

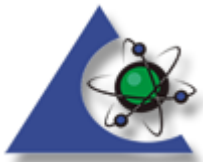
# ISO/IEC 17025:2017 Section 6.6 Externally Provided Products and Services

*Thursday, January 24, 2019 – 1:00pm EST*

Presented by:

Michael Kramer

PJLA Calibration /Inspection Program Manager



# ISO/IEC 17025:2017 Section 6.6 Externally Provided Products and Services”

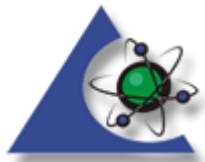
*This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.*

[www.pjlabs.com](http://www.pjlabs.com)

*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;*

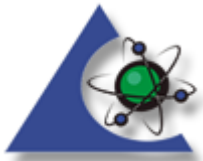


# Section 6.6 “Externally Provided Products and Services”

purchasing and subcontracting are now compiled in one section.

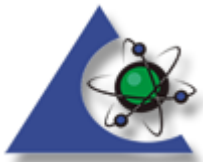
4.5 Subcontracting of tests and calibrations

4.6 Purchasing services and supplies



## Section 6.6 “Externally Provided Products and Services”

*When you are selecting a potential vendor, you are selecting a partner in your business and you will trust them to work with you in a professional and profitable manner. It is important that you chose a company that can supply your **requirements** now and future needs;*



# Section 6.6 “Externally Provided Products and Services”

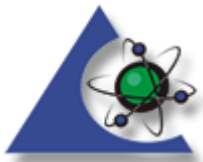
## Highlights

The laboratory should have a system to select, assess, monitor, and reassess external providers.

The laboratory shall ensure that all purchased products and services fulfil the requirements.

The laboratory shall make the following clear to the provider:

- what is to be bought,
- acceptance criteria,
- personnel competence needed,

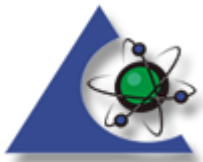


## Section 6.6 “Externally Provided Products and Services”

Three different ways (6.6.1 a, b and c) describe which products and services can be provided externally.

The procedure for reviewing requests, tenders, and contracts shall include the laboratory’s information to the customer of externally provided activities, and the customer shall approve the involvement of external providers before starting laboratory activities.

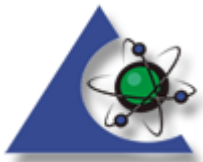
7.7.1 c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval



## Section 6.6 “Externally Provided Products and Services”

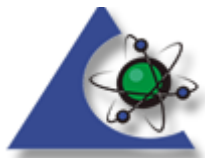
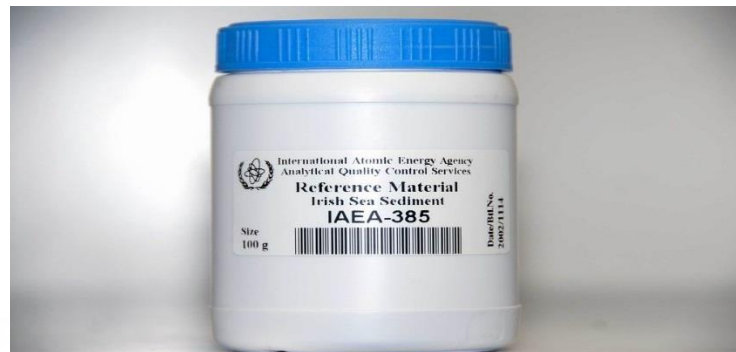
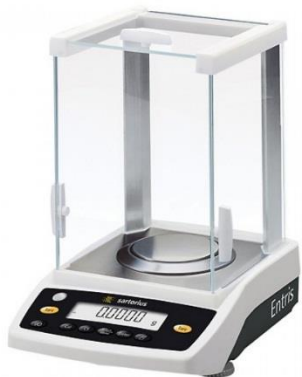
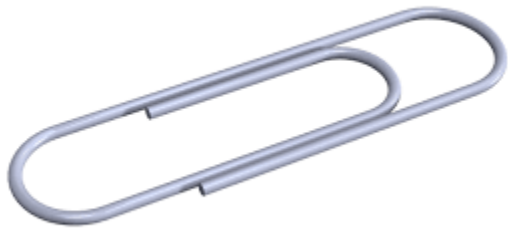
**6.6.1** The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- a) are intended for incorporation into the laboratory’s own activities;
- b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider; - subcontracting
- c) are used to support the operation of the laboratory



# Section 6.6 “Externally Provided Products and Services”

The laboratory shall ensure that only suitable externally provided products and services that **affect laboratory activities are used**,





# Section 6.6 “Externally Provided Products and Services”

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services

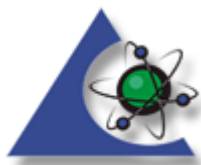
## Support Functions



**PROFICIENCY  
TESTING**



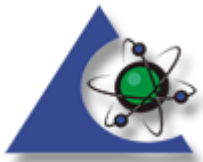
Target Dates for 2016	12/31/15	3/31/16	6/30/16	9/30/16	12/31/16
...	...	...	...	...	...



## Section 6.6 “Externally Provided Products and Services”

**6.6.2** The laboratory shall **have a procedure** and **retain records** for:

- a) defining, reviewing and approving the laboratory’s requirements for externally provided products and services;
- b) defining the criteria for evaluation, selection, monitoring of performance and **re-evaluation** of the external providers;
- c) ensuring that externally provided products and services conform to the laboratory’s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.



# Section 6.6 “Externally Provided Products and Services”

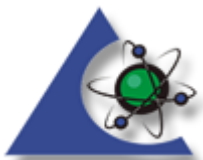
*Got rid of the list as 2017 is more electronic driven - Added monitoring & re-evaluation*

*From ISO/IEC 17025:2005*

**4.6.4** The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and **list those approved**

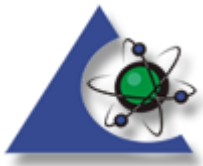
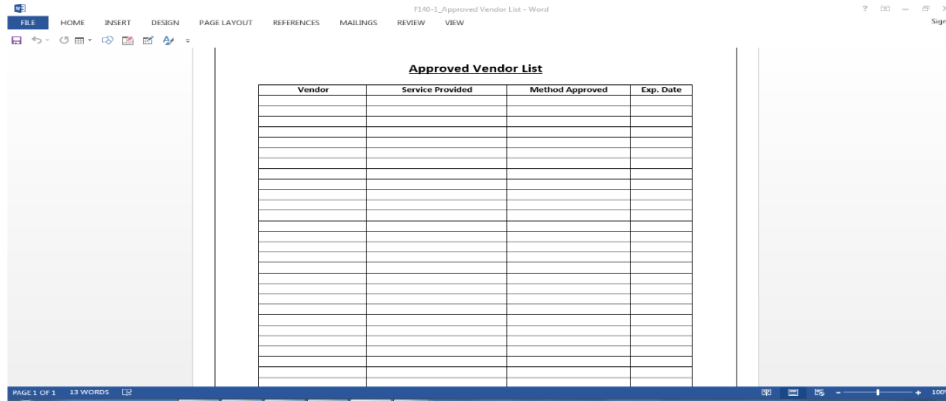
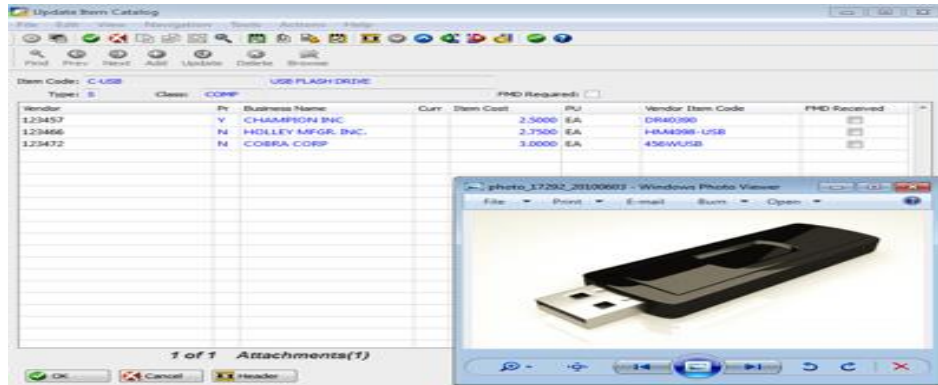
VENDOR APPROVAL STATUS RECORD

VENDOR NAME	MARKET / CREDIT	OVERALL PERFORMANCE	SURVEY CONDUCT	SURVEY COMPLETED	INTERNATIONAL STANDARD SYSTEM (ISO / IEC / OSHA)	INITIAL APPROVAL	MATERIAL APPROVAL	VENDOR APPROVAL COMPLETED	DUE DATE	STATUS / UPDATE	APPROVAL TIME	REMARKS



# Section 6.6 “Externally Provided Products and Services”

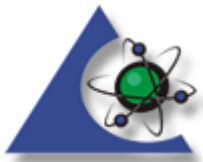
*Laboratory has more Flexibility*



## Section 6.6 “Externally Provided Products and Services”

Criteria for defining evaluation, selection, monitoring of performance and re-evaluation of the external providers may include:

- Accreditation to ISO/IEC 17025
- ISO/IEC 17011
- ISO/IEC 17043
- ISO 9001
- On time delivery
- Supplier Audits
- Testimonials and references these are valuable if you can check that the vendor is reliable and as they claim to be
- Years in business - need to know that the organization is established and ready to service your requirements
- Accuracy requirements and capabilities: Scope of Accreditation “Range and CMC’s



# Ranges and CMC's for Calibration Laboratories

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Torque <sup>FO</sup>	10 oz•in to 200 oz•in	0.33 % of reading	CDI Torque System
	5 lb•in to 50 lb•in	0.66 % of reading	
	25 lb•in to 250 lb•in	0.33 % of reading	
	100 lb•in to 1 000 lb•in	0.33 % of reading	
	25 lb•ft to 250 lb•ft	0.33 % of reading	
	100 lb•ft to 1 000 lb•ft	0.33 % of reading	

## Thermodynamic

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Pressure/Vacuum <sup>FO</sup>	0 in H <sub>2</sub> O to 300 H <sub>2</sub> O	0.05 %	Heise Pressure Transducers
	-10 psi to 15 psi	0.05 %	
	0 psi to 300 psi	0.05 %	
	301 psi to 1 500 psi	0.05 %	
	1 501 psi to 6 000 psi	0.1 %	
	6 001 psi to 10 000 psi	0.15 %	
Temperature <sup>F</sup>	-20 °C to 200 °C	0.045 °C	Hart SPRT/Liquid Bath

# Ranges and CMC's for Calibration Laboratories

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*Repeaters, Syringes, Laboratory Balances, Scales, Temperature Devices, and  
Temperature Measurement  
(As detailed in the supplement)*

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:



<i>Initial Accreditation Date:</i> June 12, 2010	<i>Issue Date:</i> October 26, 2018	<i>Expiration Date:</i> November 30, 2020
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Tracy Szerszen President/Operations Manager	<i>Accreditation No:</i> 64303	<i>Certificate No:</i> L18-493
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Perry Johnson Laboratory  
Accreditation, Inc. (PJLA)  
755 W. Big Beaver, Suite 1325  
Troy, Michigan 48084

*The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: [www.pjilabs.com](http://www.pjilabs.com)*

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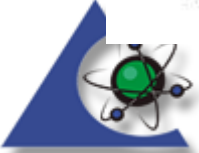
# Section 6.6 “Externally Provided Products and Services”

**6.6.3** The laboratory shall **communicate its** requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that the laboratory, or its customer, intends to perform at the external provider's premises;



Your Company		PURCHASE ORDER No.	
Your Street, Your Town, Your County, Postcode		Order Date:	
Your Telephone Number, Your Fax Number		Requested Date:	
Your Email Address, Your Website Address		Ordered By:	
		Account Number:	
Invoice to:		Deliver to (if different):	
QTY	DESCRIPTION	PRICE	
TOTAL €			



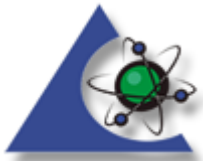


## 6.6 Externally Provided Products and Services”

- ❑ *The laboratory shall **communicate** its requirements to external providers*

*There is no requirement for a record or document; The 2005 Standard was specific in regards to purchasing documents. A purchasing document such as a PO can still be used and comply with the requirement that the lab communicates its requirements however it is not required.*

**4.6.3 Purchasing documents** for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release;

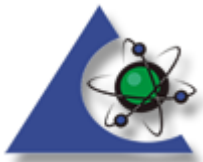


## ISO/IEC 17025:2017 Section 6.6 Externally Provided Products and Services



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

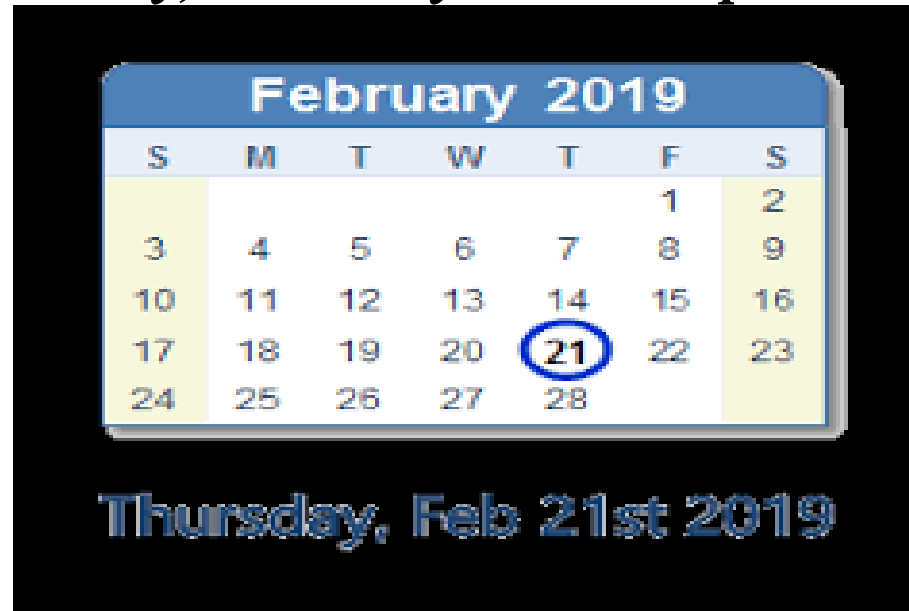
*Please keep questions related to the topic covered in this webinar;*



# Save the Date

*Next PJLA Webinar*

***Thursday, February 21 – 1:00pm EST***



ISO/IEC 17025:2017 Section 8.7 Corrective Actions

