applicable) |
| <p>3. Update demographic information, locations, and activities for accreditation in database within 1 day.</p> <p>Save pre assessment materials to Sharepoint database by facility ID</p> | <p>AABB National Office</p> <p>Assessment Coordinators</p> | <ul style="list-style-type: none"> • Prepopulated FDVR <p>Renewal forms on AABB website</p> <ol style="list-style-type: none"> 1. Accreditation process checklist 2. Planning Information form 3. Data Form for Additional Activities 4. Locations Table (if applicable) 5. CLIA forms (if applicable) 6. CLIA Personnel Verification form (if applicable) 7. Annual Statistics Table 8. Contact Information form 9. Florida forms (if applicable) 10. Pre assessment materials <ul style="list-style-type: none"> ➤ Current organizational chart ➤ Brief description of quality plan ➤ Master list of documents ➤ List of internal and external assessments ➤ Last AABB assessment summary report including signature page ➤ List of proficiency testing performed ➤ IRL cases (if applicable) ➤ RT cases (if applicable) |
| <p>4. Based upon activities to be accredited, assign Assessor(s) and email 'Assessor Acceptance of Assignment' to</p> | <p>AABB National Office</p> <p>Assessor</p> | <ul style="list-style-type: none"> • Assessor Acceptance of Assignment |

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| assessor(s) within 14 days. | Coordinator | |
| 5. Respond to assignment within 24 hours to AABB National Office. Sign HIPAA and HITECH form and return via fax/scan email. | Lead/Sole Assessor and team members | <ul style="list-style-type: none"> Completed Assessor Acceptance of Assignment |
| 6. Fax Acceptance of Assessor(s) to facility once complete team has accepted the assignment within 2 days | AABB National Office Assessor Coordinator | <ul style="list-style-type: none"> Facility Acceptance of Assessor(s) |
| 7. Complete 'Acceptance of Assessor' form and return by fax within 7 days to AABB National Office. | Facility | <ul style="list-style-type: none"> Completed Acceptance of Assessor |
| 9. Forward preassessment packet to assessor(s) within 7 days. | AABB National Office Assessment Coordinators | <p>to lead/sole assessor</p> <ul style="list-style-type: none"> Letter to Sole (Lead) to Perform Assessment Authorization letter Pre-assessment packet (see step 8) Letter to coordinate AABB assessment and CAP inspection (if applicable) Assessment Summary Report form Post Assessment Questionnaire (PAQ) Lead/Sole Assessor's Report form Trainee Checklist (if applicable) On-Site Trainee Evaluation form (if applicable) Applicable assessment tools (see AABB Web Site) Travel policy and reimbursement form FDA Warning Letter since previous assessment (if applicable) Verification of CLIA compliance (CLIA facilities only) Verification of HRSA compliance (HRSA facilities only) Notification letter of assessment date (for assessor use) (announced assessments only) |

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| | | <p>to team members</p> <ul style="list-style-type: none"> • Letter to Team to Perform Assessment • Applicable assessment tools (see AABB Web Site) • Pre-assessment packet from step 8 • Team Assessor’s Report form • Travel policy and reimbursement form |
| <p>10. Contact team members upon receipt of packet to schedule a mutually agreeable date for the assessment. Assessment must be performed before the accreditation expiration date. Lead assessor should verify available dates with team members. Take into consideration the facility 5 blackout dates and do not schedule assessment on federal holidays</p> | <p>Lead/Sole Assessor</p> | <p>Note: If assessment is coordinated with a CAP inspection, assessment must occur within AABB cycle AND before CAP anniversary date.</p> |
| <p>11. Notify AABB National Office and team members within 10 days of receipt of preassessment materials of mutually agreed upon assessment date. If not able to perform before the accreditation expiration date, an explanation must be provided to AABB National Office</p> | <p>Lead/Sole Assessor</p> | <ul style="list-style-type: none"> • E-mail (accreditation@aabb.org) • Note: If the assessment is CAP-coordinated notify CAP of the assessment date. |
| <p>12. Perform desk assessment. Lead to contact AABB National Office to facilitate the request for additional documents and records from facility if necessary.</p> | <p>Lead/Sole Assessor (Team)</p> | <ul style="list-style-type: none"> • Preassessment packet • Assessment Summary Report • Last assessment summary report and corrective action • FDA warning letter since last assessment (if applicable) • Applicable assessment tool(s) |

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| 13. Develop assessment schedule and send to team members. | Lead/Sole Assessor | <ul style="list-style-type: none"> • Tentative assessment schedule |
| 14a. Perform assessment. Contact the AABB National Office for guidance in questionable issues and <i>Standards</i> interpretation questions as they occur. Fax form if instructed. | Lead/Sole Assessor (Team) | <ul style="list-style-type: none"> • Applicable <i>Standards</i> • Applicable assessment tool(s) • <i>Standards</i> Interpretation form |
| 14b. Communicate with facility representatives during course of assessment and update schedule accordingly. | Lead/Sole Assessor | |
| 14c. Conduct periodic team meetings and update schedule as necessary. If assessment is for multiple days, hold daily update meetings with team and facility. | Lead/Sole Assessor | |
| 14d. Develop summary report. Complete Verification of CLIA Compliance Forms, HRSA Compliance Forms or Equivalency Forms (if applicable) | Lead/Sole Assessor (Team) | <ul style="list-style-type: none"> • Applicable <i>Standards</i> • Applicable assessment tool(s) • Assessment Summary Report form • Verification of CLIA Compliance, HRSA Compliance and Equivalency Forms (if applicable) |
| 14e. Conduct summary session to report assessment findings. Modify report if clarifications arise during discussion with facility representatives. | Lead/Sole Assessor | <ul style="list-style-type: none"> • Assessment Summary Report form |
| 14f. Finalize summary report, including signatures of lead assessor and authorized | Lead/Sole Assessor (Team) | <ul style="list-style-type: none"> • Copy of Assessment Summary Report • PAQ (completed with facility ID, assessment |

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| <p>facility representative. Leave a copy with an authorized facility representative. All pre-assessment materials, assessor notes, records and copies are left with authorized facility representative.</p> | | <p>date(s), and assessor name(s))</p> <ul style="list-style-type: none"> • Preassessment packet (all copies) • FDVR (all copies) • Assessment Summary Report • Corrective Action Plan from last assessment (if applicable) • FDA Warning Letter (if applicable) |
| <p>15. Send post assessment materials to AABB National Office in Fed Ex envelope provided within 1 day. (CAP-coordinated assessments: send CAP paperwork directly to CAP)</p> | <p>Lead/Sole Assessor</p> | <ul style="list-style-type: none"> • Original of Summary Report • Lead/Sole Assessor's Report • Commendable Practices form (if applicable) • <i>Standards</i> Interpretation Form (if applicable) • Trainee checklist (if applicable) • On-Site Trainee Evaluation (if applicable) • Verification of CLIA Compliance (CLIA facilities only) • Verification of HRSA Compliance (HRSA facilities only) • Equivalency forms for Florida licensed facilities • Reimbursement form with original receipts |
| <p>16. Receive post-assessment packet and verify as complete.</p> | <p>AABB National Office Assessment Coordinators</p> | <ul style="list-style-type: none"> • Original of Summary Report • Lead/Sole Assessor's Report • Commendable Practices form (if applicable) • <i>Standards</i> Interpretation Form (if applicable) • Trainee Checklist (if applicable) • On-Site Trainee Evaluation (if applicable) • Verification of CLIA Compliance (CLIA facilities only) • Verification of HRSA Compliance (HRSA facilities only) • Equivalency forms for Florida licensed facilities • Reimbursement form with original receipts |
| <p>17. Complete and submit reimbursement forms within 30 days of assessment to AABB National Office.</p> | <p>Assessment Team Members</p> | <ul style="list-style-type: none"> • Team Assessor's Report • Reimbursement forms with original receipts |

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| <p>18. Send follow-up letter to facility within 7 days of post-assessment packet receipt.</p> | <p>AABB National Office Assessment Coordinators</p> | <ul style="list-style-type: none"> • Follow-up letter (with or without nonconformances) |
| <p>19. Prepare corrective action plan and PAQ. Send to AABB National Office within 30 days of summary session.</p> | <p>Facility</p> | <ul style="list-style-type: none"> • Corrective/Preventive action plan • PAQ |
| <p>20a. Evaluate Corrective action plan and request additional information as needed within 20 days of receipt.</p> <ul style="list-style-type: none"> • If plan needs clarification, contact facility for additional documents or clarification and/or contact the assessor for clarification of nonconformances • If nonconformances are deemed to affect patient or donor safety, request documentation of plan implementation prior to issue of certificate. • If reassessment is recommended, forward corrective action plan and associated documents to APC Review Group. | <p>AABB National Office Technical Specialists</p> <p>Director of Accreditation</p> | <ul style="list-style-type: none"> • Facility response |
| <p>20b. Submit additional documentation or clarification to AABB National Office within 10 days of request</p> | <p>Facility</p> | <ul style="list-style-type: none"> • Facility response |

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| <p>21. Send accreditation documents within 15 days of approval of corrective action plan and receipt of implementation documentation as appropriate.</p> | <p>AABB National Office</p> | <ul style="list-style-type: none">• Letter of Accreditation• Certificate of Accreditation• Accreditation Kit |
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