

### ASSESSOR QUALIFICATIONS/REQUIREMENTS

Item	Assessor
<p><b>Definition of Assessor roles:</b></p> <p>Team member Sole Lead</p>	<p>Assessor who participates as a member of an assessment team. Assessor who performs assessments as the sole representative of the AABB. Assessor who is the leader of a team of assessors.</p>
<p><b>Responsibilities</b></p>	<p><b>All assessors:</b></p> <ul style="list-style-type: none"> <li>• Abide by time frames set by the accreditation program</li> <li>• Use pre-assessment materials to prepare for assessment</li> <li>• Perform assessment</li> </ul> <p><b>Lead/sole assessor:</b></p> <ul style="list-style-type: none"> <li>• Serves as the contact person to the facility, if applicable</li> <li>• Prepares the summary report that is left at the facility</li> <li>• Submits the assessment report to National Office</li> </ul> <p>In addition, the lead assessor:</p> <ul style="list-style-type: none"> <li>• Communicates with team members</li> <li>• Serves as the spokesperson for the team</li> <li>• Coordinates the assessment</li> </ul> <p><b>Trainee</b></p> <ul style="list-style-type: none"> <li>• Observe experienced assessors as they perform all aspects of the assessment</li> <li>• Assist experienced assessors by applying the information obtained from new assessor training workshops to assessment process (trainees are not to work independently)</li> <li>• Work with experienced assessors to complete training checklist and evaluation</li> <li>• Observe the preparation of the summary report</li> </ul>
<p><b>Education</b></p>	<p><b>Donor, Transfusion Assessors</b> - Bachelors degree or equivalent in a related science</p> <p><b>Cell Therapy Clinical Assessors</b> – MD, Physician’s Assistant, Nurse Practitioner, BSN with patient care experience.</p> <p><b>Cell Therapy Assessors</b> (HPC, Cord Blood, Somatic Cell) - Bachelors degree in a biological science</p> <p><b>Relationship Testing Assessors</b> - advanced degree (e.g. PhD or MD) or BA/BS degree in biological science, with experience</p> <p><b>Perioperative Assessors</b> - minimum 2 year degree in related science</p> <p><b>Immunohematology Reference Laboratory Assessors</b></p> <ul style="list-style-type: none"> <li>- Bachelors degree or equivalent</li> <li>- Must meet the requirements of a “supervisor” as defined in the current edition of <i>Standards for Immunohematology Reference Laboratories</i></li> </ul> <p><b>Molecular Testing Laboratory Assessors</b></p> <ul style="list-style-type: none"> <li>- Bachelors degree or equivalent</li> </ul>

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	<ul style="list-style-type: none"> <li>- Must meet the requirements of a “laboratory supervisor” as defined in the current edition of <i>Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens</i></li> </ul> <p><b>Specialist in Blood Banking Program Assessors</b></p> <ul style="list-style-type: none"> <li>- Bachelors degree in a related science with related experience (bench, supervisory, &amp;/or teaching)</li> <li>- SBB, MEd, or equivalent as approved by SBB CoA</li> </ul> <p><b>Patient Blood Management Program Assessors</b></p> <ul style="list-style-type: none"> <li>- Bachelors degree or equivalent in a related science with related experience (PBM program Medical Directorship, management, program coordinator, or program member)</li> </ul>
<p><b>AABB Membership</b></p>	<p><b>Active Individual Member</b></p>
<p><b>Technical Training and Experience</b></p> <p><i>Note: Direct work experience = actual experience performing technical/patient care duties</i></p>	<ul style="list-style-type: none"> <li>• <b><u>Donor Center, Transfusion Service, and Relationship Testing Assessors</u></b> <ul style="list-style-type: none"> <li>- Minimum <b>3 years</b> direct (hands on) work experience, a portion of which has occurred in the last 3 years.</li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>- Minimum 3 years direct work experience &gt; 3 years in the past AND current active involvement in a related field that allows an individual to keep informed of scientific, technical, and accrediting requirements of the activity. (considered when applicant has had direct work experience in the past and now works in a capacity such as supervisor of operations or quality assurance)</li> </ul> </li> <li>• <b><u>Immunoematology Reference Laboratory Assessors</u></b> <ul style="list-style-type: none"> <li>- Minimum <b>3 years</b> direct work experience in an immunoematology reference laboratory (a portion of which has occurred in the last 3 years).</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>- Active involvement in a related field that allows individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of IRL-APU).</li> </ul> </li> <li>• <b><u>Perioperative Assessors</u></b> <ul style="list-style-type: none"> <li>- Minimum <b>3 years</b> direct work experience (a portion of which has occurred in the last 3 years).</li> </ul> </li> <li>• <b><u>Cellular Therapy Assessors</u></b> (Clinical)           <ul style="list-style-type: none"> <li>- Minimum of <b>3 years</b> of experience in an established clinical program, 3 years of which has occurred in the last 5 years, <b>and</b></li> <li>- Program experience to include direct patient care. Program examples include, but not limited to: HPC, Cord Blood, Apheresis/Marrow Transplant Program, Pancreatic Islet transplant Programs, other CT products, <b>and</b></li> <li>- Direct work experience with research protocols preferably as a principle investigator, <b>and</b></li> <li>- Working knowledge of investigational products desired (IND, BLA, and relevant international regulatory experience also helpful), <b>and</b></li> <li>- Maintain continuing education in the field current to the last year, i.e. specific to clinical transplant activities, patient care and research.</li> </ul> </li> <li>• <b><u>Cellular Therapy Assessors, Collections and Laboratory Processing</u></b> (HPC, Cord Blood, Marrow)           <ul style="list-style-type: none"> <li>- Minimum of <b>3 years</b> direct work experience related to HPC (Apheresis and Marrow) or</li> </ul> </li> </ul>

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	<p>Cord Blood activities, 3 years of which has occurred in the last 5 years, <b>and</b></p> <ul style="list-style-type: none"> <li>- Direct work experience to comprise of product collection and/or product processing including storage and shipping requirements, <b>and</b></li> <li>- Maintain continuing education in the field current to the last year, i.e., specific to cellular product collection/processing activities.</li> </ul> <ul style="list-style-type: none"> <li>• <b><u>Cellular Therapy Assessors</u></b> (Somatic Cell)           <ul style="list-style-type: none"> <li>- Minimum <b>2 years</b> direct work experience in a cGMP environment, 2 years (a portion of which has occurred in the last 4 years), <b>and</b></li> <li>- Have IND experience and experience working with investigational products, <b>and</b></li> <li>- Maintain continuing education in the field in the last year, i.e., specific to that area</li> </ul> </li> <li>• <b><u>Molecular Testing Assessors</u></b> <ul style="list-style-type: none"> <li>- Minimum <b>2 years</b> direct work experience in a Molecular Testing laboratory (a portion of which has occurred in the last 2 years)</li> <li style="text-align: center;">OR</li> <li>- Active involvement in a related field that allows individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of MT-APU)</li> </ul> </li> <li>• <b><u>Specialist in Blood Banking Program Assessors</u></b> <ul style="list-style-type: none"> <li>- Teaching Experience includes presentations / lectures given, on-site teaching, mentoring, <b>and</b></li> <li>- Active participation (through either a managerial, educational or technical position) in managing a quality program or having responsibilities for quality-related practices that include cGMP related functions, <b>and</b></li> <li>- Successful completion of site visitor quiz found at <a href="http://www.caahep.org">www.caahep.org</a></li> </ul> </li> <li>• <b><u>Patient Blood Management Program Assessors</u></b> <ul style="list-style-type: none"> <li>- Minimum <b>3 years</b> direct work experience in a Patient Blood Management program (a portion of which has occurred in the last 3 years).</li> <li style="text-align: center;">OR</li> <li>- Active involvement in PBM activities that allows the individual to keep informed of scientific, technical, and accrediting requirements of the activity (requires review and approval of PBMAC).</li> </ul> </li> <li>• <b><u>All Assessors:</u></b> <ul style="list-style-type: none"> <li>➤ Understanding of quality programs (Quality System Essentials), audit practices or other quality practices either through actual experience or training;</li> <li style="text-align: center;"><b>and</b></li> <li>➤ Active participation (through either a managerial or technical position) in managing a quality program, performing assessments, or having responsibilities for quality control, process control or other quality-related practices that include cGMP related functions.</li> <li style="text-align: center;"><b>and</b></li> <li>➤ Successful completion of AABB Accreditation Program's New Assessor Training.</li> <li style="text-align: center;"><b>and</b></li> <li>➤ Successful completion of assigned trainee assessment by accompanying an approved assessor to assess a facility.</li> </ul> </li> </ul>
<p><b>Commitment</b></p>	<ul style="list-style-type: none"> <li>• Participate in at least 2 facility assessments per year, when requested</li> <li>• Participate in Assessor Continuing Education Program</li> <li>• Abide by Code of Conduct</li> </ul>

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	<ul style="list-style-type: none"> <li>• Abide by Confidentiality Agreement               <ul style="list-style-type: none"> <li>➤ Please note that some assessments may last more than 1 day and may involve travel outside of your local area.</li> </ul> </li> </ul>
<b>Attributes/Abilities</b>	<ul style="list-style-type: none"> <li>• Knowledgeable in assessed activities</li> <li>• Good verbal/written communication skills</li> <li>• Objective (use only facts)</li> <li>• Professional (fair, report exactly what is found)</li> <li>• Punctual</li> <li>• Positive (judge on basis of effectiveness of a quality system; consider nonconformances as an opportunity for improvement)</li> <li>• Practical (assessment beneficial to facility being assessed)</li> <li>• Prepared</li> </ul> <p>When performing as a lead or sole assessor:</p> <ul style="list-style-type: none"> <li>• Demonstrate facilitation skills</li> <li>• Demonstrate organizational skills to accomplish group activities</li> </ul>
<b>Continuing Education</b>	<p>Must successfully recertify as an assessor by participating in the Assessor Continuing Education Program.</p>
<b>Competence Requirements</b>	<p>Competence will be assessed by input from the following:</p> <ul style="list-style-type: none"> <li>• Facility feedback on assessment (Post-Assessment Questionnaire)</li> <li>• Validation assessment conducted by AABB</li> <li>• CMS validation results if performed within 60 days of AABB assessment (when available)</li> <li>• Lead/Sole Assessor's Report</li> <li>• Team Assessor's Report</li> <li>• Adherence to timeframes, completeness/clarity of assessment reports</li> </ul> <p>Assessors will be evaluated on the following attributes:</p> <ul style="list-style-type: none"> <li>➤ Represents the AABB with Integrity</li> <li>➤ Manages facility information in a confidential manner</li> <li>➤ Communicates effectively with team and facility</li> <li>➤ Demonstrates knowledge of AABB standards</li> <li>➤ Relates observations to specific standards</li> <li>➤ Synthesizes information by asking open ended questions</li> <li>➤ Applies systems analysis to the assessment process</li> </ul> <p>In addition to evaluation from assessment feedback, competence will also include biennial submission of continuing education and attendance at annual meeting assessor day (or AABB Live Learning Center review).</p>