



Guidance Document

Training and Competency

[No. 10, December 19, 2017]

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The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to creating this document.

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AATB GUIDANCE DOCUMENT
Training and Competency

I. INTRODUCTION

AATB Standard J2.200 Competency states, “Technical staff must demonstrate competency for their designated functions (including a thorough understanding of relevant policies, procedures, process controls, and regulatory requirements).” The purpose of this guidance document is to help meet this requirement and provide tissue banks with a framework for a robust training and competency program.

A. History and Purpose

Training and competency can be conducted and documented in a multitude of ways. This guidance document will outline some different approaches that may be undertaken to accomplish training/competency but will by no means be an all-inclusive list.

Training and competency has to be an organizational wide effort. The training process begins when an employee is first hired and receives their initial training/competency and follows through periodic reviews of that competency. This includes retraining/competency checks as required by deviations, complaints or audits and when processes are changed or added. The Quality Department plays a prominent role in ensuring that training and competency are completed effectively through audits, monitoring of the training program and CAPAs.

Current education and training scientific literature supports the use of a competency-based assessment framework as the guiding paradigm for training as well as the documentation of these activities. Based on current and emerging technologies related to the training process, there are diverse modes and venues to both provide training and ensure its provision is clearly and accurately documented.

An effective training/competency program should take into account the different learning styles adults have: (Visual, Auditory and Kinesthetic). Developing trainers who can teach students in all three of these learning styles is a key foundation to an effective training program. The training/competency program is not a static program as it is continuously evolving as the needs of the Tissue Bank and its employees change.

Each tissue bank should develop the scope of their training and ongoing competency programs based on current national standards to include, but not limited to: The Food and Drug Administration (FDA), The American Association of Tissue Banks (AATB), and the Association of periOperating Room Nurses (AORN). The training program should also incorporate the SOPs and protocols of the organization and any tissue partner organizations.

The Components of a Training Program, Documentation of Training and Metrics as outlined in this document provide guidance for a framework that Tissue Banks can use to meet the intent of standard J2.200 Competency.

B. Definitions and Abbreviations

The following abbreviations are used in this Guidance Document:

1. QAPI - is a data-driven, proactive approach to improving the quality that involves members at all levels of the organization to: identify opportunities for improvement; address gaps in systems or processes; develop and implement an improvement or corrective plan; and continuously monitor effectiveness of interventions.

II. TRAINING AND COMPETENCY

A. Components of a Training Program

A robust training program is not static, but always evolving and improving. Managers of training programs should always be evaluating and analyzing the effectiveness of the program. A training program requires design, development, proprietorship, documentation and metrics.

B. Design – Developing a Training Policy

The Training Policy/SOPs will set the overall design of the training program. These documents should include the following;

Outline of how training will be conducted, which should include the following categories:

- New hire training
- Position specific training
- Annual training
- Retraining

Description of training methods used by the tissue bank; a diverse set of training methods provides a better opportunity to meet the individual needs of each team member, these could include:

- Read and understand
- Trainer/preceptor led
- Competency/test based
- Computer-based
- Simulation
 - Wet-lab
 - Conferences/Workshops
- AATB webinars and conferences

Training Plan for each Position Description, this may be contained in:

- Employees position description
- Separate training document

- Described in company policies and procedures

Description of how training will be documented for the various methods.

- Paper
- Electronic
- Combination of paper and electronic

Storage/management of training files

- Length of retention
- Location
- Access
- Auditing responsibility

C. Development - Train/Certify the Trainers

A key element of a solid training and competency program is to ensure that those employees responsible for training are trained themselves and are effective at training others.

Organizational trainers must not only possess a working knowledge of critical tasks related to their role, but have the ability to demonstrate continuous proficiency of these critical tasks and the ability to train these tasks. Technical staff responsible for training must also understand the various learning styles (Visual, Auditory and Kinesthetic) and be able to apply training techniques to these learning styles during training sessions.

A “train the trainer” program fosters competence of trainers and facilitates the professional development of technical staff that serves as trainers.

1. Documented process for becoming a trainer

It is important to be mindful that the most appropriate organizational trainer may not be the most senior staff member. A trainer should be selected for their combination of technical skill, communication ability and willingness to train others. An important question to consider for the tissue bank is whether or not the trainer should have an active credential (i.e., CTBS). Credentialing is a means of backing the discipline.

A robust training and competency program should implement a train the trainer program which certifies/qualifies the staff member to be a trainer. A staff member selected as a trainer should be required to attend initial, annual, and additional training workshops (as necessary) to gain and maintain their status as a trainer as required by the tissue banks Training Policy/SOPs.

The organization’s internal audit program should include routine audit of training files to ensure compliance of the documented process for becoming a qualified organizational trainer and maintaining that qualification.

2. Quality involvement in training program

Implementation of a committee (i.e., Organizational Development Committee, QAPI, Training and Competency Performance Improvement Team, etc.) that is responsible for the continuous improvement of the training and competency program introduces a quality element. This committee provides a mechanism for measuring and monitoring the

organization's standard of practice against industry standards and making adjustments as necessary.

Initial and annual competency assessments are conducted to ensure demonstrated proficiency of technical staff. Organizational certified trainers should be the only technical staff with the authority to sign off on competencies related to critical tasks. An initial competency checklist should be able to show progression of a critical task, beginning with 1) reading the procedure, 2) witnessing the procedure, 3) demonstrating the procedure under supervision, and 4) demonstrating proficiency of the procedure. While progression through each area may be documented only once, multiple exposures and/or attempts may be necessary for progression to demonstrated proficiency.

3. Role and Responsibilities of Trainers/Preceptors

A trainer/preceptor should serve as a role model and resource for new employees. The trainer/preceptor, in conjunction with the manager/director, provides an organized orientation for new employees for the roles and responsibilities of their job function. In addition, new employees will be socialized to their new environment, fostering an atmosphere of trust and acceptance. The trainer/preceptor performs activities related to orientation, competency assessment, and competency verification. The trainer/preceptor identifies orientation and competency needs, and collaborates with their manager/director to develop a plan to meet these needs.

Some of the functions of Trainers/Preceptors could include:

- Serve as a role model of organization's mission, vision, core values, and guiding principles;
- Serve as a resource for new employees;
- Follow orientation lesson plan established for the new employee, and updates/revises those plans as needed;
- Employ adult learning strategies appropriate to the new employee;
- Validate and document competency by observing performance;
- Plan, select, and facilitate experiences to meet new employee's identified training needs;
- Provide ongoing feedback to the new employee regarding performance; holds evaluation meetings with new employees at regular intervals (including manager when possible);
- Promote independent functioning consistent with level of experience;
- Promote critical thinking development of new employee;
- Facilitate socialization into the division and organization;
- Complete all documentation required for evaluation of new employee, including specific task evaluations, etc.;
- Attend and complete the "train the trainer" workshop;
- Consults with committee responsible for continuous improvement of the training and competency program as needed;
- Participate in meetings with other trainers/preceptors as determined by department manager.

D. Proprietorship - Training Program

1. Documentation Management

The management of the training program documentation (which includes initial training, annual competency, training metric tracking, and retraining) should be assigned to a designee or designated department depending on the organization's size and needs. This allows for consistency of documentation within the organization.

This designee may or may not be involved in actually assessing competency, but should be able to identify deficiencies in an employee's training file so they can notify the party responsible for conducting training about the incomplete documentation. A training specialist position or training department dedicated to managing training files for the organization is most the efficient way to monitor the training program if resources allow.

Other suggested designee(s):

- **Quality Group** - This is the second best option - the review/auditing of training charts conducted by someone outside of the department in which training occurs should be considered best practice.
- **Designee(s) from each individual department** - It is more difficult to ensure consistency across departments with individual departments managing their own files, but is an acceptable option- if other resources are not available.

2. Training of Non-Company Staff

Depending on the nature of business relationships the tissue bank has, there can be times that the tissue bank may need to provide training to another outside organization. The training needs of the outside organization will need to be assessed and an appropriate training partnership with the outside organization will need to be developed.

An example of this would a tissue processor and a recovery agency (note the following provides examples on this relationship but the types of training apply to many situations). There are a couple of different options that can be used to provide training for recovery staff:

- **In-House recovery training**
Recovery agencies are primarily responsible for ensuring their recovery staff is adequately trained and proficient before performing essential recovery tasks. Tissue processors can audit the recovery agency and determine if recovery agencies training program is acceptable to meet their needs.
- **Processor provided training**
Tissue processors have a vested interest in ensuring that their recovery partners have received adequate training on their tissue recovery requirements. Tissue Processors should work with recovery agencies and provide regular training to ensure quality tissue is recovered according to their procedure/requirements.

Due to differences in procedures among processors, recovery agencies should look to each tissue processor to provide training for their specific procedures/requirements.

E. Documentation

The methods by which training and competency are recorded are diverse, and can include documents completed on paper, as well as those completed electronically. If documentation is maintained electronically, it should be compliant with the applicable technical standards, (i.e., a Learning Management System (LMS) compliant with a Sharable Content Object Reference Model (SCORM)). Each organization should develop their documentation process in collaboration with other functional areas such as, Quality, Clinical, and/or Education departments.

Types of documentation may include, but are not limited to:

1. **Training Checklists**, which include the objectives and skills required for competency for a given position description.
2. **Training Maps**, which utilize the documentation of training in a format that includes - Theory Phase, Simulation Phase, and On the Job Training(OJT) Phase – and creates a flexible format for pacing learning and skills demonstration.
3. **Training Matrices** – lists requirements and types of training for each position and can be used to identify, define and document training for positions within any organization. Additionally, a matrix can also help an organization determine training needs and opportunities for talent development. There are many possible ways to set up a Training Matrix. (Appendices A and B illustrate two possible options; one based on AATB Standards and the other based on Functional Competencies). These matrices can be used as foundations for a Training Plan, On the Job Training Checklists or alternative methods that meet an organization's training needs.

Categories in matrices, and language for documentation within the categories could include:

- Training Category: Specific course or Skills Set area
- Groups that need to complete this training category: Job Roles required to do the listed training
- Timeframe for Delivery of Training: Upon hire, within one month, within six months of hire, etc.
- Training Delivery Methods: Reading SOPS, Learning Management System (LMS) or computer training (Online), Classroom or Instructor led training (Classroom); On the Job Training (OJT), Performance of task/Demonstration of Competency (DOC), Simulation based training (Simulation), Wet Lab Training (Wet Lab), etc.
- Certified Trainers: List staff certified to teach courses and train on Competencies and Standards
- How Training is Documented: Read and Understand, Completion of Course, Show Competency, Demonstration of Competency, Observed Independent, Signed off as Trained, etc.
- Refresher Training Frequency: Define if refresher training required, and when- Monthly, Quarterly, Annually, etc.

The categories listed are not all-inclusive and can be modified to meet individual needs of your organization.

4. **Gantt Chart** - defines the metrics for competency and creates objective measurable timeframes for the completion of training in core skills. This model also recognizes that training does not only occur in a serial manner, but consists of incremental and overlapping competency attainment over the course of a defined period. Through the use of a Gantt Chart format, organizations can develop target timeframes for training, and use these as a measure of training effectiveness by both the trainers as well as the learners.
5. **Components of a Training Files**; these files should include:
 - Training Checklist- electronic and/or paper
 - Evidence of review of the checklist by supervisors
 - Evidence of all individual training sessions attended, internally or externally including any exams and quizzes completed.
 - Evidence of any certifications (internal and external) – CTBS, CPTC, CPR, ACLS, EBAA etc.

6. **Training Files Management**

- Organizations should determine where Training Files reside- electronically and/or on paper
- Organizations should determine which department (s) are responsible for housing the files; this will be outlined in their Training Policy/SOPs
- Organization should also determine which department serves as a resource for providing training files to external auditors for review and document this in their Training Policy/SOPs
- Regular internal audits should be performed of training files to ensure their completeness

F. **Metrics**

It is hard to specify a “norm” regarding duration of training and milestones. Because individuals each have varying learning styles and levels of cognitive ability, the duration of effective training becomes individualized. Indicating a number of cases observed and/or assisted on provides exposure, but falls short in its ability to demonstrate proficiency of critical tasks associated with recovery.

Training and competency programs should have a degree of adaptability to allow for individualization of moving a new employee to demonstrated competency. Routine meetings (i.e., 30-60-90 days) with the new employee, trainer, and manager/director allow time for providing feedback, clarifying expectations of all parties, and discussing strengths, weaknesses, and short-term goals related to their role. During these meetings, performance improvement plans can be developed to document guidance toward job proficiency.

Training feedback should be specific, factual, descriptive, clearly understood by the trainer and new employee, timed to be most useful, sensitive to the trainer and new employee, constructive,

and directed at behavior rather than personality traits. Whenever possible, provide positive feedback. When necessary, provide constructive feedback. Avoid giving negative feedback if at all possible.

New employees need frequent feedback on the things they are doing well, the areas they need to work on, and their progress toward orientation and competency assessment goals. Continuous feedback allows trainers to:

- motivate and positively reinforce learning
- diagnose the nature and extent of any problem areas
- offer constructive criticism when needed
- identify areas for remediation
- determine the effectiveness of the learning activities

After an employee is deemed proficient in a skill or task, competency should be routinely reassessed. The use of a performance tracking log is invaluable for this purpose. The log should be used to track actionable performance measures based on the employee's essential job functions where established expectations or goals are made and thresholds for evaluations are determined. This means that if an employee is not meeting a certain quality of work over a pre-determined period of time, an automatic evaluation occurs, assessing the reasons why that employee is not meeting the standards set. This allows retraining to occur, if warranted, or a re-evaluation of procedures if the established procedure is determined to be at fault.

The use of reports (from processor, labs, customers etc.) offers an objective review of how effective training is for staff. Using this data in a performance tracking log allows a comprehensive review of a staff member's performance and shows trends in performance. These reports either highlight successful execution of a process and helps identify potential preceptors/trainers and those deserving recognition, or identify those who have opportunities for improvement.

III. References

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IV. Appendices

A. Training Matrix - AATB's Standards

Training & Competency Matrix based on AATB's Standards	Call Center Operations Staff [✓ = Required Training]	Donation/Clinical Coordinators [✓ = Required Training]	Recovery Staff [✓ = Required Training]	Tissue Processing Staff [✓ = Required Training]	Central Processing Staff [✓ = Required Training]	Quality Systems Staff [✓ = Required Training]	After-Care Staff [✓ = Required Training]	TIMEFRAME FOR DELIVERY OF TRAINING [Upon Hire, Within 1 month, Within 6 months, Within 1 year of start date, etc.]	TRAINING DELIVERY METHODS [Reading SOPs (SOPs), Online LMS or Computer based training (Online), Classroom or Instructor Led (Classroom), On the Job Training (OJT), Performance of Task/Demonstration of Competency (DOC), Simulation based training (Simulation), Web-Lab Simulations (Web-Lab Sim., etc.)]	CERTIFIED TRAINERS [List anyone that is Certified to Teach Course(s), Train on Competency (ies) or Standard(s)]	HOW TRAINING IS DOCUMENTED [Read & Understand, Completion of Course, Shown Competency, Demonstration of Competency, Observed Independent, Signed off as Trained]	REFRESHER TRAINING FREQUENCY [Define when (monthly, quarterly, annual, none, etc.) and if refresher training is required.]	Add additional category to suit your organization's needs (define to suit your organization's needs)
	NEW HIRE TRAINING (Core Overview Training) List your Organization's New Hire Orientation/Training Courses or include a summary your Organization's New Hire Orientation program (i.e. Introduction and overview of the organization's functions, regulatory requirements and best practices)	✓	✓	✓	✓	✓	✓	✓	Within 1 month of start date	Online	John Smith	Completion of Course	none
CORE CURRICULUM (Organization/Role Specific Training) List Core Courses for role specific curriculum or list required competencies													
TISSUE RECOVERY (General Competencies) Authorization													
D2.000 AUTHORIZATION													
D2.100 Requirements													
D2.200 Conditions													
D2.300 Signatures and Documentation													
D2.400 Core Elements for Authorization													
D2.500 Notification of Gift													
D2.600 Services to Donor Families													
Informed Consent for Living Donors													
D3.000 INFORMED CONSENT FOR LIVING DONORS													
D3.100 Requirements													
D3.200 Conditions													
D3.300 Signatures and Documentation													
D3.400 Core Elements for Informed Consent													
D3.500 Services Involving Living Donors													
Donor Suitability													
D4.000 DONOR SUITABILITY													
D4.100 Donor Screening													
D4.110 Age Criteria													
D4.120 Physical Assessment													
D4.130 Physical Examination													
D4.140 Donor Risk Assessment Interview													
D4.150 Revelant Medical Records Review													
D4.200 Donor Testing													
D4.210 Blood Specimens													
D4.220 Infectious Disease Testing													
D4.230 Required Infectious Disease Tests													
D4.240 Archive Samples													
D4.250 Semen Analysis													
D4.300 Information Sharing													
Recovery and Collection Policies & Procedures													
List all relevant AATB standards													

B. Training Matrix – Functional Components

APPENDIX B														
<h1>Training & Competency Matrix by Function</h1>	Call Center Operations Staff [√ = Required Training]	Donation/Clinical Coordinators [√ = Required Training]	Recovery Staff [√ = Required Training]	Tissue Processing Staff [√ = Required Training]	Central Processing Staff [√ = Required Training]	Quality Systems Staff [√ = Required Training]	AfterCare Staff [√ = Required Training]	TIMEFRAME FOR DELIVERY OF TRAINING	TRAINING DELIVERY METHODS	CERTIFIED TRAINERS	HOW TRAINING IS DOCUMENTED	REFRESHER TRAINING FREQUENCY	Add additional category to suit your organization's needs	
	NEW HIRE TRAINING (Core Overview Training)													
	List your Organization's New Hire Orientation/Training Courses or include a summary your Organization's New Hire Orientation program (i.e. Introduction and overview of the organization's functions, regulatory requirements and best practices).	✓	✓	✓	✓	✓	✓	✓	Within 1 month of start date	Online	John Smith	Completion of Courses	none	
	CORE CURRICULUM (Organization/Role Specific Training)													
	List Core Courses for role specific curriculum or list required competencies													
	PRE-RECOVERY (General Competencies)													
	Referral													
	Has knowledge to complete an Asystolic and Heartbeating Referral													
	Preliminary Tissue Screening													
	Understands age, gender, social and medical criteria for each potential tissue													
Accurately completes a Tissue Screening by obtaining the clinical course, clinical values, past medical history and current medications														
Able to determine if a given referral has donation potential														
Understands how to qualify either a premortem or postmortem blood sample for serological testing														
Tissue Approach														
Follows appropriate family approach guidelines and uses language to optimize donation opportunity														
Donor Risk Assessment Interview (DRAI)														
Understands how to properly conduct the DRAI														
Understands when to find an alternate or additional historian														
Understands how to conduct the DRAI for pediatric donors														
Authorization / Disclosure														
Understands how to use the State priority chart to determine the Legal Next of Kin														
Knows how to search and verify an individual's donor designation status														
Knows how to properly complete both a Authorization and Disclosure for Tissue donation														
Understands all the required elements														
Case Set-Up														
Understands how to assign a unique donor identification number														
Knows how to obtain appropriate clearance for donation from other involved entities (Medical Examiner, Coroner, Private Autopsy, District Attorney, etc.)														
Knows how to conduct a preliminary chart review of the decedent's medical record														
list additional functions...														
list any additional competencies...														