

	Standard Operating Procedure Management Review of Quality Metrics		SOP Number A-118	Revision 5
			Effective Date	Page Page 1 of 3
Written by/ Date <i>Jessica Kog 11/05/25</i>		Reviewed by/ Date <i>Melissa M... 11-05-25</i>		Approved by/ Date <i>M... 11/05/25</i>
Title: QA Compliance Supervisor		Title: Analytical Quality Assurance Specialist		Title: Quality Director

1.0 Purpose

The purpose of this procedure is to outline the requirements for Management Review of Quality Systems and define the manner and frequency in which KPI data and metrics are reviewed.

2.0 Scope

This procedure applies to quality systems in place to comply with regulations associated with products manufactured by Ion Labs.

3.0 Responsibility

- 3.1 Department heads are responsible for providing data necessary to support the evaluation of identified KPI values. This data must be provided on a monthly basis as applicable.
- 3.2 QA is responsible for identifying and tabulating KPI values.
- 3.3 Quality Management is responsible for reviewing tabulated KPI data and determining if action is required.

4.0 Definitions

- 4.1 **KPI** – Key Performance Indicator; a measureable value that demonstrates the effectiveness of a quality system
- 4.2 **MRB** – Material Review Board; a group consisting of company leadership (with the responsibility of discussing and deciding the appropriate outcome for any issues that may affect product quality, regulatory status, or GMP compliance.

5.0 References

- 5.1 C-502, SOP, Record Storage, Retention, and Destruction
- 5.2 D-120, SOP, Laboratory Management Structure and Position Requirements
- 5.3 21 CFR Part 111, 117, 201, 210, 114

6.0 Procedure

- 6.1 Routine Review of Quality Systems
 - 6.1.1 Quality Management will identify KPI values to monitor quality systems.
 - 6.1.2 The choice of the KPI values to monitor may change based on changes in system risk, changes in operational processes, and identification of new risks discovered during internal and/or external audits.
 - 6.1.3 Departments where data for KPI values are generated will provide necessary data to QA on a quarterly basis. Review will be conducted the month after the quarter was completed.
 - 6.1.4 If the quarterly review of KPI data indicates risks or problems with a Quality System, Quality Management will take action as required. Typical action to be taken includes but it not limited to:
 - 6.1.4.1 Discussion of action needed with applicable departments.
 - 6.1.4.2 Initiation of a CAPA.
 - 6.1.4.3 Initiation of a meeting with Executive management or the MRB.
 - 6.1.5 Laboratory Management Review is conducted to ensure effectiveness of the laboratory management system (LMS) in meeting objectives and in meeting the requirements of ISO 17025. Refer to SOP D-120 Laboratory Management Structure and Position Requirements.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/22/14	New	14-0411	S. Millar
1	02/09/15	Added OTC requirements.	14-1061	D. Popp
2	08/27/17	Revised flow chart to include additional input, output, and process points. Added examples of quality system elements that may require management review.	17-0917	S. Millar
3	01/21/19	Revised entire procedure to include reference to Executive Management KPI/Metrics Review. Added applicable CFR. Removed Process Flow	19-0067	S. Millar
4	02/17/22	Revised to ensure appropriate CFR reference (removing cosmetic and pharma) and add reference to D-120 Management -- Laboratory.	CC-22-0078	S. Millar
5	11/05/25	Revised to update logo and business name. Metric review will be performed on a quarterly basis. Removed reference to business metrics. AQR will be covered under metric reporting.	CC-25-0443	J. Kiger