DOECAP-Accreditation Program Trends Analysis

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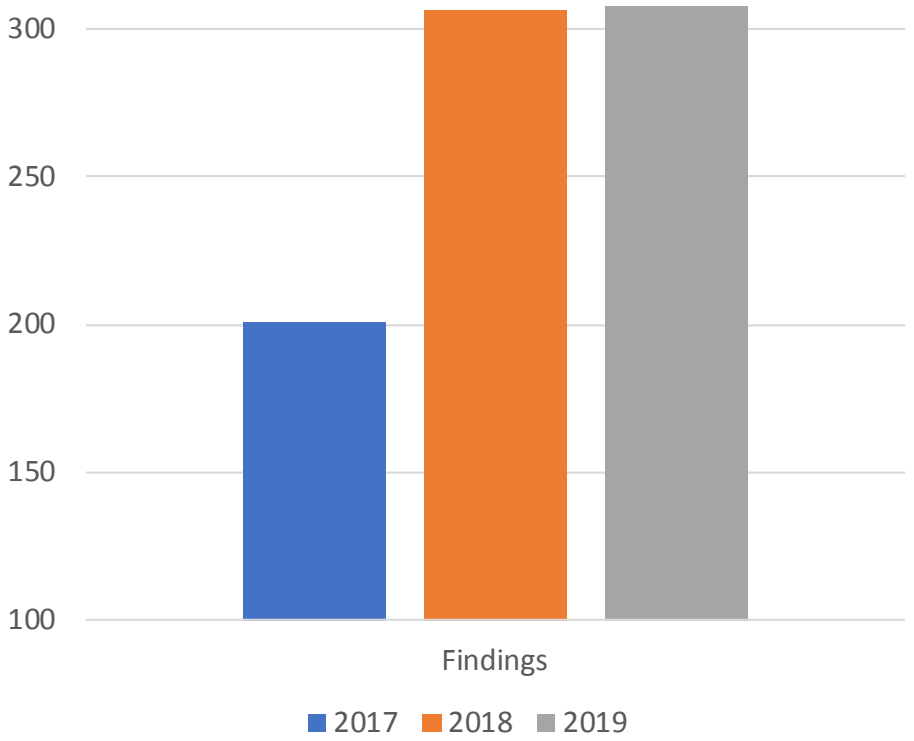
Topics of Discussion

Trending of laboratories will examine:

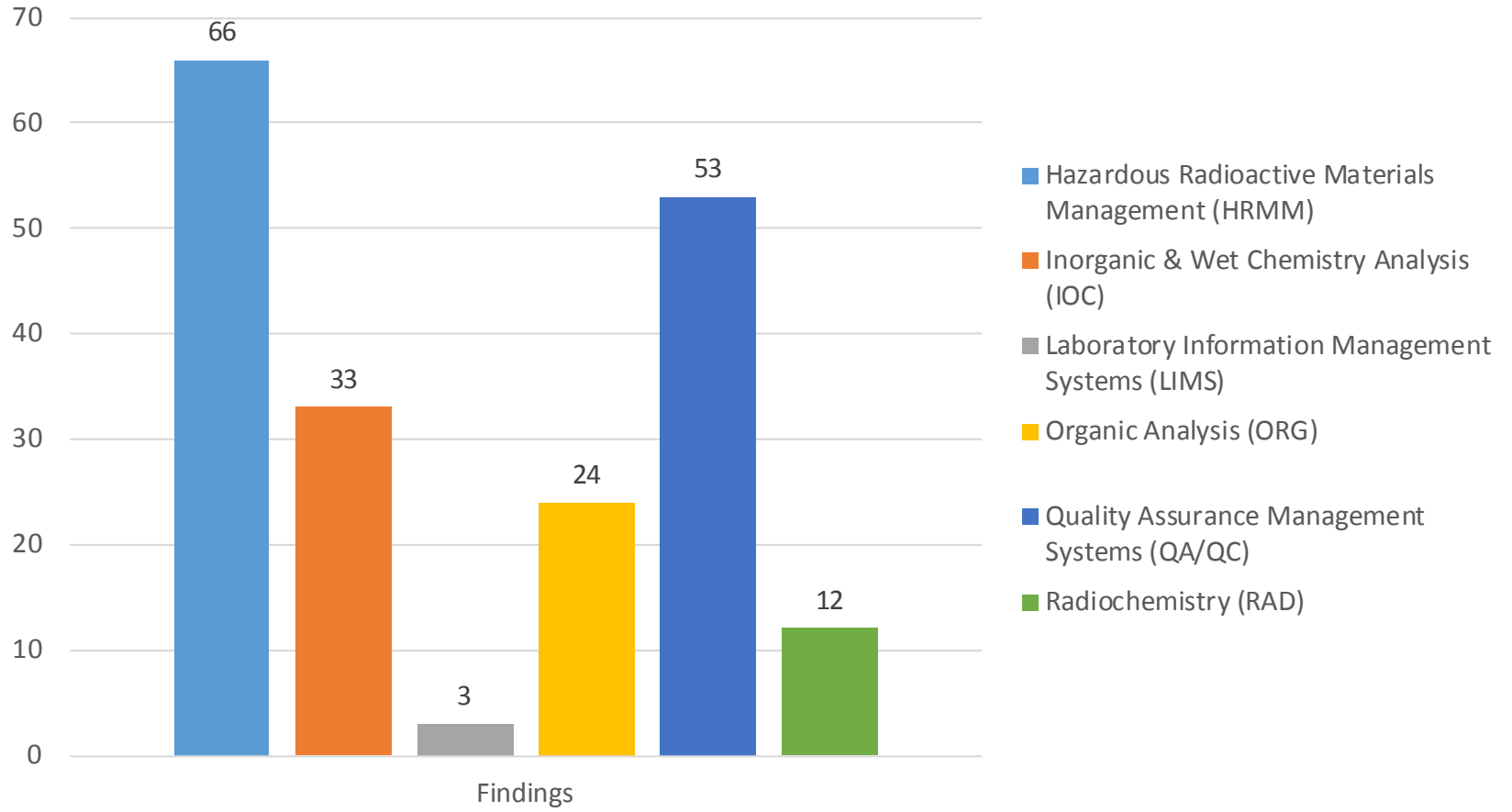
- Total findings in calendar year 2017, 2018 and 2019
- Total findings by concentration in 2017
- Total findings by concentration in 2018
- Total findings by concentration in 2019
- Percentage of findings for each concentration related to total number of findings in 2019 assessments
- Frequent findings in each concentration for 2019
- Common trends

2017, 2018, 2019 Total Findings

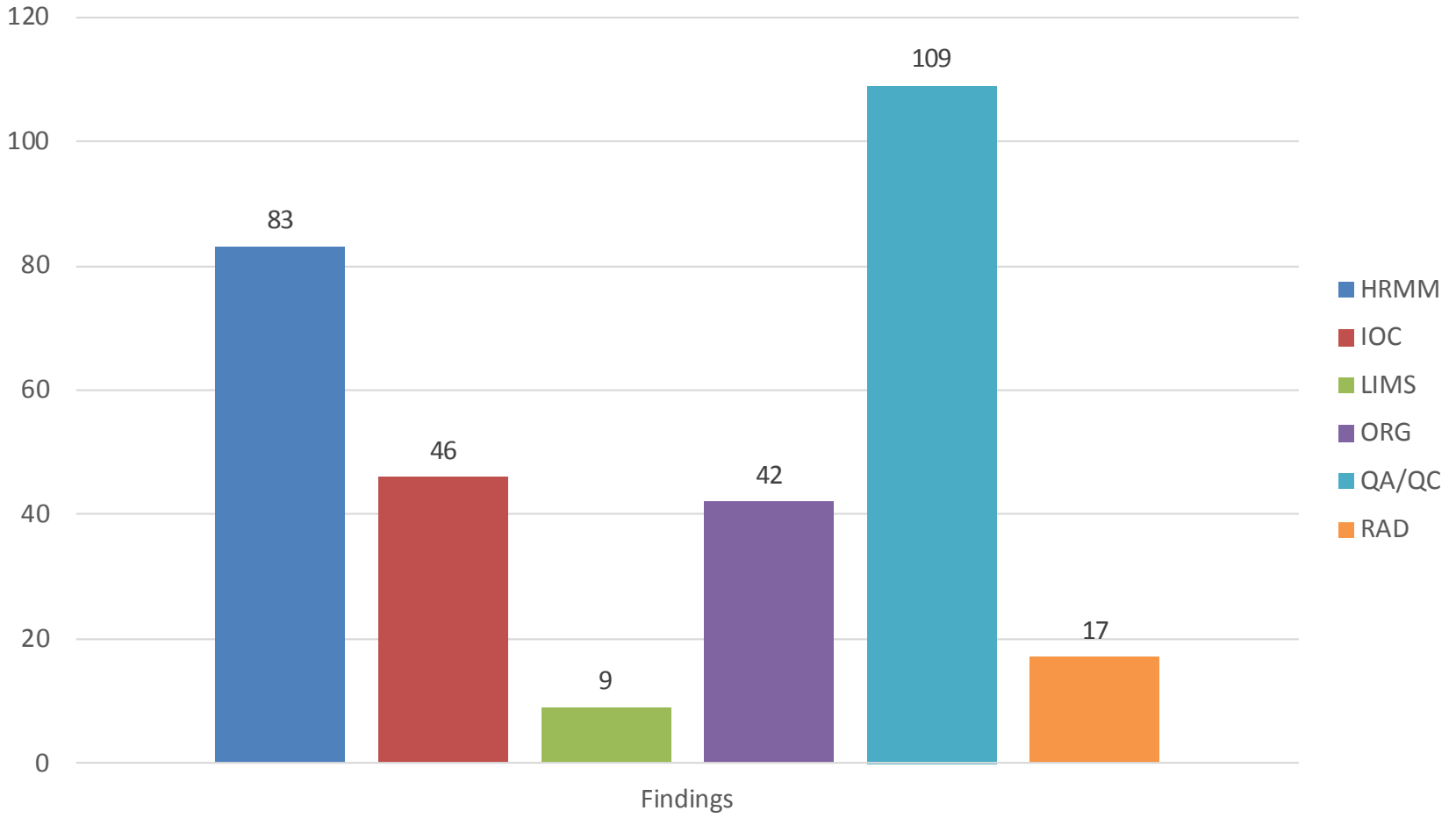
- 201 findings in 2017
- 306 findings in 2018
- 308 findings in 2019



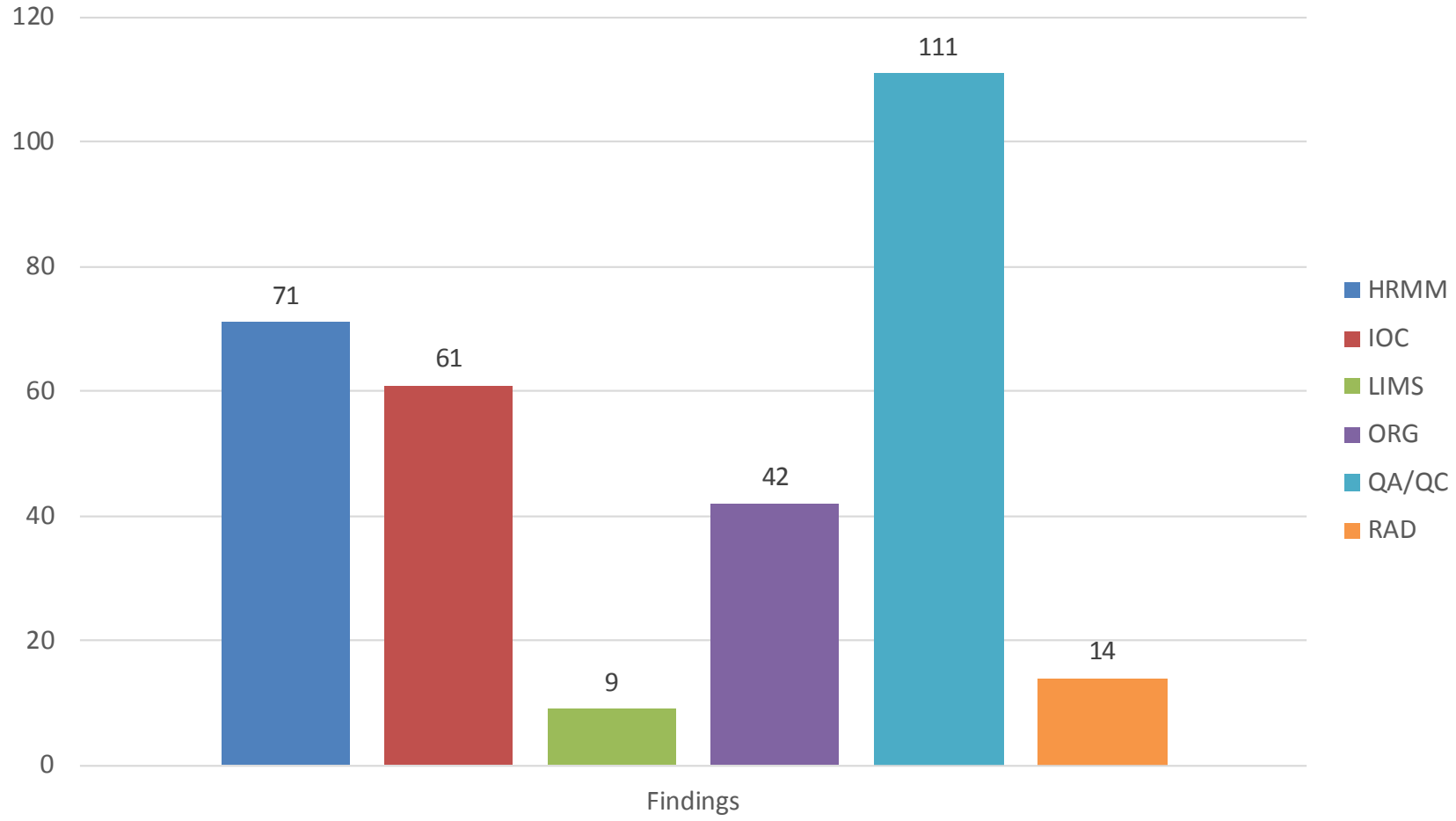
Findings by Concentration 2017



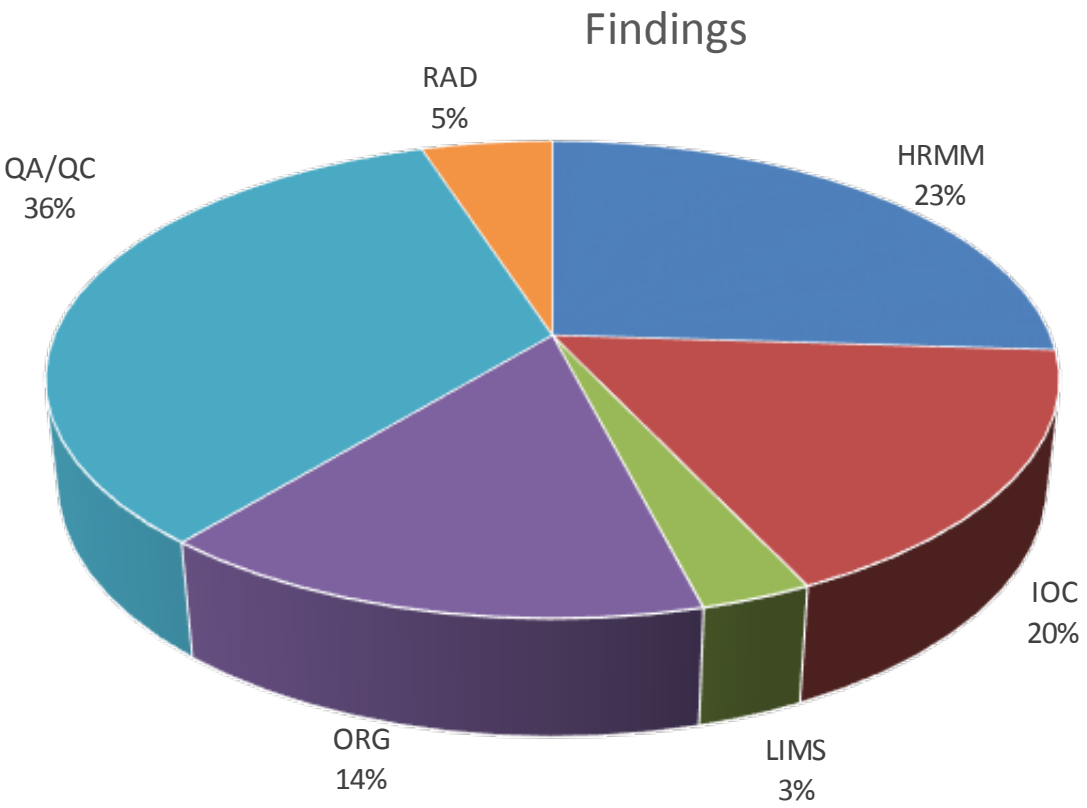
Findings by Concentration 2018



Findings by Concentration 2019



Percentage of Findings by Concentration in 2019 Assessments



Frequent Findings Quality Assurance

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Management	4.2.8.5	Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.
Calibration Requirements	5.5.13.1	All support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use.

Frequent Findings Quality Assurance

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Document Control	4.3.2.1	All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.
Control of Records	4.13.3	All information necessary for the historical reconstruction of data shall be maintained by the laboratory.

Frequent Findings Quality Assurance

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.4	Permanent, bound laboratory notebooks (logbooks) or notebooks with measures in place to prevent the removal or addition of pages are required if utilized. Electronic logbooks are acceptable. All notebook pages must be closed when the activities recorded are completed or carried over to another page. The person responsible for performing the closure shall be the one who performed the last activity recorded. Closure shall occur at the end of the last activity recorded on a page, as soon as practicable, thereafter.

Frequent Findings Organic Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Environmental Methods and Method Validation	5.4.1	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.
Equipment	6.4.5 (ISO 17025:2017)	The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

Frequent Findings Organic Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Calibration Requirements	5.5.13.1	The results of calibration and verification of support equipment must be within the specifications required of the application for which this equipment is used, or the equipment must be removed from service until repaired. Calibration and verification records, including those of established correction factors, must be maintained.

Frequent Findings Inorganic Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

Frequent Findings Inorganic Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.3	All information necessary for the historical reconstruction of data shall be maintained by the laboratory.
Documentation and Labeling of Standards, Reagents, and Reference Materials	5.6.4.2	The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.

Frequent Findings Inorganic Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Calibration Requirements	5.5.13.1	Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis. The results of calibration and verification of support equipment must be within the specifications required of the application for which this equipment is used, or the equipment must be removed from service until repaired. Calibration and verification records, including those of established correction factors, must be maintained.

Frequent Findings Radiological Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

Frequent Findings Radiological Analysis

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.3	The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

Frequent Findings

Hazardous and Radioactive Materials Management and Health and Safety Practices

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Management	4.2.8.5	The laboratory shall develop, maintain, and implement procedures, however named, for Chemical Hygiene, Waste Management, and Radiation Protection (as applicable).
Waste Storage Areas	6.2.3.3	Waste storage areas, and containers of waste shall be monitored weekly by an operator or someone knowledgeable in waste operations specific to this facility.

Frequent Findings

Hazardous and Radioactive Materials Management and Health and Safety Practices

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Chemical Hygiene Plan	6.3.1	A CHP shall be developed and implemented in the laboratory and readily available to all employees. SOPs relating to safety and health considerations shall be developed and implemented.
Chemical Hygiene Plan	6.3.5	An emergency eye wash will be located within the immediate work area, unobstructed, and shall be readily available to all personnel. Location requirements and ease of access, frequency for testing, refilling or restocking as needed, and an emergency shower will be addressed in the plan. All tests and inspections will be clearly marked by a tag on each device. Records will be maintained by the personnel responsible for the implementation of the chemical hygiene plan.

Frequent Findings
Laboratory Information Management Systems

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Records	4.13.3	The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

Frequent Findings
Laboratory Information Management Systems

QSM 5.3 Section	QSM 5.3 Clause	QSM 5.3 Requirement
Control of Data	5.4.7.2	Periodic inspections (at least annually) of the LIMS shall be performed by the Quality Manager or designee to ensure the integrity of electronic data. The Quality Manager or designee shall maintain records of inspections and submit reports to laboratory management noting any problems identified with electronic data processing and stating the corrective actions taken.

Common Trends

- **QSM 5.3 Section 4.2.8.5 -** Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.
- **QSM 5.3 Section 4.13.3 -** The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation.
- **Same common findings identified in 2018.**

These findings show issues with:

- Following, maintaining and implementing procedures
- Accurately creating and maintaining records

Questions