
DoD EDQW Conference-2015

PJLA Update

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Before We Start ... DoD ELAP... Labs



About PJLA

- Private accreditation body that accredits testing and calibration laboratories, reference material producers, and field sampling organizations to International and National Standards (i.e. ISO/IEC 17025, ISO Guide 34 DoD ELAP, TNI NEFAP)
- Operating since 1999
- Located in Troy, MI
- Over 700 Accredited Organizations/ 28 Accredited DoD ELAP Organization/ 3 in Application stage
- Also offer training sessions (free webinars, public training and on-site training)
- Obtain international approvals to accredit organizations by (ILAC and APLAC)



PJLA Transfer Process-SOP-13

- PJLA recognizes the need for organizations to transfer from time to time (i.e. price, service, assessor fit, AB qualification)
- Keeping in mind the intention of the APLAC and ILAC MRA initiatives.
- Per our SOP-13 Transfer Policy.....
 - At no such time should PJLA and its staff offer discounts for transfer services to obtain business from another ILAC or APLAC MRA Partner that would not be offered to all other accredited (CABs)
 - PJLA does not disparage the service of another MRA partner's accreditation program or services offered during a discussion with another (CAB) seeking to transfer.
 - (CABs) only willing and open to transferring to PJLA should be acted upon.
 - At no such time, should PJLA quote (CABs) for services when the (CAB) has no interest in leaving their current accreditation body.



PJLA Transfer Process-To PJLA

- Laboratories must hold an active accreditation with another ILAC MRA Signatory to be considered
- The accreditation should be in good standing
 - Previous findings must be closed
 - Proficiency Tests and LOD/LOQS must be up to date
 - Must be up to date on maintenance activities (internal audits, management reviews from the last 12 months) and also on routine visits with current AB

PJLA Transfer Process-To PJLA

Cont'd

- Initial Transfer via Documentation Review
Consisting of:
 - Quality Manual/SOPS
 - PT(s)
 - LOD/LOQs
 - Last Assessment Reports (at least full system assessment)
 - Example Test Reports

PJLA Transfer Process-To PJLA

Cont'd

- If no major issues with the review then it goes to our accreditation decision committee for approval
 - Certificates are issued based on former AB expiration; extensions may be given from PJLA only up to 90 days in the case of assessor availability issues
 - Assessment schedules are recognized based on former AB scheme if possible

PJLA Transfer Process-To PJLA

Cont'd

- If the transfer process is not successful then we inform the lab and let them know the next steps to transfer to PJLA
 - i.e. on-site visit may be required first
 - It could be a 1 day visit to investigate a previous finding or a longer visit based on former assessment schedule
 - If we cannot transfer based on loss of accreditation or lack of closure of previous report then an initial assessment will be required

PJLA Transfer Process- Away from PJLA



- PJLA will work with organizations wishing to transfer to another Accrediting Organization
 - Must inform us of the effective date –Do not ignore requirements in your contract!!
 - Ensure this date will give you enough time to transfer and receive a certificate on the other AB website and Denix
 - We must agree to this date
 - If the date puts PJLA in a position that we are keeping an accreditation active for longer than ISO 17011 allows then we may not be able to honor the date or provide you a date that is acceptable



PJLA Transfer Process- Away from PJLA



- Maintaining Accreditation/Contractual Obligations
 - Complete assessments surveillance or reassessments every 12 months
 - Meet financial obligations
 - Meet assessment criteria obligations (i.e. respond to corrective action on-time)
- Once an agreed upon inactive/withdrawal date is issued an official letter will be issued from our office and members of the EDQW will be notified
- Again if ignored, our normal suspension and withdrawal process will be enforced

DoD EDQW Presentation – “Off-site Scope Expansions”

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April 2015



Scope Expansions - General

- Scope Expansions (testing):
 - Location/Site
 - Field of Testing: Chemical, Biological, etc.
 - Materials/Matrix Tested
 - Properties
 - Technology: GC/TCD, GC/MS, ICP etc.
 - Method (incl. prep method)
 - Analytes
- “On Site” vs “Off Site” has a lot to do with these ... and requirements of the program



Scope Expansions - General

- Most scope expansions ... on-site coordinated with a planned/scheduled assessment – a surveillance or re-assessment
- Most (all?) require some additional time - if not to the surveillance - to the re-accreditation to allow time for the additional witnessing/verification needed (which then affects subsequent surveillance time)
- These would be “On Site”

Scope Expansions – “Off Site”

- Possible with a change in Material/Matrix
 - Ex: Drinking Water, Ground Water; Aluminum, Mild Steel, etc. – but the properties, technology, method, analytes are essentially the same or very similar
- Mostly – expanding/adding a method, analytes
- These could be candidates for “Off Site” review – still require some judgment/consideration, history with the laboratory

Scope Expansions – “Off Site”

- “Off Site” scope expansion handled like an “off site” surveillance - reduced paperwork, assessor time, reporting per PJLA procedures
- Material submitted by the laboratory is sent PJLA HQ which uploads them to the PJLA Sharepoint site for the assessor to review on the appointed/scheduled day
- The laboratory personnel should be available to answer questions and provide additional information as needed.
- Reviewed and approved by PJLA Executive Committee

Scope Expansions – “Off Site”

- Items to be submitted:
 - Evidence of method
 - Procedure/work instructions incl. preps – ref. in QAM and/or evidence as controlled document(s)
 - Equipment description/specifications – equipment list
 - Traceability evidence – calibrations, reference materials, second source/second lot, etc
 - Evidence of reagents, materials as required
 - LOD/LOQ, DLs, range information, calculations
 - Uncertainties (as required/appropriate) – LCS and/or budget based
 - Proficiency Testing evidence – appropriate to scope
 - IDOC/CDOCs with evidence, training/qualification/authorization
 - Report(s)
 - ???

DoD ELAP Non-conformances 2014

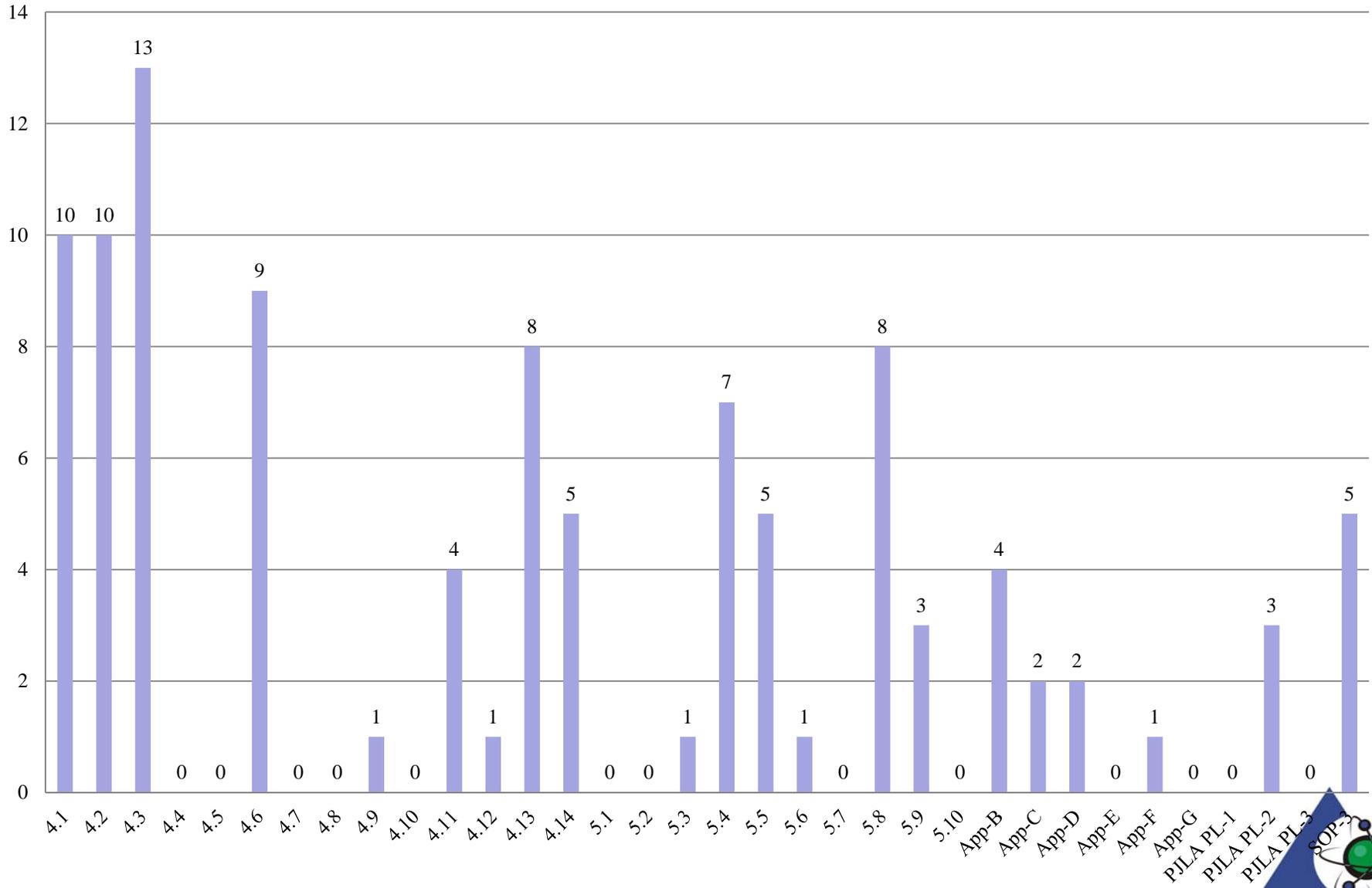
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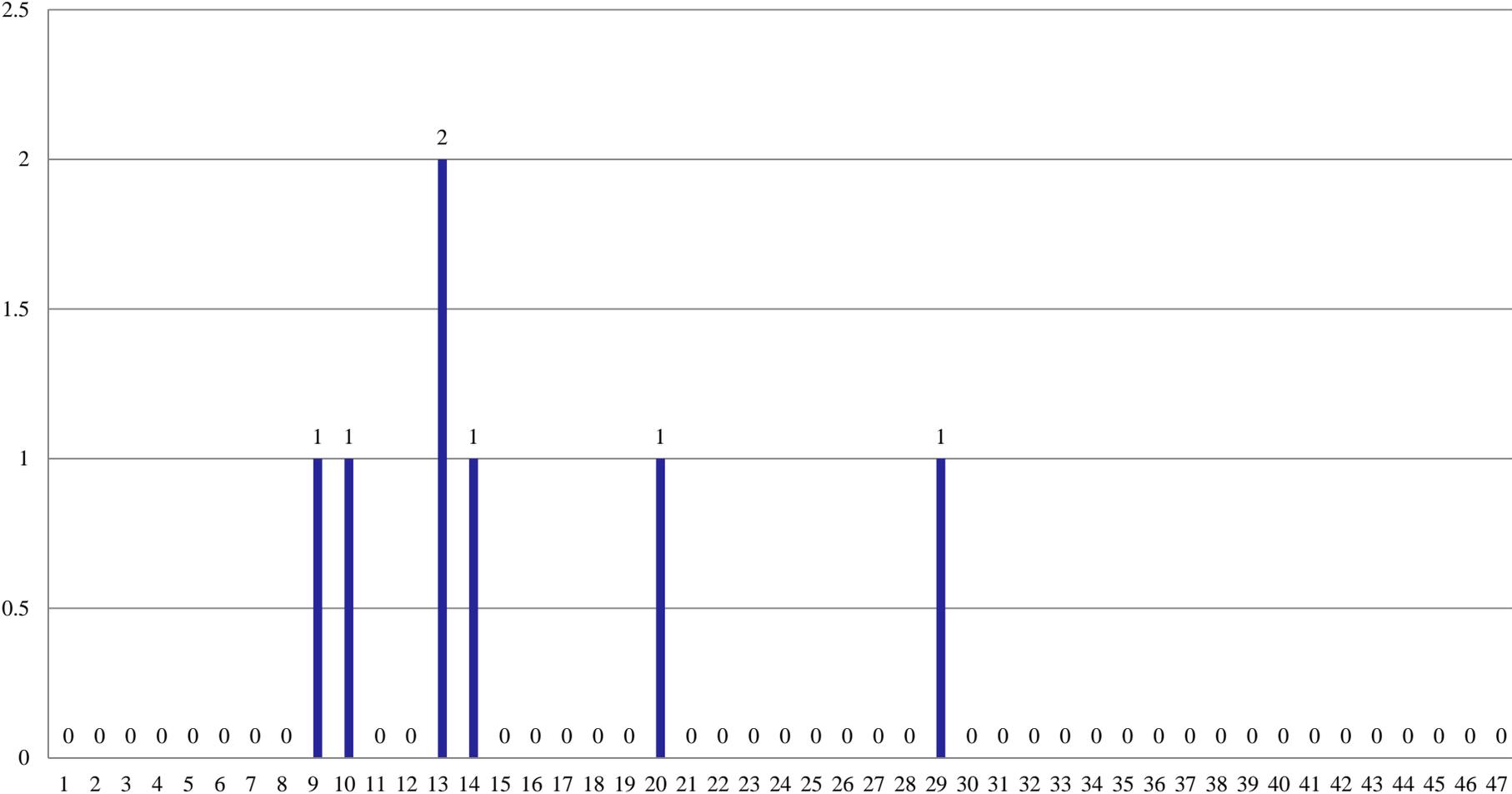
April 2015



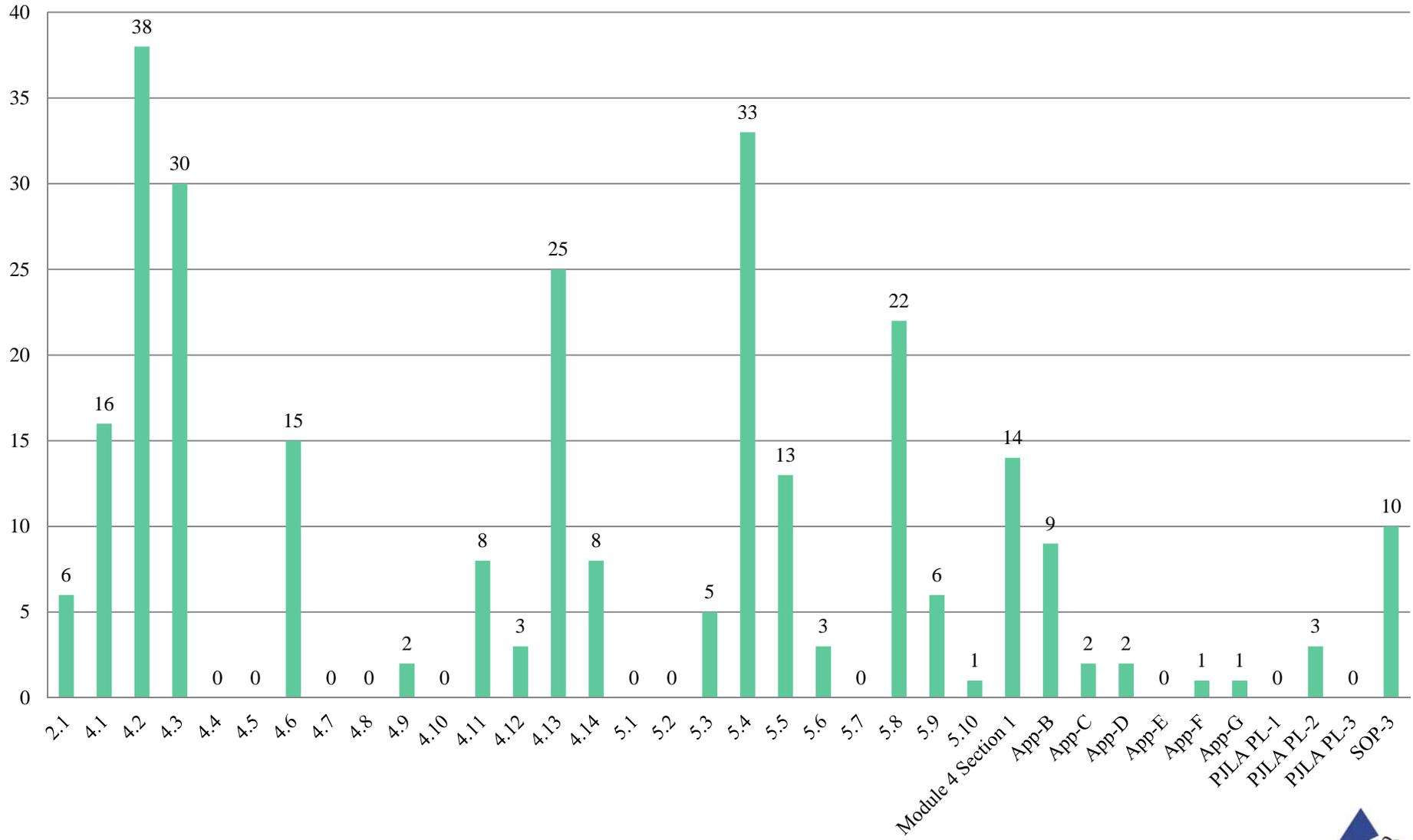
DoD QSM version 4.2 NCRs 2014
Sections 4.1-5.10, App B, C, D ,E, F , PJLA PL 1, 2, & 3, & SOP-3



DoD QSM version 4.2 NCRs 2014 Grayboxes 1-47



DoD QSM version 5.0 NCRs 2014



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Time for ...

