
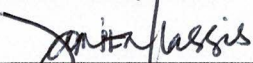

	Standard Operating Procedure Training Procedure		SOP Number A-113	Revision 10
			Effective Date 03/01/24	Page Page 1 of 14
Written by/ Date  12/28/23		Reviewed by/ Date  01/02/24		Approved by/ Date  01/02/24
Title: Director of Quality Control		Title: Employee Training Coordinator		Title: Director of Quality Assurance

1.0 Purpose

The purpose of this procedure is to define the training requirements and procedures in terms of new employee training, temporary employee training, new/revised document training, practical training (OJT), continued training, training associated with employee status changes/transfers/promotions, other training requests, and regulatory/certification requirements.

2.0 Scope

This procedure is applicable to all employees and contractors at Ion Nutritional Labs.

3.0 Responsibility

- 3.1 The Training Department will set up and maintain training programs based on the needs of the company, employees, job functions, and current regulations and certification requirements. The Training Department will use various methods to deliver the information that may include, but are not limited to: written documents, videos, computer-based training, and practical training (OJT).
- 3.2 The Training Department, under the supervision of Quality Assurance, will maintain GMP Training. The Training Department will provide GMP training to all new employees during New Hire Training activities and to all current employees annually at a minimum.
- 3.3 New Employees: It is the responsibility of a new employee's Manager/Supervisor to welcome the new employee and introduce themselves. The manager/supervisor must be involved in the new employee's training development.
- 3.4 Temporary Employees: It is the responsibility of the HR department to provide proper

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 2 of 14
--	-------------------------------	----------------------------	-------------------------------

training documents (e.g. cGMP Policy for Temporary Employees) to the approved staffing agency to ensure all temporary employees have general GMP knowledge.

- 3.5 It is the responsibility of the Department Manager/Supervisor to ensure any temporary employees in assessment are provided Practical Training (OJT) and SOP/Document Training with the Training Department, if necessary.
- 3.6 It is the responsibility of the Department Manager or designee to complete an Employee Access Form if the employee needs computer access/email etc. It is the responsibility of IT to ensure the employee is setup prior to the start date/effective date.
- 3.7 It is the responsibility of the Hiring Manager or designee to ensure new employees have the proper tools (pens, notepad etc.) prior to their start date and, if the new employee has a desk/cubicle, contact facilities to clean and sanitize area. The same procedure applies if an active employee is transferred or promoted.
- 3.8 It is the responsibility of the Department Manager/Supervisor or designee to provide the training department a schedule if a new employee is not starting at the usual time.
- 3.9 It is the responsibility of Department Manager/Supervisor or designee to perform or coordinate practical training (OJT), and to ensure that the training is effective and the employee comprehends the job task/responsibility.
- 3.10 The Training Department will provide SOP training for new and current employees.
- 3.11 It is the responsibility of the Department Manager/Supervisor to provide/review the SOP List that is assigned to each job position/department, to ensure all necessary training is applicable and current. Each department will be required to review their SOP list annually or when necessary.
- 3.12 It is the responsibility of the Department Manager/Supervisor to complete an Employee Status Update form if an employee has a title change, department transfer, level change, or shift change, and ensure that the Training Department reviews/signs off.

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 3 of 14
---	------------------------	---------------------	------------------------

- 3.13 It is the responsibility of the Department Manager/Supervisor to ensure that the employee signs the appropriate job description (new employees and employee status changes, transfers, or promotions).
- 3.14 It is the responsibility of the Department Manager/Supervisor requesting a training session/training room (e.g. CRP/First Aid Training, Redzone, etc.) to coordinate the need with the Training Department.
- 3.15 It is the responsibility of the Training Department to maintain the training matrix and all employee training records.

4.0 Definitions

- 4.1 **cGMP** – Current Good Manufacturing Practice
- 4.2 **SOP** – Standard Operating Procedure
- 4.3 **CFR** – Code of Federal Regulations
- 4.4 **QA** – Quality Assurance
- 4.5 **OJT** – On the Job Training (see practical training)
- 4.6 **Group Training** – a trainer is presenting information to a group of individuals
- 4.7 **Individual Training** – training that is either self-done or a trainer is presenting information to an individual
- 4.8 **Practical Training** – on the job training; instruction for employees that takes place at work, typically involving a combination of observing others and hands-on experience completing tasks under the supervision of a training manager, coworker or outsourced professional trainer
- 4.9 **New Hire** – a person hired as a new employee to Ion Nutritional Labs

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 4 of 14
--	-------------------------------	----------------------------	-------------------------------

- 4.10 **Job Description** –a document which explains the tasks, duties, function and responsibilities of a position
- 4.11 **Temporary Employee** – individual contracted from an approved Staffing Agency
- 4.12 **Day Temp** – day laborer; if a day temp comes in and stands out, they would be asked to return
- 4.13 **Temp in Assessment** – a temporary employee showing potential; management approves to proceed and provide with additional tasks to continue assessment
- 4.14 **Core Temp** – a temp that passes the initial assessment period and returns to meet their required hours so they can be hired on as an employee
- 4.15 **SME** – Subject Matter Expert; a person who possesses a deep understanding of a particular subject such as a job task, process, piece of equipment, software, etc.
- 4.16 **Employee Access Form** – HR Form which includes employee name, personnel equipment requirements, personnel IT requirements, access requirements, and approval signatures
- 4.17 **Employee Status Update Form** – HR Form which includes employee name, date/effective date, job title change, department transfer, shift transfer, reason, and approved signatures
- 4.18 **Qualification Manual** – manual utilized for associates in operations to document job level skills; Practical and SOP training is signed off by the associate and supervisor/manager/trainer
- 4.19 **HR** – Human Resources
- 4.20 **IT** – Information Technology

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 5 of 14
---	-------------------------------	----------------------------	-------------------------------

5.0 References

- 5.1 A-113-F1, Form, Group Training Form
- 5.2 A-113-F2, Form, Individual Training Form
- 5.3 A-113-F3, Form, Practical Training Form
- 5.4 A-114- F1, Form, Employee Register
- 5.5 A-108, SOP, Good Manufacturing Practices and Personal Hygiene
- 5.6 A-117, SOP, Personnel Qualifications
- 5.7 C-403, SOP, Change Control Procedure
- 5.8 C-502, SOP, Record Storage, Retention, and Destruction
- 5.9 Employee Access Form
- 5.10 Employee Status Update Form
- 5.11 cGMP Policy for Temps
- 5.12 Employee Training Matrix/Records
- 5.13 21 CFR part 111, 114, 117, 121, 210, and 211

6.0 Procedure

- 6.1 Employee Training
 - 6.1.1 New Hire Orientation/Training
 - 6.1.1.1 HR will send a New Hire announcement email to all associated personnel and training department. Email consists of New Hire name, title, department, shift, and start date.

<p style="text-align: center;">Standard Operating Procedure Training Procedure</p>	<p style="text-align: center;">SOP No A-113</p>	<p style="text-align: center;">Rev No 10</p>	<p style="text-align: center;">Page 6 of 14</p>
---	---	--	---

- 6.1.1.2 An Employee Access Form needs to be filled out five business days prior to New Hire Start Date if possible. Ensure the new hire has the proper tools such as pens/notepad and the desk/cubicle is clean, if applicable.
- 6.1.1.3 HR will submit the completed Employee Access Form through the ticketing portal to IT. IT in turn needs to ensure all items on the Employee Access Form are completed prior to new hire arrival. If there are items on the Employee Access Form not completed or issues with the request, this must be communicated to the Hiring Manger/Training Department prior to new employee arrival.
- 6.1.1.4 Hiring Manager/HR must communicate to the Training Department New Hire arrival time.
- 6.1.1.5 Arrival of New Hire: HR will ensure new hire onboarding is complete and employee receives a badge. New Hire onboarding may include but not limited to review the employee handbook, policies and requirements as well as general company information. Background and drug screens are required; reference A-117 Personnel Qualifications.
- 6.1.1.6 HR will accompany the employee to the Training Department, if the hiring manager does not have a scheduled prepared.
- 6.1.1.7 HR will provide a copy of the New Hire Job Description to the Training Department for the employees training record.
- 6.1.1.8 If an Employee Access Form was completed prior to New Hire arrival, IT Orientation will be necessary to ensure the employee can access their account/email setup, phone, company files (e.g. F: drive/U: drive), shown printer location, and knows how to submit a help ticket, etc.
- 6.1.1.9 Training Department will provide New Hire Training. Each new hire will be trained to pre-determined SOPs that are appropriate for that respective

<p style="text-align: center;">Standard Operating Procedure Training Procedure</p>	<p style="text-align: center;">SOP No A-113</p>	<p style="text-align: center;">Rev No 10</p>	<p style="text-align: center;">Page 7 of 14</p>
---	---	--	---

job description/task. Every New Hire must complete any Mandatory DCC Training assigned to them. New Hire Training, Standard Operating Procedure, and DCC training will be conducted in the training room, although training maybe conducted in other areas as needed or online.

6.1.1.10 After New Hire Training is complete, the new employees' manager/supervisor or designee will escort the employee to their respective department/location for Practical Training. Documented training used for employee comprehension of a subject(s) will be provided to the Training Department (Form A-113-F1 Group Training Form, A-113-F2 Individual Training Form, A-113-F3 Practical Training Form, or Qualification Manual if applicable).

6.1.2 Temporary Employee Training

6.1.2.1 Ion Nutritional Labs utilizes approved Staffing Agencies when temporary employees are needed. Background and drug testing is required/completed by the temp agency.

6.1.2.2 The approved temp agency will provide temporary employees any required training documents (e.g. cGMP Policy for Temps) to review/sign.

6.1.2.3 HR will send the Training Department an updated list for Temps in Assessment/Core Temps on a frequent basis.

6.1.2.4 Temps in Assessment that have potential to complete additional tasks will come to the Training Department to complete SOP Training/any other related documents. Temps in Assessment are identified by their respective department manager/supervisor and is communicated to HR.

6.1.2.5 Training Department will request a copy of the Temp cGMP Policy once training has been completed.

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 8 of 14
---	-------------------------------	----------------------------	-------------------------------

6.1.2.6 Core Temps must have completed any necessary training for their job function.

6.1.2.7 Any temp that receives additional training will have an Employee Training Record and will be maintained by the Training Department.

Note: If the employee/temp is proficient in any language other than English, a translator or translation device will be provided if the training department's translation tools are not effective.

6.1.3 For Laboratory employees, the New Employee Orientation will include the following:

6.1.3.1 New employees will undergo initial orientation to introduce the management system, basic laboratory operations, and awareness of actions required to address ISO 17025 accreditation.

6.1.3.2 As part of orientation, employees will participate in ISO 17025 Awareness Training to ensure they understand the laboratory management system structure and the location of the associated procedures. This training will also ensure employees are aware of the relevance and importance of their job as it relates to the Ion Nutritional Labs quality policy, how their work activities contribute to the achievement of objectives, the importance of meeting customer requirements and the importance of understanding and following procedures.

6.1.3.3 Orientation activities will include information regarding the importance of performing work in an impartial manner, and the necessity of keeping confidential all information obtained or created during the performance of laboratory activities (except as required by law).

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 9 of 14
--	-------------------------------	----------------------------	-------------------------------

6.1.4 Annual Training

6.1.4.1 Current employees will be provided GMP training, including an assessment. General Training consists at a minimum an overview of cGMP based on 21 CFR part 111, 114, 117, and 121 for Pet Products, Food Products, and Dietary Supplements.

6.1.4.2 Additional training may consist of an overview of HACCP/HARPC, Food Safety/Food Defense, Allergen Control and safety-related SOPs. An interactive computer presentation is provided for each type of GMP/safety-related topics as to engage the employee in the training.

6.1.4.3 Employees will be trained on the different types of Product Certifications such as Non-GMO Project Verified, Certified Organic, Kosher, Halal, and Gluten-Free. Training will include a basic understanding of the certification, material segregation, and tasks related to the manufacture and handling of certified products.

6.1.5 SOP/Form Training

6.1.5.1 An employee may train on an SOP or a Form by using a copy (paper or electronic) of the most current revision or through electronic access to the SOP file located under the company's shared files.

6.1.5.2 New or Revised SOPs or Forms that require training will be submitted to the Training Department by the QA Director or designee (training copy of the SOP/form).

6.1.5.3 Authors, reviewers, or approvers of new or revised SOPs and forms do not have to complete the training since they already wrote/reviewed/approved the document. The QA Director or designee will provide the Training Department the names of additional reviewers listed on the change control.

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 10 of 14
---	-------------------------------	----------------------------	--------------------------------

6.1.5.4 New or Revised SOP paper hard copies (stamped COPY) that are distributed with Training Packets must be shredded when training is complete. Under no circumstance can the training copy be kept by the trainer/trainees, nor can it replace the official copy. All training copies will be clearly stamped as such.

Note: Any new or revised SOPs or forms will not be considered effective until all training has been conducted and documented by the appropriate designee (reference C-403 Change Control Procedure). Only laboratory methods are excluded from this requirement (D-700 / D-1000 SOP number series). SOP training is not required for laboratory methods.

6.1.6 Continued Training

6.1.6.1 Continued Training may be used to develop and strengthen the skills of the employee. Continued Training may be in the form of on-line courses, in-house training, seminars/webinars, and educational conferences.

6.2 Employee Status Change/Transfers/Promotion

6.2.1 Department manager/supervisors must complete the Employee Status Update Form and submit to HR. HR will ensure the employee signs a new job description, if necessary.

6.2.2 An Employee Access Form will need to be completed if the employee needs computer access, etc. and submit to HR.

6.2.3 Employee Training needs to be scheduled with the training department before the training department signs off on the Employee Status Form. If the department manager/supervisor has prior knowledge of the upcoming employee status change, training must be completed prior to the change.

6.2.4 The training department will review the employee's current training records to see if there is additional Practical or SOP training that needs to be complete. If the

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 11 of 14
---	-------------------------------	----------------------------	--------------------------------

employee needs practical training, the department manager/supervisor should document the training and provide the form to the Training Department (Form A-113-F1 Group Training Form, A-113-F2 Individual Training Form, A-113-F3 Practical Training Form, or Qualification Manual).

6.2.5 Once training has been reviewed, scheduled and/or completed, the Training Department will sign/submit the Employee Status Update Form to HR. HR will maintain completed forms.

6.3 Laboratory Training

6.3.1 In addition to SOP and form training as described above, QC Laboratory personnel are required to perform specific practical training activities.

6.3.2 When a QC laboratory analyst is trained on a new testing technique, the following activities should occur:

6.3.2.1 Observe trainer perform testing technique

6.3.2.2 Perform testing technique alongside trainer

6.3.2.3 Execute testing technique under the observation of the trainer

6.3.3 All practical training activities will be documented on Form A-113-F3 Practical Training Form. Data generated during these activities will be identified for training purposes only.

6.3.4 After successful completion of practical training, both the trainer and trainee will sign form A-113-F3 Practical Training Form.

6.3.5 If the trainee fails to successfully complete the practical training, further review by departmental management and HR should occur.

6.3.6 Any data generated from training activities will be filed with all other training in the personnel training record.

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 12 of 14
---	------------------------	---------------------	-------------------------

6.3.7 Experienced Analysts

6.3.7.1 QC Laboratory personnel that have previous experience on specific laboratory testing techniques are not required to complete practical training.

6.3.7.2 In lieu of completing this testing, these techniques can be captured at time of hire on Form A-113-F3 Practical Training Form as “N/A, previous experience”.

6.4 Employee Rehire

6.4.1 HR will inform the training department of any rehires (by email with name, title, department, shift, date of rehire). If the rehire has been absent for more than (6) months, the employee will have to complete the New Hire/SOP/Practical/Annual GMP Training or any other requested training during their absenteeism as a refresher.

6.5 Other Training

6.5.1 Department heads and/or Quality may determine that one or more employees need training/retraining/counseling. A trainer will be designated and a training session will be conducted as appropriate.

6.5.2 Any department can request a training session on any subject, or request the use of the training room. These steps must be followed to ensure the training is conducted appropriately:

6.5.2.1 Department manager/supervisor must give the training department advance notice of the training request and verify the scheduled training dates are available. (Requests may be approved or denied)

6.5.2.2 If the training department is conducting a training session per the request of department manager/supervisor, an SME must be appointed to ensure

Standard Operating Procedure Training Procedure	SOP No A-113	Rev No 10	Page 13 of 14
--	-------------------------------	----------------------------	--------------------------------

employees are given the proper information and questions can be answered. The SME must be available during the scheduled training dates and times. If the SME is not available during the scheduled training, another designated person must be assigned and it must be communicated to the training department.

Note: Review the internal company calendar “Training Room” prior to scheduling to ensure the training room is available.

6.6 Documentation and Filing of Training Records

- 6.6.1 HR will provide the Training Department a copy of the New Hire Job Description to be placed in the employees training records.
- 6.6.2 Any required training should be reviewed with the Training Department prior to training to verify all documentation is correct.
- 6.6.3 Supporting training aids and documents may be provided with forms for proof or verification of the training.
- 6.6.4 The Training Department will provide the Trainer and/or Employee with the appropriate form(s) based on the type of training that is needed.
- 6.6.5 After training has been completed, the Group/Individual/Practical Training Form or Qualification Manual will be returned to the Training Department, who will verify the document for accuracy and completeness and enter the information into the Training Matrix.
- 6.6.6 The Training Department retains all employees training records and any other documents pertaining to training (i.e. certifications, presentations, handouts, register).
- 6.6.7 QA department may, at its sole discretion, conduct an evaluation of any part of the training process (i.e. training sessions, trainees, trainer, training material, etc.) to

verify training effectiveness.

6.7 Record Management

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

8.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	04/19/10	New	-	-
1	07/11/11	Added sections 4.2 and 4.3. Changed forms.	-	-
2	04/04/13	Changed SOP format and number. Updated SOP and forms.	13-271	V. Ilcheva
3	04/02/14	Revised entire SOP. Updated format.	14-0272	S. Millar
4	02/09/15	Added 210 and 211 for OTC requirements	14-1062	D. Popp
5	03/05/18	Complete rewrite to incorporate new training program.	18-0082	K. Tyrell
6	11/05/21	Added in ISO 17025 requirements for laboratory personnel.	CC-21-0419	J. Sassman
7	02/02/22	Complete rewrite to current procedures.	CC-22-0076	C. Horelle
8	10/18/22	Updated to current practices. Removed checklists and training request form. Changed Quality Systems Manager title.	CC-22-0413	C. Horelle
9	08/15/23	Revised 6.1.4 to Annual Training and to add Product Certification training.	CC-23-0411	C. Horelle
10	12/28/23	Added laboratory OJT Training. Added back Form A-113-F3, Practical Training Form.	CC-23-0617	J. Sassman



Practical Training Form

Form: A-113-F3

CCR No. CC-23-0617

Revision: 3

EMPLOYEE INFORMATION

Employee Name (Printed Name)		Employee Initials (Print)	
Department		Job Title	
Type of Training	<input type="checkbox"/> New Learning		<input type="checkbox"/> Continued Training

DESCRIPTION OF JOB TASK

<u>Task(s) to perform:</u>	<u>How to instruct task(s):</u>
----------------------------	---------------------------------

DOCUMENT EMPLOYEE LEARNING

	Task	Observations of Instructor	Instructor Initials			
			Failed Attempts			Pass
			1	2*	3**	
1						
2						
3						
4						
5						
6						

EMPLOYEE SIGN-OFF

I understand the task(s) that have been demonstrated.

_____	_____	_____
Employee Name (print)	Employee Signature	Date

EMPLOYEE SIGN-OFF

Employee has performed all tasks and shown understanding. Employee can perform task without direct supervision.

_____	_____	_____
Instructor Name (print)	Instructor Signature	Date

* 2nd Failure in training: reassess training needs per SOP.

** 3rd Failure in training: send issue to HR for review.