

ISO 17025 Accreditation/Quality Management Systems Panel Discussion

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Laboratory Methods & Service Committee

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Training Competency – Documentation & Assessment

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Relevant Sections of the Standard

Section 5 - Technical Requirements

5.2 Personnel

- 5.2.1 Ensuring competence of qualified staff based on education, training, experience and skills
- 5.2.2 Training policies and procedures & evaluation of effectiveness
- 5.2.5 Maintaining records of authorized staff for competence, qualifications, experience, and training, as well as authorizations.



Personnel

- The laboratory **selects** employees with the defined knowledge, skills and abilities to perform their duties in a competent manner.
- **Training plan developed** (includes a standardized checklist of required new employee training).
- Adequate supervision is provided for employees undergoing training.
- Personnel are initially **authorized** by their supervisor to perform tests, perform internal audits, and operate equipment. Records of this authorization are maintained. This includes contracted or temporary staff! Competency is assessed periodically.
- Even **supervisors were initially authorized** (I used annually updated CVs as proof of competency) and any supervisory/leadership training that was attended during the past year.

Training and Competency Verification

- All training must be documented
 - Personnel must be trained on all management system policies and procedures as well as the Quality System Manual prior to analytical method training.
 - Must have written training procedures
 - Must have system to verify competency (Training sign-off, quizzes, demonstration of competence , PT samples, etc..)
 - Training documents are looked at heavily by the auditor!
- Three Phase Training System for analytical methods (i.e. test procedures) is an often used successful approach
 - Phase I – Trainee observes trainer
 - Phase II - Trainee performs procedure under supervision of trainer
 - Phase III – Trainee performs procedure independently and passes a PT or known reference material.



Training Records

- Hard copy records
 - Definitely need to organize
 - We kept rosters for groups by date in a notebook
 - We kept rosters for individuals in files
 - Standardized required training titles-same each year
 - Multiple SOP trainings-had one roster, attached training list
- Database records (i.e. Microsoft Access)
 - Steep learning curve to initially set up (not nice) but allowed us to produce
 - Individual training record
 - Training course attendees
 - Reports for Department (# trained/trainings in-house, external, etc.)



Competency Records

- Used spreadsheets with most success
- Initial authorization with a form, then tracking after that with spreadsheet
- Have to regularly review spreadsheet, or have a system in place to periodically reassess competency per your SOPs (one suggestion, at annual review)
- Initially, some were considered competent based on past PT performance, etc.
- New staff trained by senior staff-sometimes, that in itself is difficult

Tips, Challenges and Benefits

- Staff not used to submitting external training and had to follow up a lot (suggest assigning staff that does travel to ask for this as well-harder in a large facility)
- Hard to trap laggards-usually this was the nonconformance
- Hard to track multiple trainings on a single day
- Internal training was captured well
- Used form for “Read and Understood” (minor changes), as well as specific wording needed for things such as Select Agent training.