Adding DOECAP-AP Accreditation to a DoD-ELAP Accredited Laboratory

Presented by:

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PJLA Technical Program Manager

Who Are We?

Perry Johnson Laboratory Accreditation is cross-sector accreditation body recognized in the areas of testing, calibration and medical laboratories, inspection bodies, reference material producers and proficiency test providers

ISO/IEC 17025

ISO/IEC 17020

ISO 15189

ISO/IEC 17043

ISO 17034

Governmental Schemes

Upcoming Webinar

Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2023

Friday, Jan 19,2024 1:00 PM - 2:00 PM EST

https://attendee.gotowebinar.com/register/1108985455931701340

2024 Educational Series

- Free Webinars of QA topics including:
  - Corrective Action
  - Risk Based Thinking
  - Measurement Uncertainty for Testing Labs
  - Measurement Uncertainty for Calibration Labs
  - Intro to Internal Auditing
  - And More…

https://www.pjlabs.com/training

NOTE

Please hold all questions and comments until end of presentation or add them to the chat.

Feel free to email msica@pjlabs.com following the presentation.

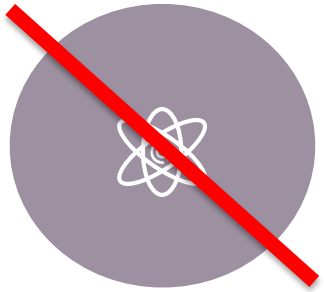
Disclaimer

- This webinar is intended to be informational
- While every attempt is made to provide reliable and accurate information, it shall be noted that this webinar is intended to provide key concepts
- This webinar is not a substitute for the standard
- Due to time constraints details for all requirements cannot be discussed, refer to the standard
- This webinar will not provide specific approaches to achieve compliance with any specific requirement

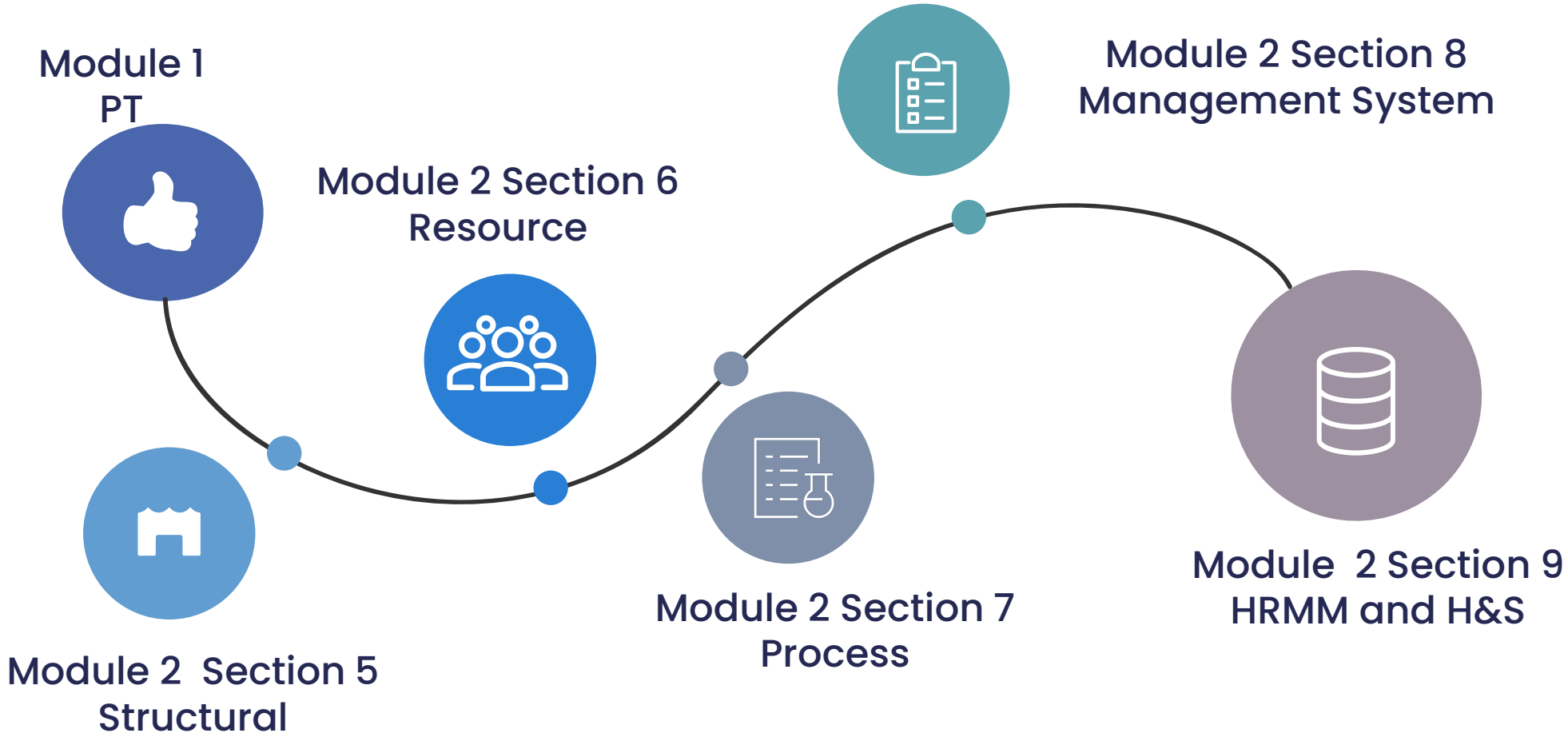
Objective

- Identify DOE only requirements of QSM 6

  Note: Some of the M2 requirements parallel current TNI requirements



Sources of DOE requirements



Considerations for Adding DOECAP-AP

No Available ISO/IEC 17043 Accredited PT Sample or PT Provider

- QSM requires: Lab to shall submit in writing to AB
  - List of items on its scope of accreditation for which no suitable commercial PT is available
- **DOE only addition**
  - Laboratory shall also submit this information in writing to all impacted DOE Customers

Considerations for Adding DOECAP-AP

DOE only additions

- Technical manager duties and responsibilities
- Quality manager duties and responsibilities

- Compare to 2016 TNI EL V1 M2 Clause 4 requirements

Structural

Considerations for Adding DOECAP-AP

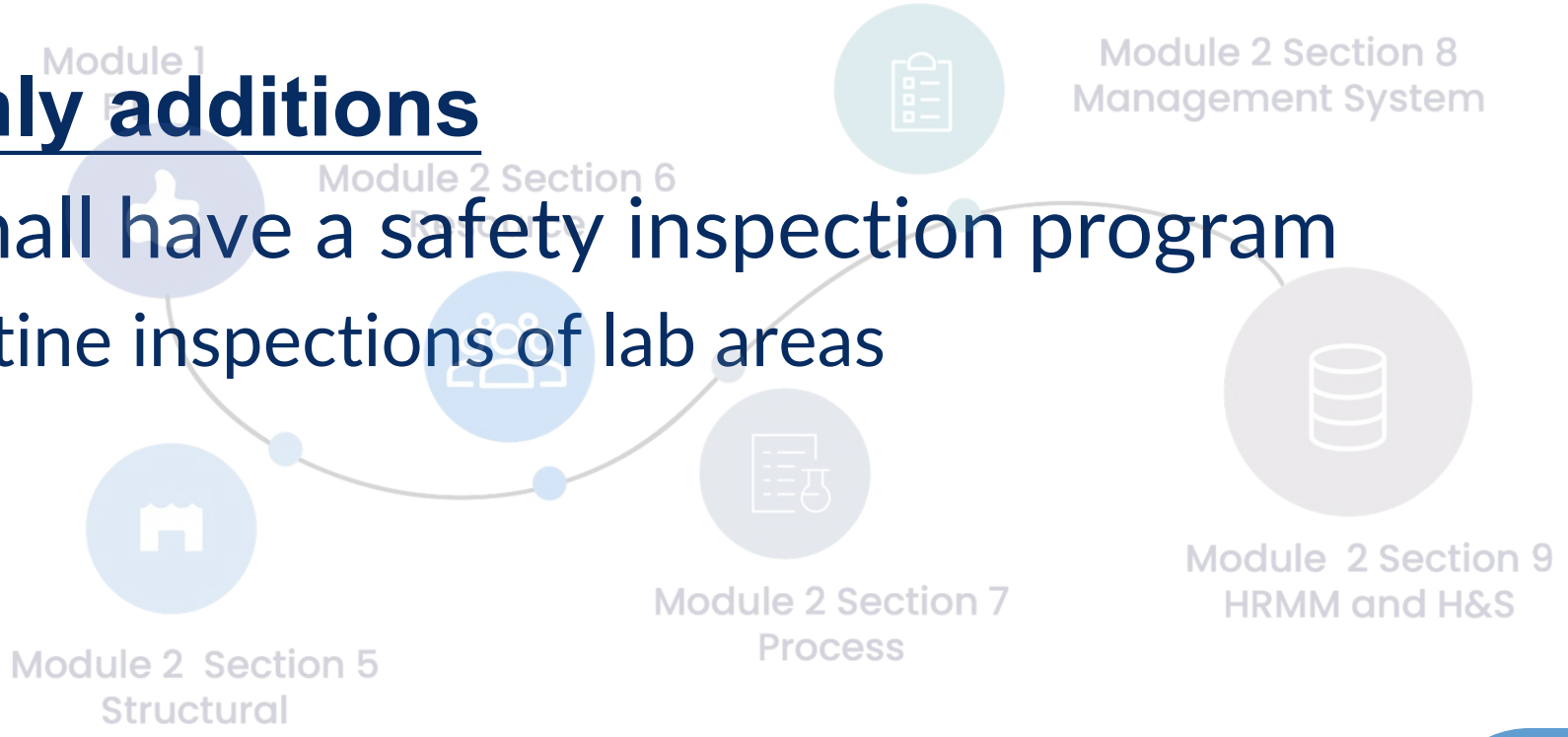
DOE only additions

- Documentation developed for educational and experience qualifications
  - Technical Manager
- Quality Manager
  - Training in QA/QC Procedures
  - QMS
  - Knowledge of methods (which data review is performed)

Considerations for Adding DOECAP-AP

DOE only additions

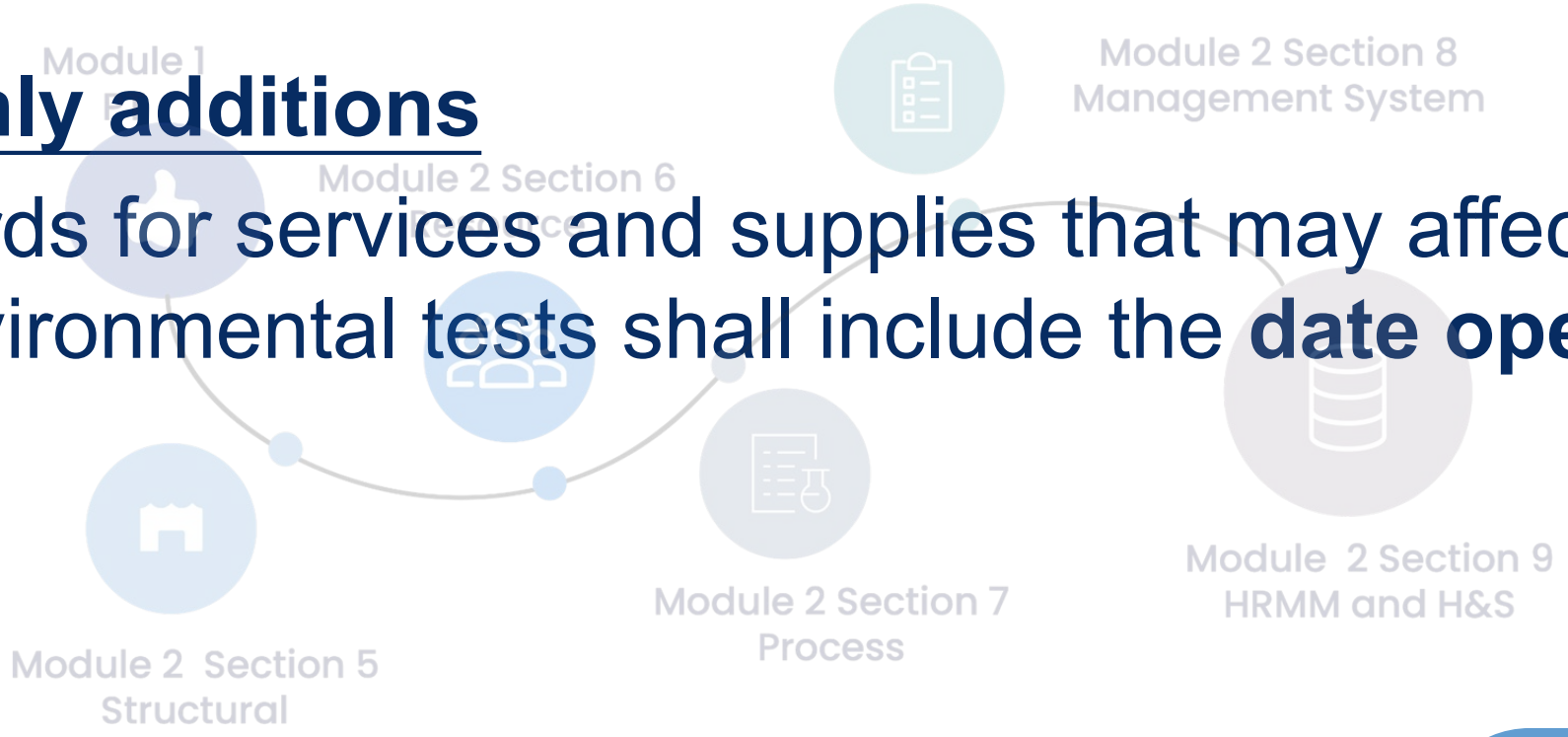
- Lab shall have a safety inspection program
  - Routine inspections of lab areas



Considerations for Adding DOECAP-AP

DOE only additions

- Records for services and supplies that may affect quality of environmental tests shall include the **date opened**.



Considerations for Adding DOECAP-AP

DOE only additions

- Instructions shall include or reference the following topics where applicable:
  - Cleaning labware
  - Approaches to address background corrections

Considerations for Adding DOECAP-AP

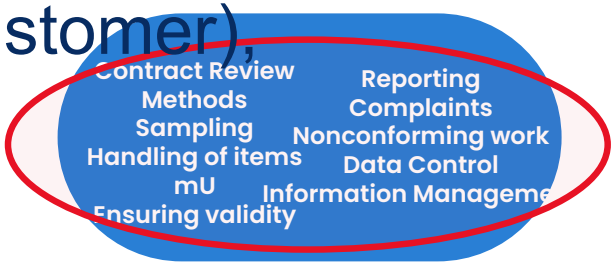
DOE only additions

- Laboratory shall track authorized departures from procedures and periodically evaluate if formal procedure revision is appropriate

Considerations for Adding DOECAP-AP

DOE only additions

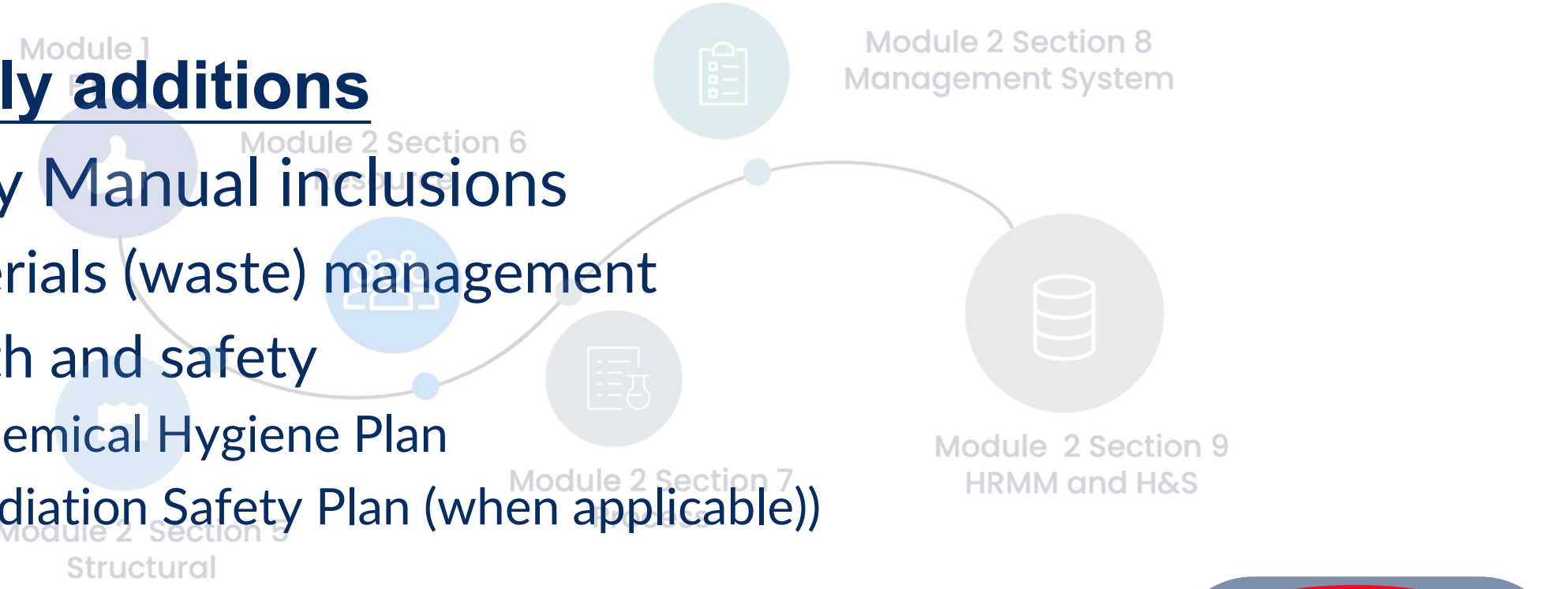
- Requirement related to records disposition of samples, their digestates, leachates, extracts, or other sample prep products
- Record
  - Date of disposal,
  - Nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to customer),
  - Name of the individual who performed task.

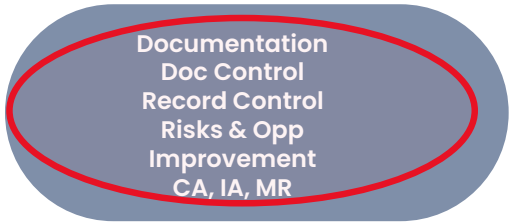


Considerations for Adding DOECAP-AP

DOE only additions

- Quality Manual inclusions
  - materials (waste) management
  - health and safety
    - Chemical Hygiene Plan
    - Radiation Safety Plan (when applicable))

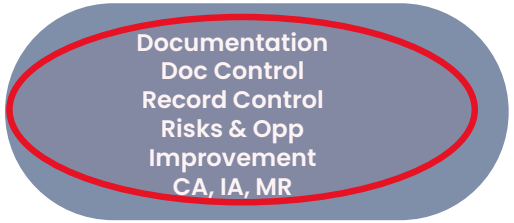




Considerations for Adding DOECAP-AP

DOE only additions

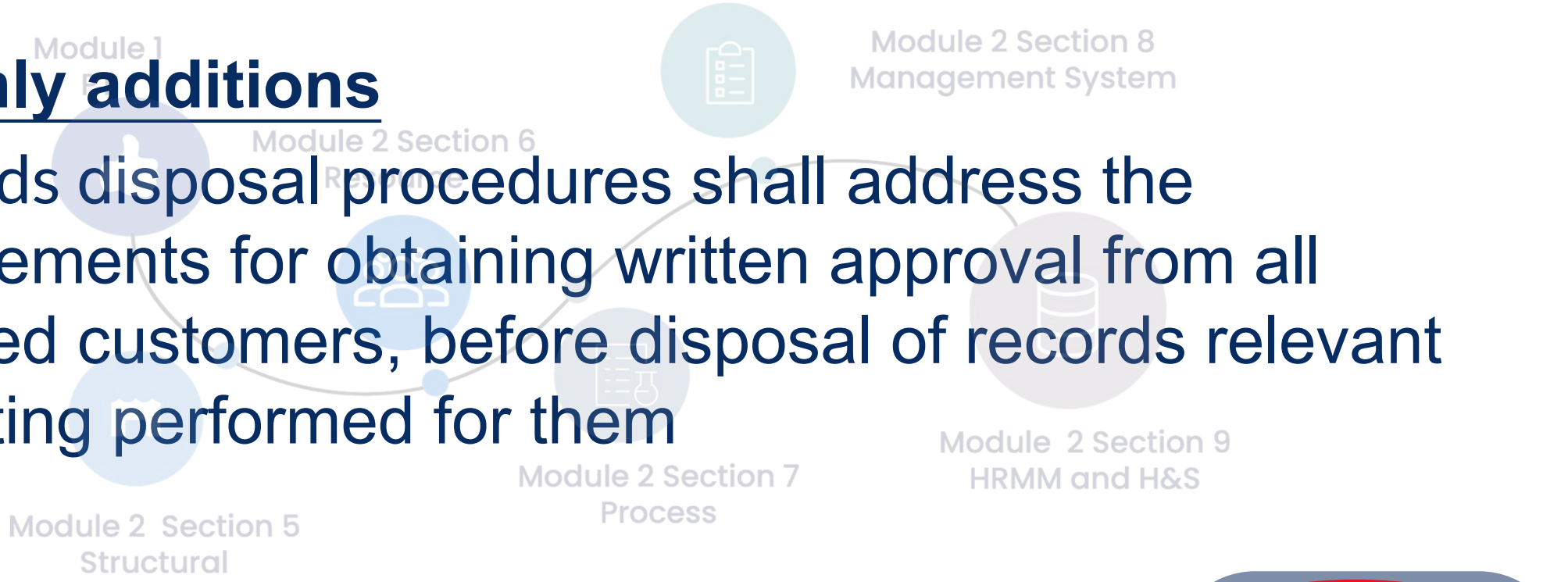
- Quality manual shall contain the signed and dated concurrence (with appropriate names and titles) of all responsible parties, including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager.

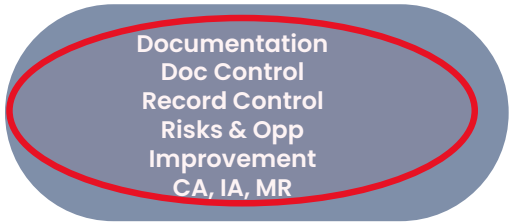


Considerations for Adding DOECAP-AP

DOE only additions

- Records disposal procedures shall address the requirements for obtaining written approval from all affected customers, before disposal of records relevant to testing performed for them

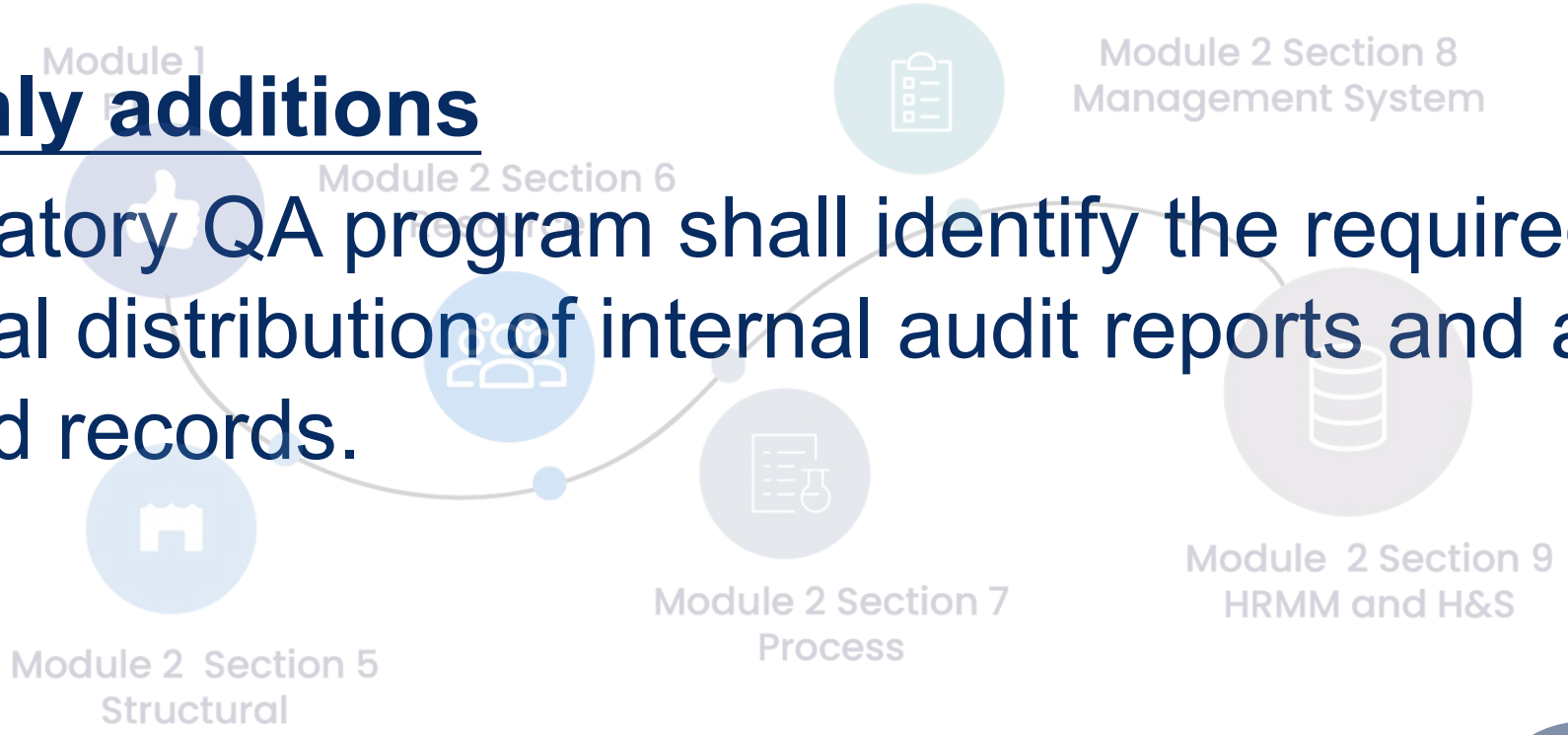


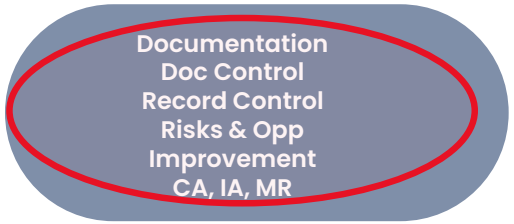


Considerations for Adding DOECAP-AP

DOE only additions

- Laboratory QA program shall identify the required internal distribution of internal audit reports and all related records.

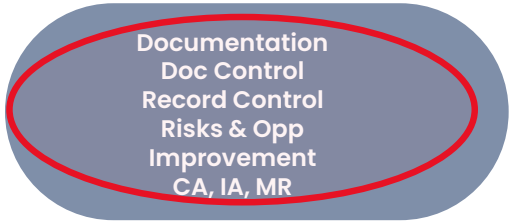




Considerations for Adding DOECAP-AP

DOE only additions

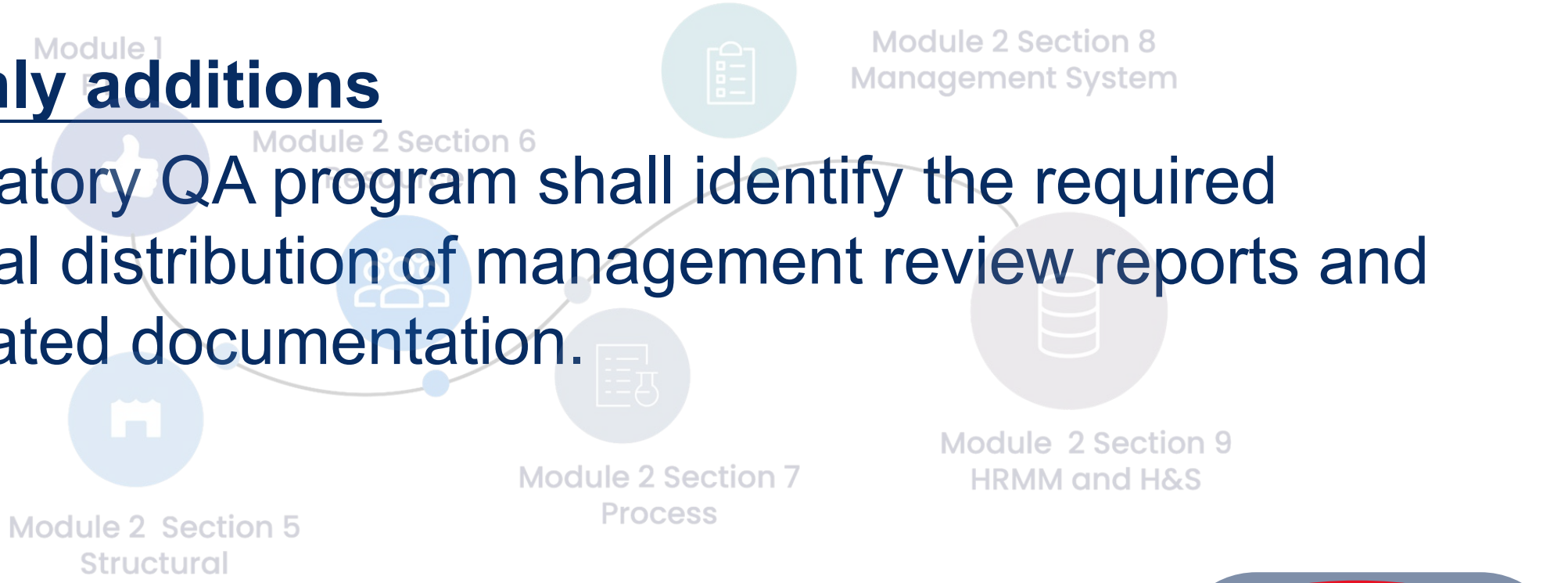
- Management reviews shall also include laboratory radiation health and safety, radioactive hazardous waste, and radioactive materials management functions, where applicable (i.e., when radioactive samples are analyzed).

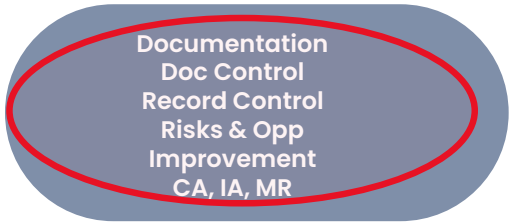


Considerations for Adding DOECAP-AP

DOE only additions

- Laboratory QA program shall identify the required internal distribution of management review reports and all related documentation.





Considerations for Adding DOECAP-AP

DOE only additions

- Hazardous and Radioactive Materials Management and Health and Safety Practices
  - Radioactive Materials Management Plan
  - Waste Management Plan
  - Chemical Hygiene Plan
  - Sample Receiving and Control
  - Records
  - Training

HRMM and H&S Practices

QSM 6 DOE only in summary

M1 4.7.3.a

M2 5.2.1; 5.2.1.a-f

M2 5.2.2; 5.2.2.a-l

M2 6.2.8

M2 6.2.9

M2 6.3.4.f.vii.

M2 7.2.1.2.c.ii.g-h

M2 7.2.1.2.e

M2 7.4.23.c

M2 8.2.1.a.xxxii-xxxiii

M2 8.2.3.a

M2 8.4.5

M2: 8.8.7

M2 8.9.6

M2 8.9.8

M2 Section 9
9.1 (rad labs only)
9.2-9.6 (all DOE labs)

Special Thanks for the Opportunity, Review and Comments

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