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## 2. RESOURCES

### 2.0 Resources

The facility shall identify and provide adequate staffing, materials, equipment, and facility infrastructure to perform, verify, and manage all activities covered by these *CT Standards*.

### 2.1 Human Resources

The facility shall have a process to ensure that there is an adequate number of qualified individuals.

 **2.1.1 Job Qualifications**

The facility shall identify qualifications for each job position on the basis of education, training, and experience.

 **2.1.2 Personnel Identification**

Records of names, signatures, initials or identification codes, and inclusive dates of employment shall be maintained.

 **2.1.3 Job Descriptions**

The facility shall establish and maintain job descriptions defining the roles and responsibilities for each job position related to the requirements of these *CT Standards*.


 **2.1.4 Training**

The facility shall establish and maintain policies, processes, and procedures for the following:

- 1) Orientation.
- 2) Initial job specific training.
- 3) Quality-systems-related training.
- 4) Ongoing job-specific training.

**2.1.4.1** The facility shall define the qualifications and approve subject matter experts who provide training.


 **F 2.1.5 Personnel Records**  
Personnel records for each employee shall be maintained.

 **C 2.1.6 Competence**  
Evaluations of competence shall be performed before independent performance of assigned activities.

**2.1.6.1** Competence shall be evaluated annually for defined tasks and activities.\*

**2.1.6.2** For individuals who perform moderate- and high-complexity testing, semi-annual reviews of competence shall be performed in their first year of employment. For facilities located in the United States, specified requirements apply.†

**2.1.6.3** Competence shall be assessed when new or novel processes or procedures are introduced. Standard 5.2.3 applies.

 **C 2.1.6.4** Corrective action shall be taken when competence has not been demonstrated. Standard 9.1 applies.

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\*42 CFR 493.1413(b)(8) and 42 CFR 493.1451(b)(8).

†42 CFR 493.1413(b)(9) and 42 CFR 493.1451(b)(9).

## 2.1.7

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### **2.1.7 Continuing Education**

Requirements for relevant continuing education in activities performed by the facility as required by these *CT Standards* shall be defined for and met by all employees who perform critical tasks.

**2.1.7.1** The facility shall ensure that the medical, laboratory, procurement, and clinical program directors, and the quality representative, annually complete 10 hours of educational activities relevant to the role and the associated cellular therapy activity or activities performed in the facility.\* Standards 1.1.3.1, 1.1.4.1, 1.1.4.2, and 1.1.5.2 apply.

## **2.2 Access to Ancillary Services and Direct Patient Care**

The clinical facility shall have an agreement in place to ensure comprehensive care and relevant resources required for patient care in cellular therapies, including but not limited to:

- 1) Transfusion medicine.
- 2) Services related to pharmacy.
- 3) Radiology.
- 4) Laboratory services.
- 5) Acute care or medical facilities.
- 6) Social and psychological support.
- 7) Long-term follow-up based on protocol or treatment plan.

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\*42 CFR 493.1413(b)(8) and 42 CFR 493.1451(b)(8).