

**PJLA**

# The 5 Steps to the Accreditation Process

Presented by: Tracy Szerszen, President



# Presentation Overview

- ▶ Review the 5 Major Steps to the Accreditation Process
- ▶ Review Examples of Forms, Logo Usage, etc.
- ▶ FAQs about Various Parts of the Process
- ▶ Q & A Session

# Webinar Housekeeping

This webinar will be recorded and available on the PJLA website shortly after the conclusion.

All attendees are muted. Please utilize the question tool bar to type in your questions to be answered at the end.

# Step 1

## The Application Process

Think About.....

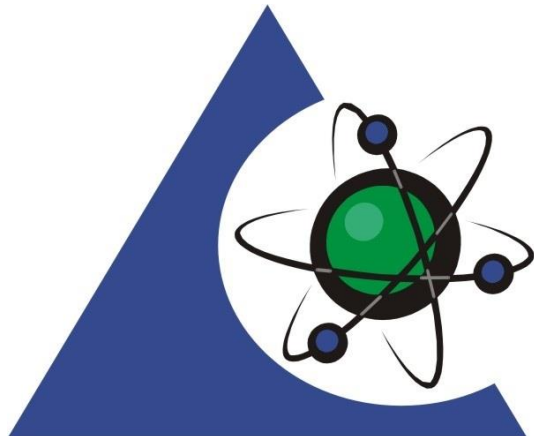
What standard do you need to be accredited for?  
ISO/IEC 17025, 17020, 15189, etc..

What tests, calibration, inspections, etc. do you want to be accredited for?

When do you want to be accredited by?

# Step 1

## The Application Process

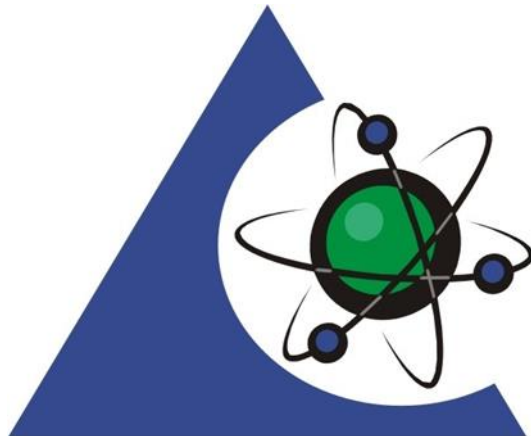


**PJLA**

- ▶ A Project Manager will provide you with an **application** and have a discussion with you on your needs i.e. timelines, readiness, optional preliminary assessment, may assist with completing your application
- ▶ Upon return of the application they will provide:
  - ▶ A quotation for service
    - ▶ Includes the time and the cost for a 2-year accreditation cycle
  - ▶ An overview of the process, timelines, and assessor availability
  - ▶ Additional tools, PJLA policies needed, references
  - ▶ **Website Sign Up**, Notification of Free Webinars, Updates to Policies
  - ▶ Overall guidance through the process

# Step 1

## The Application Process



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- ▶ Project Managers will request a commitment to accreditation
  - ▶ Signed agreement and deposit which is credited off the initial assessment invoice
  - ▶ Upon signature of the agreement and deposit, a Pending Letter of Accreditation will be provided:
    - ▶ Demonstrates company's commitment to becoming accredited
    - ▶ Includes the standard and timeframe of the commitment
    - ▶ Assists customers with satisfying their customer requirements

## Step 2 Preliminary Assessment Process



- ▶ PJLA has designated Accreditation Program Assistants (APAs) for each account fully supporting every client from scheduling the assessment to certificate issuance.
- ▶ Upon receipt of the signed contract, the APA “scheduler” will contact each client within 24-48 hours
  - ▶ Pending Letter
  - ▶ Timeframe
  - ▶ Scope Confirmation

## Step 2

### Preliminary Assessment Process



The Scope will be reviewed and commented on by Technical Program Management.



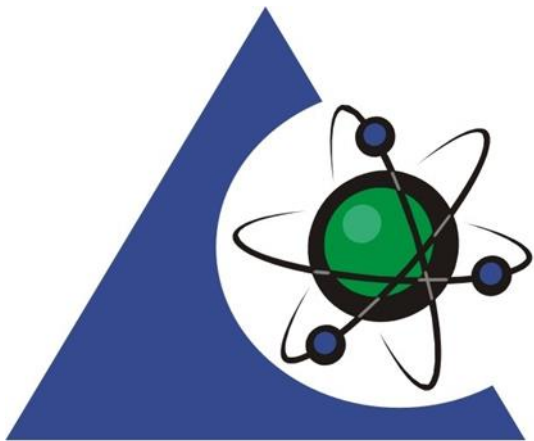
Once the scope is established, an assessor will be assigned to align with preferred dates.



Once the date is established, pre-documents must be turned in 30 days in advance to avoid cancellation.



## Step 2 Preliminary Assessment Process

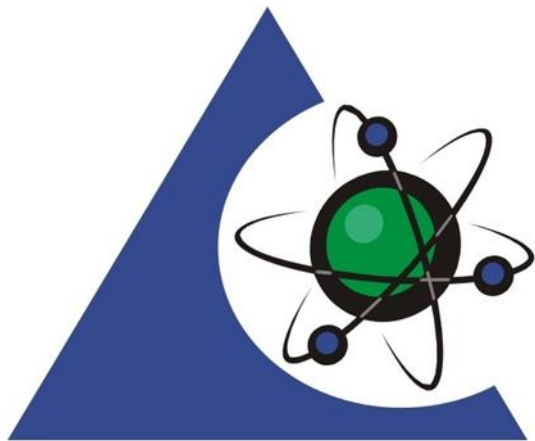


PIIA

- ▶ Pre-Documentation Requirements **LF-116**
- ▶ Prepares assessors for your assessment and avoids premature assessments
- ▶ Clients are also asked to sign a scheduling acknowledgement
  - ▶ Confirm assessor has no conflicts
  - ▶ Bios of Assessors may be requested
  - ▶ Clients have the right to object
- ▶ Cancellation Policy - If an assessment needs to be changed, please do so within 21 days of the assessment to avoid charges

# Step 3

## The On-Site Assessment



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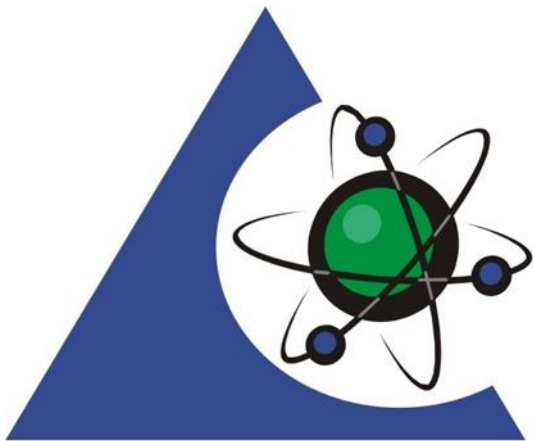
- ▶ Assessors will reach out to client at least 14 days or earlier to develop an assessment plan
  - ▶ Start times, scope of the assessment, guides, online tools (if applicable), confidentiality requirements, general questions about doc review

An opening meeting will be held at the start of the assessment with pertinent personnel (quality manager, lab manager, presidents)

- ▶ Confirm scope, standard, guides, review of plan

# Step 3

## The On-Site Assessment



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- ▶ If more than one assessor is assigned they may split off based upon the plan (i.e. one for quality management system requirements typically the lead assessor and one assessing the activities in the facility (i.e. lab, off-site at client sites (calibration, inspections))
- ▶ What to expect...
  - ▶ We want to see as much as possible and interview personnel performing activities.
  - ▶ Witnessing of activities is required. Some items may be reviewed through record verification depending on work being performed at the time.

# Step 3

## The On-Site Assessment

- ▶ Quality Management Review
  - ▶ Organizational Structure
  - ▶ Confidentiality
  - ▶ Impartiality
  - ▶ Internal Audits
  - ▶ Corrective Action Process
  - ▶ Management Review
  - ▶ Improvements
  - ▶ Record and Doc and Data
  - ▶ Supplier Review
  - ▶ Contracting

This includes discussions with the quality manager and relevant staff

How do you manage these processes?

Where are the requirements documented (procedure, work instructions) ?

How are they recorded (records, evidence) ?

# Step 3

## The On-Site Assessment

### ► Technical Review

- Personnel Competency
- Equipment
- Environmental Conditions
- Methods, SOPS, Validation, Verification
- Proficiency Testing Data
- Records, Logs
- Reference Material, Standards
- Traceability
- Measurement Uncertainty
- Reporting

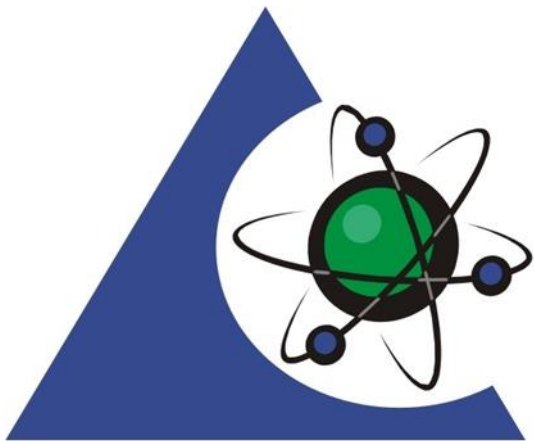
This includes discussion with technical personnel responsible for performing test, calibrations, inspections, etc.

Witnessing of tests, partial or in full (sample prep, logs, data)

Review of proficiency testing performance records

Verification or validation of method records

## Step 3 The On-site Assessment



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- ▶ During the time of the assessment, the lead assessor should brief the quality manager of the findings or potential findings detected
- ▶ A closing meeting will be held at the end of the assessment with all pertinent staff to review and accept the assessment reports: LF-8 Non-Conformance Report, LF-9-Final Assessment Report and finalize the scope
- ▶ Assessors will inform you of the right to dispute any findings as indicated in PJLA SOP-10 Dispute and Appeal Procedure available on PJLA's website

# Step 3

## The On-Site Assessment

- ▶ Non-conformances shall be clear and include the finding, objective evidence, and standard citation.

<b>NUMBER &amp; TYPE</b> (Major, Minor or Observation)	<b>FINDING &amp; OBJECTIVE EVIDENCE</b>	<b>REQUIREMENT</b>
<b>NCR 1-Minor</b>	<p><b>Finding</b> - Not all equipment observed was labeled to identify its calibration status.</p> <p><b>Objective Evidence</b> - Thermometers used for monitoring environmental temperatures were not labeled with the calibration due date.</p>	<p><b>ISO/IEC 17025:2017 6.4.9</b> - All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.</p>

a Identify assessment Number and NCR# in the objective evidence discussion.

# Step 4

## Assessment Closure



At the close of the meeting and within the final report LF-9, the assessor will provide the timeframe for when corrective action is due.



Corrective Action is due to the assessor by email and sent to [CA@pjlabs.com](mailto:CA@pjlabs.com) within 60 days from the last day of the assessment.



If requested, a recommendation letter can be issued from our office after the conclusion of the assessment.

(Assists customers inform pertinent customers of their status in the process )



# Step 4

## Assessment Closure

- ▶ Corrective Action shall be submitted on your corrective action form:
  - ▶ Include objective evidence of the correction
  - ▶ Ensure your form includes a cause analysis
  - ▶ Ensure files are labeled clearly for the assessor by NCR # preferably
    - ▶ Avoids a delay in the review process or potentially a rejection
- ▶ Corrective Action should be thought through.
- ▶ What was the cause of this? It could be multiple things: it wasn't written down, no training, broken process
- ▶ Corrective Action isn't just for us, it's to make your process better!



# Step 4

## Assessment Closure

- ▶ Upon receipt of corrective action, the assessor will review them to ensure:
  - ▶ The corrective action effectively closes the finding
  - ▶ The objective evidence provided supports the closure
  - ▶ Decide to approve or reject the submission
    - ▶ Rejections of corrective action responses is not a failure. Sometimes a little more work needs to be done.
  - ▶ Corrective Action should be reviewed no later than 7 days from the submission by the assessor
  - ▶ Once approved, the assessor will notify the client of the approval and provide final assessment material to PJLA and close the assessment

# Step 5

## The Final Accreditation Process



- ▶ Once all assessment material is submitted it is reviewed by PJLA staff and prepped to go to the Final Accreditation Decision Committee “PJLA Executive Committee” to decide to grant or deny accreditation.
  - ▶ Independent from the assessor performing the assessment
  - ▶ No conflict of interest with the assessment
  - ▶ Qualified for the standard assessed and the field of accreditation
- ▶ If the material is rejected, the lead assessor will be notified for correction and possibly the client.
  - ▶ Rejections are re-reviewed resulting in the granting of accreditation.

# Step 5

## The Final Accreditation Process

Upon approval by the Executive Committee, PJLA staff will be notified that a certificate can be generated.

Certificates are based on the final scope issued in the final assessment package.

A draft is created, reviewed by PJLA program management, and sent to the client for review.

Clients should review it thoroughly, approve and return the acknowledgement in order to receive a final copy. Also, all outstanding balances shall be paid. An e-copy and hard copy certificate is provided to each client and posted on the PJLA website.

# Step 5

## The Final Accreditation Process

### Example Certificate



**PERRY JOHNSON LABORATORY  
ACCREDITATION, INC.**

### Certificate of Accreditation

*Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:*

**Best Testing Lab**  
5125 5th Avenue, Sunny, FL 33333

*(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:*

**ISO/IEC 17025:2017**

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO/IEC/JAF Consensus dated April 2017):

**Chemical, Microbiological and Non-Destructive Testing**  
*(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 consents with the Accreditation body's duty to observe and comply with the said rules.


For PJA:

Initial Accreditation Date	Issue Date	Expiration Date
January 25, 2018	January 25, 2018	May 31, 2020

Review Date	Accreditation No.:	Compliance No.:
March 23, 2020	12045	1/8-00

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 PJA website: [www.pjalabs.com](http://www.pjalabs.com)

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### Certificate of Accreditation: Supplement

**Best Testing Lab**  
5125 5th Avenue, Sunny, FL 33333  
Contact Name: Jim Smith Phone: 555-555-5555

*Accreditation is granted to the facility to perform the following testing:*

FIELD OF TEST	TYPICAL MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE, WHERE APPROPRIATE, AND DETECTION LIMIT
Chemical	Cannabis Plant Material Marijuana Infused Products Cannabis Extracts Hemp Plant Material and Extracts	<b>Cannabinoids:</b> CBG CBD THCV CBN Total THC -THC -THCa CBC Delta 8-THC Delta 9-THC	Best Labs SOP SOP/XXX (HPLC)	D.L. = 0.01 % w/w
		<b>Heavy Metals Screening:</b> Cadmium Lead Arsenic Mercury	Best Labs SOP SOP/XXX (ICP-MS)	D.L. = 20 ppb D.L. = 50 ppb D.L. = 20 ppb D.L. = 10 ppb
	Marijuana Infused Products Cannabis Extracts Hemp Plant Extracts	<b>Residual Solvents:</b> 1,2-Dichloroethane 1,1-Dichloroethene Acetone Acetonitrile Benzene Butanes (iso-butane) Butanes (n-butane) Chloroform Ethanol Ethyl Acetate Ethyl Ether Ethylbenzene Ethylene Glycol Ethylene Oxide Heptane Hexanes (n-hexane) Isopropyl alcohol	Best Labs SOP SOP/XXX GC/MS	D.L. = 0.2 ppm D.L. = 0.3 ppm D.L. = 75 ppm D.L. = 6 ppm D.L. = 0.1 ppm D.L. = 500 ppm D.L. = 500 ppm D.L. = 0.2 ppm D.L. = 500 ppm D.L. = 40 ppm D.L. = 50 ppm D.L. = 5 ppm D.L. = 40 ppm D.L. = 0.5 ppm D.L. = 500 ppm D.L. = 25 ppm D.L. = 50 ppm

Issue: 01/2018      This supplement is in conjunction with certificate #L18-47-R6      Page 3 of 7

# Step 5

## The Final Accreditation Process



- ▶ Certificates include an initial accreditation date, issue and expiration date, certificate number, and accreditation number.
  - ▶ **Initial Accreditation Date** - the first date a client became accredited
  - ▶ **Issue Date** - the executive committee approval date
  - ▶ **Expiration Date** - the date that the certificate will expire; expiration dates follow with our 2-year accreditation cycle; they are issued based on the client's month to schedule + 120 days (i.e. client goes every February the expiration date will be June 30). This allows for consistent monthly scheduling and no lapse in accreditation when renewal comes along.
  - ▶ **Certificate Number** - number issued each time a certificate is issued, revised, etc.
  - ▶ **Accreditation Number** - a permanent number issued to the client

# What Happens After You Become Accredited?

- ▶ 12 months from the initial accreditation date, a surveillance visit will be required
  - ▶ A partial review of the scope of accreditation and maintenance checks
    - ▶ Follow up on corrective actions from the last assessment
    - ▶ Internal Audits
    - ▶ Management Reviews
    - ▶ Complaints
    - ▶ Proficiency Testing
  - ▶ Similar corrective action process; no certificate issued
  - ▶ On-site at the first accreditation cycle; documentation review only after renewal if the customer qualifies

# What Happens After You Become Accredited?

- ▶ 12 months after the surveillance, a reassessment will be required to renew the certificate
  - ▶ Needs to be completed on time to avoid a lapse in accreditation
  - ▶ Full system review of the standard assessed and all items on the scope of accreditation
  - ▶ Same corrective action process
  - ▶ Same executive committee review process
  - ▶ New certificate issued for two more years



# What if you want to expand your scope?

- ▶ Scope Expansions can occur at anytime
  - ▶ Contact your accreditation program assistant/scheduler to complete scope expansion forms; we only need to know what you are adding
  - ▶ Routine assessments -Surveillance or Reassessments
  - ▶ Alone
  - ▶ Corrective Action Process
  - ▶ Executive Committee Process
  - ▶ Certificate Revision Process
- ▶ Some scope expansions will not require an on-site when the technique has not changed; a documentation review may be requested only

# What are the obligations to maintain accreditation?

- ▶ All clients are issued an agreement for services and should follow those terms and PJLA Accreditation Procedure Requirements SOP-1
  - ▶ Schedule On Time
  - ▶ Meet Financial Obligations
  - ▶ Avoid any activity that may put PJLA's reputation in jeopardy (i.e. unethical practices, misleading marketing, improper use of accreditation)
  - ▶ Allow PJLA assessors the ability to witness all activities over time
  - ▶ Answer complaints in a timely manner
  - ▶ Always follow the ISO standard
  - ▶ Notify us of any major changes (ownership, address, staff/contact information, equipment changes)

# What happens if my accreditation gets suspended or withdrawn?

- ▶ Suspension are due to organizations failing to meet contractual obligations (as stated in previous slide)
  - ▶ Typically, Warning Letters are sent specifying a date or timeframe to correct the issue
  - ▶ No response results in a suspension with a timeframe to make a correction in order to avoid a withdrawal of accreditation
  - ▶ During Suspension Stage- no claim of accreditation, accredited reports, moved to the suspended list on PJLA Website

Withdrawal of Accreditation - The period to resolve an issue has passed ;organizations must re-apply and start the process over

Voluntary Withdrawal - Client withdrawals accreditation - noted separately on PJLA website

**SOP-11-Suspension, Withdrawal and Reduction of Scope Located on the PJLA Website**

# How can you market your accreditation using the PJLA Accreditation Symbol or ILAC MRA Mark?

- ▶ Upon receipt of your final certificate, you will receive your PJLA accreditation symbol. This is not the same as our logo. This must be utilized in accordance with SOP-3 Use of Accreditation Claims and Language Procedure (Note-Mandatory Document for all Clients to be Aware of)
- ▶ Clients may also use the ILAC MRA Mark once appropriate forms are completed, and approval is obtained



- ▶ If you can't use the PJLA logo on test, calibration or other reports and it is intended to be an accredited report you shall at least reference PJLA, Testing, Accreditation Number

# What happens if I change location, ownership, or company name?

- ▶ Any changes to ownership or location should be sent to your accreditation program assistant
- ▶ Location change will require a site review within 60 days of the move to review environmental conditions, equipment capability
- ▶ Ownership change will require proof of ownership change and a statement of how this change will impact any activities related to the accreditation; effective date
- ▶ Name change will require proof of name change; effective date

# Other than the standard, what other documents will I be assessed to?

- ▶ PJLA is required by ILAC to have policies on proficiency testing criteria, traceability, measurement uncertainty and accreditation symbol usage
- ▶ PL-1 Proficiency Testing
- ▶ PL-2 Traceability
- ▶ PL-3 Measurement Uncertainty
- ▶ PL-4 Policy on Calibration Scopes
- ▶ WI-8 Testing Scopes and Flexible Scopes
- ▶ WI-9 Inspection Body Scopes
- ▶ SOP-1 Accreditation Procedure
- ▶ SOP-3 Use of Accreditation Claims and Language Procedure
  - ▶ These documents are listed on PJLA's website and all clients will be notified of changes
  - ▶ Add these to your external list of documents
  - ▶ Monitor PJLA website for changes
  - ▶ Any shall is a requirement and a NC can be written

# What if I can't find a third-party PT Provider?

- ▶ PL-1 PJLA PT Policy provides alternatives
  - ▶ Inter Lab Comparisons (find another lab to compare data) -no PJLA approval
  - ▶ Intra Lab Comparisons -compare results internally
    - ▶ Must seek PJLA approval on SOP for doing this and provide a reasoning
  - ▶ Repeatability Studies
    - ▶ Must seek PJLA approval and provide reasoning
- ▶ Proficiency Testing shall be a planned activity and documented on an 4 year plan
  - ▶ Plans only need to be approved for Intra Lab and Repeat Studies
  - ▶ PT shall be conducted annually for at least one field of accreditation and the remaining over 4 years
  - ▶ PJLA has a list of PT providers on our website as a source. This list is not an exhaustive list and more providers may be available.

# What if the calibrator of my instruments is not accredited how do I meet PL-2 PJLA Traceability Requirements?

- ▶ If your calibrator is not ISO/IEC 17025 accredited then evidence of Traceability must be on file
- ▶ This information shall be completed on the [LF-123](#) Traceability Form for your assessor to approve. This is also available on the PJLA website.
- ▶ This shall be updated frequently to ensure your supplier continues to meet the requirements



# What if I don't agree with an assessment finding or a decision made by PJLA?

- ▶ All clients have the right to dispute and appeal a decision made regarding nonconformities, suspension, withdrawal activities, etc.
- ▶ PJLA's Dispute and Appeal Procedure SOP-10 is located on the website
- ▶ All disputes are reviewed for legitimacy and sent to an Ad Hoc committee for a decision
- ▶ NCR findings should be sent within 10 days of the last day of the assessment

# Does PJLA have a complaint process ?

- ▶ If organizations have a concern, please share this with us right away. Accreditation Program Assistants will contact you about a week after the assessment. Surveys are issued. We want to know how we are doing!
- ▶ We also want to know about our accredited organizations issues found so we can act.
- ▶ A formal complaint can be lodged at any time, which requires us to take corrective action or the organization to take action.
- ▶ PJLA Complaint Procedure SOP-9 is listed on the PJLA website.

## What type of training does PJLA offer?

- ▶ Free Monthly Webinars
- ▶ Public Courses and Client Facility Course
  - ▶ Internal Auditor
  - ▶ Measurement Uncertainty
  - ▶ Free Measurement Uncertainty Calculators

# How do I take advantage of PJLA client Spotlights, Press release, Social Media

Client spotlights are issued in our quarterly newsletter

Press Releases announcing a new accredited company

Social Media  
Facebook or LinkedIn pages include shared articles, spotlights, and press releases

We are always looking for more companies to contribute!

No charge to the client!



# Time for Questions and Answers



# Contact Information

**Perry Johnson Laboratory  
Accreditation, Inc.**

755 West Big Beaver Road, Suite 1325

Troy, MI 48084

Tel: (248)-519-2603

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

Email: [tszerszen@pjlabs.com](mailto:tszerszen@pjlabs.com)



# PJLA

Join us for our Next Webinar  
Wednesday, September 29th - 1:00pm EST

A Look at ISO/IEC 17025:2017 - Section 6.6:  
Externally Provided Products and Services



**PJLA**

Thank You!