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.