

previously ASHI-DTRC approved laboratory director), board certification (eg, Diplomate ACHI (ABHI), ABMLI), or current license (if required) **AND**

- ✓ Work history in related field **AND**
- ✓ CAP letter of acceptance for new histocompatibility section directors

#### REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1449(h)].
- 2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

**\*\*REVISED\*\* 08/24/2023**

### HSC.40100 Notification of Change in Key Personnel

**Phase II**



**The laboratory notifies the CAP's Laboratory Accreditation Program when there is a change in the histocompatibility director (technical supervisor) and other key personnel, as applicable.**

*NOTE: All laboratories must notify the CAP when there is a change of histocompatibility section director and submit records for review by the CAP as requested.*

*Histocompatibility testing laboratories that participate as a member of the United Network for Organ Sharing (UNOS) must also notify the CAP when there is a change in other key personnel, including the general supervisor and/or clinical consultant.*

*Notification must occur no later than 30 days prior to the change; or in the case of an unexpected change, no later than 2 working days afterwards. For changes in laboratory directorship, refer to GEN.26791.*

#### REFERENCES

- 1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

**\*\*REVISED\*\* 12/26/2024**

### HSC.45000 Testing Personnel Qualifications - Histocompatibility

**Phase II**

**Personnel performing the technical work of histocompatibility have at least one year of training and/or experience in histocompatibility and qualify as high complexity testing personnel with a minimum of the following:**

1. **Bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or**
2. **Associate degree in a laboratory science or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in GEN.54750 for high complexity testing.**

*NOTE: A more detailed listing of personnel qualifications can be found in the CAP Personnel Guidance Document located in e-LAB Solutions Suite on cap.org (log-in required) under Accreditation Resources - Accreditation Checklists.*

*Persons with less than one year of training and/or experience must work under the supervision of persons who are qualified.*

#### **Evidence of Compliance:**

- ✓ Records of section director/technical supervisor qualifications including diploma, transcript(s), primary source verification report, equivalency evaluation, board certification, or current license (if required) **AND**
- ✓ Work history in related field

#### REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2023(Dec 28):[42CFR493.1489].
- 2) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.