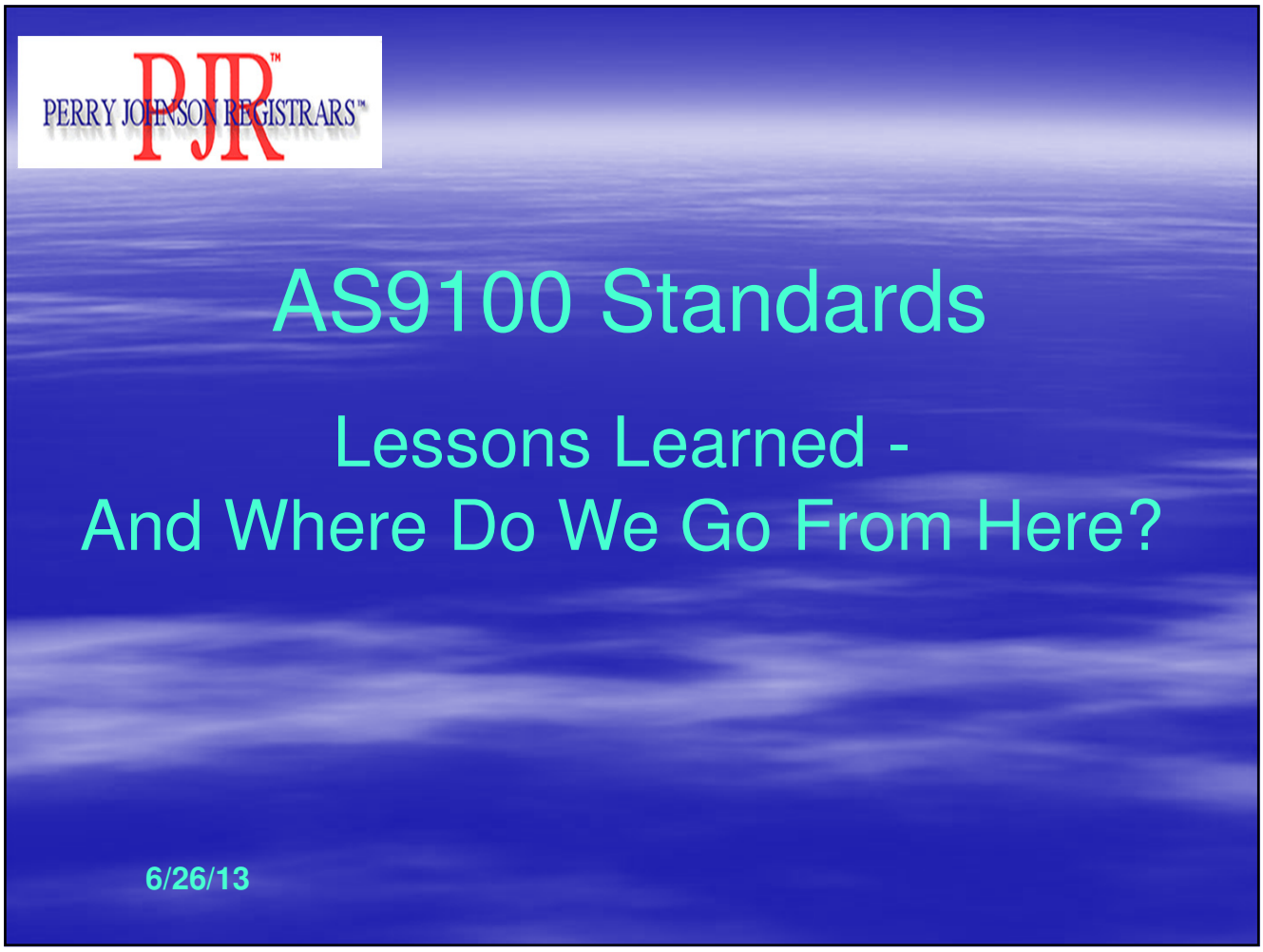
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AS9100 Standards
Lessons Learned -
And Where Do We Go From Here?
6/26/13

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# Today's Subject Matter

- What we've learned *about* the 9100 transition(s)
- What we've learned *because of* the 9100 transition(s)
- What we've learned *independent of* the 9100 transition(s)
- What is still left to learn…

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# About…

- First and foremost we have learned that…it just was not as difficult as it was made to appear.
  - We have all gotten through it
  - We are growing as an industry

*"A challenge only becomes an obstacle when you bow to it."*

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## *About…*

- All those appendices…*A, B, C, D, E (not to mention F and G)!!*
- Appendix A, or the OER, though not always visible to the organization, has brought with it much conversation and concern within the auditing community.
- Considerable strides have been made in this area.

# About…Appendix A

- A better understanding in regard to the level of detail required *(PJR Guidance Tools)*
  - Repetitious requirements have been identified and addressed.
  - Unacceptable and confusing responses have been identified and clarified.
    - "NA" does NOT mean "Excluded"
    - "See PEAR" NOT acceptable as evidence without actual OE for *all specified requirements* noted In PEAR

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# About…Appendix C

We have probably learned more about the use and utility of Appendix C (The PEAR), than any other tool of the 9100 series

- These PEARs MUST correlate with the organization's identified Product Realization processes.
- NCRs written against conformity do not necessarily have a correlation to process effectiveness.
  - The score of The PEAR is based upon *performance.*

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# About…Appendix D

- The Devil is in the details.
  - Process names must match the names of the organization's identified processes.
  - NCRs must have major/minor designation.
  - Any section not audited (for whatever reason) should be left blank.

*All of these, though seemingly minor, can cause significant problems if not noted correctly.*

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# About…9100 Series

- 9100 "C" section 7.1.1 speaks to the management of Product Realization projects only (not to be confused with "maintenance" or "improvement" projects).
- 9100 "C" section 7.1.2 does NOT require a documented procedure…though it does call for a defined process. Also, this is as it relates, again, to Product Realization and not the entire QMS.

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# About…9100 Series

- 9100 "C" section 7.1.3 calls for a CM process "as appropriate" to the product. This is determined by the organization.
- 9100 "C" section 7.4.2 uses similar terminology, "where appropriate" in regard to flow down requirements. It is NOT a requirement to flow down 7.4.2 a-i inclusively. Customer requirements should dictate flow downs.


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## About…9100 Series

- 9100 “C” section 7.5.1.1 is not just for FAI, nor is it exclusive to AS9102. *If* the customer requires FA to AS9102, then it is a requirement. If no customer requirement exists, the organization is still bound by AS9100 to perform “production process verification” unless they claim a valid exclusion to 7.5.1.1.

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# About…9100 Series

- The Purchasing process MUST be audited at least annually. 9104/1 section 8.2.2n has made this a hard and fast requirement.
- Certification structures now are broken into five different classifications:
  - Single Site
  - Multiple Site
  - Campus
  - Several Sites
  - Complex

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# *Because of… Appendix B*

We have learned some lessons that impact the entire audit process *because of* the transition requirements of AS9100 - Some good and some…not so much.

- Knowledge and implementation of RCCA is still lacking.
  - There are too many organizations performing invalid RCCAs, which does no good for anyone.
    - Tools are available everywhere – use them.
    - PJR has some good material on RCCA.

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# *Because of… Appendix C*

- The PEAR has brought about many changes and opened a few eyes but, in particular, it has forced the industry (auditors, organizations, CBs and ABs) to take a closer look at process audits. Though it has been accepted and expected that audits have been process based for some time, that is simply not the case. The transition has really moved the chains in this regard.

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## *Independent of…*

The lessons learned classified as "independent of" AS9100 are really things that have been witnessed within the past 18 months or so that, though not AS specific, may have been noted due to the increased scrutiny that accompanied the transition.

Two areas, in particular, have been identified.

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## *Independent of…*

- Section 7.6 of the standard (AS and/or ISO) speaks to the Calibration requirements for organizations. It is NOT a requirement for the calibration suppliers of any organization to be certified to ISO17025, AS9100 or ISO9001. The organization must, though, ensure that any calibration (by supplier or in-house) meets all applicable requirements of 7.6.

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## *Independent of…*

- Section 8.2.2 (Internal Audits) is another area that has been the victim of many misunderstandings in the past. The transition to AS9100 C brought to light some of these misunderstandings.
  - It is NOT a requirement for internal auditors to be trained and/or certified in AS9100. Internal auditors need to be competent given the requirements of clause 6.2.1. The organization establishes the competencies…the auditor verifies them.

# Where To From Here?

- Onward and upward – all with the help of the AQMS.
  - The renewed focus on the process approach is helping to create a more solid business model.
    - Pushes toward a data driven environment
    - Affords the opportunity to better analyze trends and current business conditions.
- And remember the first lesson noted in this presentation because…

# Where To From Here?

- …there is currently a draft version of AS9101 “E” going in front of a panel for review.
- There will be more lessons learned going forward and I would expect them to be as beneficial as the one’s we have just acknowledged.