

HSC.46250 General Supervisor Qualifications - Histocompatibility**Phase II**

The general supervisor has a minimum of three years of experience in histocompatibility/transplantation.

Evidence of Compliance:

- ✓ Records of work history in personnel file

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.

HSC.47500 Continuing Education Program**Phase II**

There is a continuing clinical laboratory education program that addresses the areas of service offered by the laboratory, identifies the need for remedial training, where appropriate, and provides continuing education to improve skills in histocompatibility.

NOTE: The laboratory must have a complete continuing clinical laboratory education program that meets the needs of the various types of laboratory personnel and addresses the areas of service offered by the laboratory, including a predefined minimum number of contact hours annually. This program may be provided locally, regionally/nationally, through scientific article review and discussion, or some combination of the above.

Evidence of Compliance:

- ✓ Records of continuing education

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.

HSC.48750 Clinical Consultant Qualifications - Histocompatibility**Phase II**

The section director or other individual fulfills the responsibilities of clinical consultant.

NOTE: The clinical consultant must be an MD or DO licensed to practice medicine in the jurisdiction where the laboratory is located (if required) with appropriate training and experience in the interpretation of histocompatibility / transplantation immunology test results, or a doctoral level clinical scientist certified by a CLIA-approved specialty board.

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 **AND**
- ✓ Job description defining responsibilities of clinical consultant

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)] and [42CFR493.1455].
- 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.