

	Standard Operating Procedure		SOP Number A-117	Revision 6
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Written by/ Date SSS 11/09/21		Reviewed by/ Date R. J. Q. 11/18/21		Approved by/ Date S. A. [Signature] 11/17/21
Title: QC Laboratory Director		Title: HR Director		Title: QA Manager

1.0 Purpose

The purpose of this procedure is to define the requirements for employee hiring practices to ensure that employees are qualified through education, training and work experience to perform the specified job requirements; it is intended to meet the requirements of 21 CFR 111, 117, 210, and 211 and ISO 17025:2017

2.0 Scope

This procedure applies to all Ion Labs, Inc. departments in which employees manufacture, package, label, and hold Dietary supplements, drugs, pet products, and cosmetics, or have access to these areas. The additional requirements for ISO 17025:2017 pertaining to lab personnel who perform work for the accredited laboratory activities are also included in this procedure.

3.0 Responsibility

- 3.1 The HR Director is responsible for maintaining and implementing these requirements and manages all human resource (HR) related activities.
- 3.2 Quality Assurance is responsible for auditing this process to ensure compliance.
- 3.3 Department Managers are responsible for maintaining accurate and relevant job descriptions for each employee.
- 3.4 The designated pre-hire drug screening facility is Labcorp.

4.0 References

- 4.1 C-502, SOP, Record Storage, Retention, and Destruction

5.0 Definitions

- 5.1 **Candidate** - Potential new hire
- 5.2 **Statewide Criminal Check** - Screens the candidates for felonies and misdemeanors.
- 5.3 **Pre-Hire Process** - The process in which the HR Generalist performs the candidates

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past reference and employment check, drug screen, statewide criminal check, and proof of education (high school diploma, GED).

6.0 General Requirements

- 6.1 Candidates that will be involved in production or any quality control operation must have the education, training, and experience to perform assigned functions. Candidates that will be involved in accredited laboratory activities must have the required education, training, and experience documented in the Job Description or be provided with training that satisfy the established Competency requirements. Competency requirements are also maintained for managerial, technical, and key support personnel involved in the performance of laboratory activities accredited to ISO 17025.
- 6.2 Persons responsible for supervising those areas must be qualified by education, training, and experience to supervise and perform assigned functions.
- 6.3 An approved job description is required to be maintained by Department Managers for each position, including hourly and salary.

7.0 Job Descriptions

- 7.1 Job descriptions shall include the following:
 - 7.1.1 Job Title: Name of the position/operation
 - 7.1.2 Revision Date: Date of last revision
 - 7.1.3 Reports To: List of reporting structure for the position
 - 7.1.4 Scope of Supervision: Lists who employee supervises
 - 7.1.5 General Purpose: Provides a concise summary outline of various activities carried out on a permanent and continuing basis along with other duties that may be assigned. This summary may include responsibilities related and/or unrelated to the responsibilities described above
 - 7.1.6 Position Responsibilities: List in priority order the essential responsibilities of the position. Laboratory positions must include the appropriate authorizations. The authorizations for the following must be documented for each appropriate position:
 - Development, modification, verification and validation of methods,
 - Analysis of results, including statements of conformity or opinions and

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interpretations.

- Report, review and authorizations of results.

7.1.7 Education: Lists required and/or preferred education needed to perform the responsibilities of the position

7.1.8 Experience: Lists required and/or preferred experience needed to perform the responsibilities of the position

7.1.9 Knowledge, Skills and Abilities: Lists preferred knowledge, skills and abilities needed to perform the responsibilities of the position. Laboratory positions will also include any specific technical knowledge that is required and the competence to evaluate the significance of deviations.

7.1.10 Approval Signatures: Each Job Description is approved and signed off by the Department Manager, the Employee, Department Head and or CEO

7.1.11 Certificate or License: Any special certification or license required to perform the responsibilities of the position

7.2 Job Descriptions are revision controlled by date and will be revised appropriately, should a change in duties occur.

7.3 If there is a change to the essential responsibilities or experience required for any position, it is the responsibility of the Departmental Manager/the Department Head to notify the HR Director to revise the affected job description.

8.0 Selection Process

8.1 Upon the need to fill a new or existing position, the Department Head, CEO notifies HR.

8.2 HR locates the current job description for the position that needs to be filled.

8.3 HR posts the job description on Indeed, Monster, CareerBuilder, Craigslist, CareerSource Pinellas, or other relevant sources.

8.4 HR receives and screens resumes, ensuring that the respondents meet all requirements of the job description, then forwards them to the Supervisor, Dept. Manager/Department Head, or CEO.

8.5 Supervisor, Dept. Manager/Department Head, or CEO notifies the HR of qualified candidates they would like to interview.

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- 8.6 HR contacts the candidates and schedules interviews.
- 8.7 Upon arrival at the facility, all candidates are requested to complete an application, which is provided to Supervisor, Dept. Manager, or CEO prior to the interview for review.
- 8.8 Following a successful interview process, HR is notified to start the pre-hire process.
- 8.9 For all positions, HR checks references and past employers listed on the candidate's application, this is to verify that all of the information is accurate.
- 8.10 For all candidates, HR requests a Statewide Criminal Check through Ion's approved agency.
 - 8.10.1 After the candidate's criminal record is returned within 2-5 days, HR notifies Dept. Manager/Department Head of results.
- 8.11 For all candidates, HR sends them to Labcorp for a pre-hire drug screen.
 - 8.11.1 The drug screen results are sent to HR via email within 24-48 hours.
 - 8.11.2 If the results are positive, the job offer is void.
- 8.12 After the pre-hire process is complete, HR notifies the candidate of their results and hire status.
 - 8.12.1 It is at the sole discretion of Ion Labs to consider employment of any respective candidate.

9.0 Performance Reviews

- 9.1 Performance Reviews may be conducted at the discretion of Senior Management.
- 9.2 During Performance reviews, employees will be counseled concerning the strengths and weaknesses of their performance, attitude toward their work and co-workers, attendance, or other relevant areas.
- 9.3 Each Dept. Manager/Department Head turns in all Performance Reviews to HR for review.
- 9.4 All Performance Reviews are filed in the Employee's personnel file.

10.0 Records

10.1 Records are maintained per SOP C-502 Record Storage, Retention, and Destruction.

11.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/17/14	Created new SOP based on previous requirements in A-108. Added background check requirements. Clarified hiring practices.	14-0195	B. Gordon
1	04/07/14	Added additional responsibilities.	14-0305	S. Millar
2	11/14/14	Revised entire document to reflect current practices.	14-0919	B. Gordon
3	02/16/15	Added OTC requirements and scope.	14-1060	D. Popp
4	02/10/16	Revise to reflect current process and for clarity.	16-0135	D. Popp
5	04/16/19	Revised to reflect current titles. Added notation that Job Descriptions will be revised should a change in duties occur. Added reference to CFR 117.	19-0266	S. Millar
6	11/05/21	Added ISO 17025 Requirements.	CC-21-0418	J. Sassman