

# ISO/IEC 17025:2017 “Personnel”



*Presented by:*

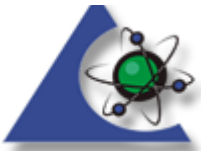
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*25-April-2019*



## ISO/IEC 17025:2017 “Personnel”

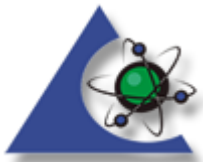
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*Go to the link for recorded webinars.*

*Duration of webinar is set for one hour.*

*You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;*

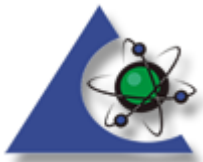




# ISO/IEC 17025:2017 “Personnel”

**6.2.1 All personnel** of the laboratory, either internal or external, that **could influence** the laboratory activities shall act **impartially**, be **competent** and work in accordance with the laboratory's management system;

*- This of course covers personnel involved directly in laboratory activities however this will also apply to internal auditors, purchasing, maintenance and contracted personnel;*



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From ISO/IEC 17025:2005 “Internal Auditing Section 4.14

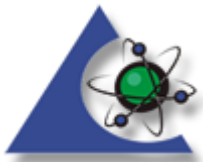
Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

This is now crossed walked over to Section 8.8 “Internal Audits” in the 2017 Standard.

COMPETENCE



Impartiality.

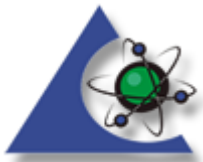


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**6.2.2** The laboratory **shall document** the competence requirements for each function **influencing the results of laboratory** activities, including requirements for education, qualification, training, technical knowledge, skills and experience  
*Each function is added*

## ISO/IEC 17025:2005

**5.2.1** The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates



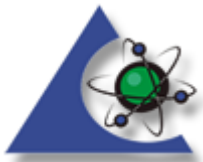
# ISO/IEC 17025:2017 “Personnel

Competence for each function **influencing results** (examples):

- Review of Contracts
- Sampling
- Method Performance
- Uncertainty Calculation
- Purchasing / Receiving
- Reporting Results

7.8.2.1 (o) identification of the person(s) authorizing the report;

- Management / Supervision
- Auditing



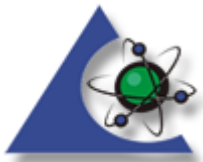
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Though not required in the 2017 Standard, a job description can be utilized to document information on expertise and experience required; diploma required qualifications and training program required; access to knowledge database at networks; and other matters (human behavior, spoken language).

Any specific competence requirements can also be documented in at job posting template’



Flexibility is given as the Standard is not specific as to where to document” Should meet the requirement and useful for the laboratory





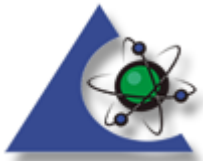
## ISO/IEC 17025:2017 “Personnel

**6.2.3** The laboratory **shall ensure** that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

*The laboratory has to evaluate for example by checking the appropriateness of the education, training, experience and/or demonstrated skills.*

*Is evidence available to demonstrate that a person meets all the criteria, he/she can be qualified?*

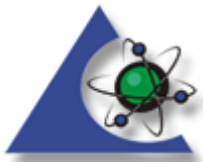
*If not, training actions have to be undertaken and the training program has to include evaluation of the new competence and the evidence of the evaluation have to be recorded. Those evidences can consist, where applicable: “(next slide)*



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## Examples of objective evidence to support competency;

- technical degree, certificate, diploma;
- involvement in publications;
- records of the involvement in calibration or testing operations and assessment of the participation;
- record of involvement in internal or external comparisons (successful PT results);
- record of involvement in research networks;
- record of involvement in standardization;
- records of specific evaluation;
- Others Past Employment - experience



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for non-frequent activities (>12 month), Records of the realization of a “reference” test.

See section 7.7 Ensuring the validity of results for possible checks on procedure and competence of individual

- Set up control chart with predefined limits of acceptance;
- Functional check(s) of measuring and testing equipment;
- use of reference materials or quality control materials;
- Incorporate check standards;



IF on the scope of accreditation it still needs to be supported;

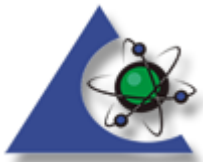


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COMPETENCE



The assessment of the competence of staff should fit for the purpose of staff being able to generate technically valid results. The better the competence specifications are defined, the easier it will be to demonstrate the fulfilment of competence requirements. It is the responsibility of the laboratory to find the good equilibrium between competence assessment of staff and other quality management system matters;



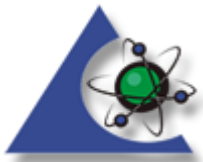
# ISO/IEC 17025:2017 “Personnel

**6.2.4** The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities

How is this done?



Even though the 2017 Standard does not require a job description it can still be used to communicate duties to personnel.



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**6.2.5** The laboratory shall have procedure(s) and retain records for:

*As an auditor you would expect to see a **procedure** - How it is done  
And a **record** – What was done*

a) determining the competence requirements;

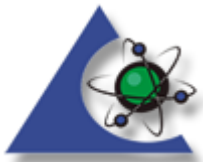
*-Job descriptions/postings (evidence of determination of competency)*

b) selection of personnel;

*-posting, interview notes, competency cross reference*

c) training of personnel;

*-Training attendance and agendas (evidence that competency was met)*



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**6.2.5** The laboratory shall have procedure(s) and retain records for:

d) supervision of personnel;

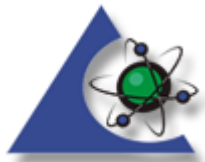
*-Training Record*



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e) authorization of personnel;

*-Can be an authorization matrix or training record sign off*

A screenshot of a web browser displaying a 'Training Matrix' form. The form has fields for 'Employee Name:' and 'Position:'. Below these is a table with five columns: 'Training Requirement', 'Trainer's Signature', 'Trainee's Signature', 'Date', and 'Trainer's Comments'. The table has three empty rows for data entry.

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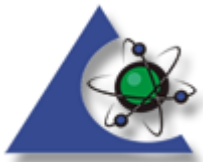
**6.2.5** The laboratory shall have procedure(s) and retain records for  
f) monitoring competence of personnel. *new*

*Laboratory will need to specify how it is done and records maintained showing it was done.*

*Lab determines how to monitor however this can utilize such vehicles as checking personnel’s data and reports, or participation in inter lab or intra lab testing.*

*Other methods can incorporate:*

- *Recertification*
- *Written Test*
- *Supervisor follow up after training is complete (60 days)*



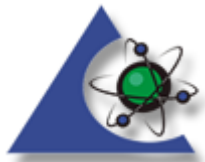


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**6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

- a) development, modification, verification and validation of methods;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) report, review and authorization of results.

Can be an expanded matrix to  
Incorporate these authorizations.



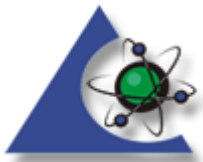


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*This time is allocated for answering questions. You should have a space provided for submitting questions.*

*Please keep questions related to the topic covered in this webinar;*



# Save the Date

*Next PJLA Webinar*



***ISO/IEC 17025:2017 Section 7.4 “Handling of Test or Calibration Items & Section 7.11 “Control of Data and Information Management”***

