



IR-4 National SOPs

An Introduction: Access, Training, Responsibilities

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Accessing National SOPs in eQA



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Workflow Status:

Job:

Location:

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Current Revision Level:

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Miscellaneous:

Active:

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View Details	Document ID ↑	Rev	Title
  	SOP N-01.1	0	SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures
  	SOP N-02.1		SOP N-02.1 iAdvantage Electronic Field Data Book Use

Magnifying glass on paper icon allows you to view.



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View History Effective Document

Current Document has not reached its effective date.

View Effective Document from History?

Continue

Cancel

If viewing before “Effective Date”, you will see this pop-up

Training on National SOPs in eQA

Training

- With eQA Access – train within **4** weeks of SOP effective date. New hires should train within **8** weeks of hire date.

Revision: 0 Effective Date: 6/21/2024 Next Review Date:5/1/2026

- Without eQA Access – Responsibility of FRD/LRD to ensure **those collecting data** are trained and that the training is documented in their training records.

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You see this no symbol because you haven't read the doc yet. After reading it, you can sign off

View/open document.



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You are claiming that you are Christina Dineen and have read the following document and understand and have completed the activity.

Password:

Due Date	Activity For	Recv'd	Comp'd	Activity Type	Document / Form	Title
6/27/2024 View	Christina Dineen	<input type="checkbox"/>	<input type="checkbox"/>	Please train on document.	SOP N-01.1 	SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures

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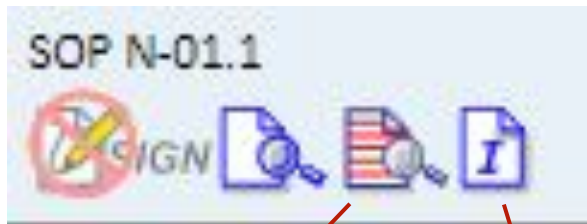
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Changes have been indicated in this red lined document






View document information

Document ID: SOP N-01.1
Title: SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures
Description/Purpose:
Current Revision Level: 0
[View Native Document \(.docx\)](#)
[View Effective Document from History](#)
Native Extension: .docx
File Source: Internal TMS File
Document Type: National Standard Operating Procedures
Location: IR-4 National SOPs
Department:
Initial Issue Date: 4/24/2024
Moved to Current and Published: Christina Dineen On: 5/22/2024 4:16:29 PM
Revision Effective Date: 6/21/2024
Active: Yes
Review Group: [National SOP Review Group](#)
Administrator: Christina Dineen
Miscellaneous:
Document Expiration Date:
Next Review Date: 5/1/2026
Proactive Reviewer/Document Owner:
Retraining Cycle (months): 0
Document Requires Current Training to View: No
Default Training Type:
Default Trainer:
Required Test Document:
Convert Document to PDF: Yes
University: (removed from drop list)
Created: 4/24/2024 12:05:18 PM By Christina Dineen
Updated: 6/7/2024 10:34:36 AM By Johanna Mazlo

Due Date	Activity For	Recv'd	Comp'd	Activity Type	Document / Form	Title
6/27/2024 View	Christina Dineen	<input type="checkbox"/>	<input type="checkbox"/>	Please train on document.	SOP N-01.1 	SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures

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<p>ACTIVITY</p> <p>Activity For: Christina Dineen Activity Type: Please train on document Due Date: 6/27/2024 Review Group: National SOP Review Group</p>	<p>SENDER</p> <p>Sender: Juliet Thompson Date Sent: 6/6/2024 2:51:10 PM Sender Notes: Please train on document</p>
<p>DOCUMENT</p> <p>Document ID: SOP N-01.1   Document Title: SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures Current Revision Level:    Reasons For Change: New document</p>	<p>RECIPIENT</p> <p>Recv'd: No - Mark As Received Comp'd: No - You must preview the document before Recipient Comments:</p> <div style="border: 1px solid gray; height: 150px; width: 100%;"></div> <p style="text-align: right;">Send Comment</p>

6/27/2024 View	Christina Dineen	<input type="checkbox"/>	<input type="checkbox"/>	Please train on document	SOP N-01.1    	SOP N-01.1 Guidelines for IR-4 National Standard Operating Procedures
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Same idea as previous slide, different view.



New Responsibilities

New Responsibilities

- National SOPs need to be immediately available, same as site SOPs
- Protocol supersedes National SOPs which supersedes site SOPs
- **SOP Deviations**
 - Study-specific – signed by person preparing deviation and Study Director
 - Not study-specific – signed by person preparing deviation, discuss with relevant Study Director(s), and signed by Testing Facility Management

New Responsibilities

Development/Revision

- Committee will take requests for new SOPs or changes.
- It's the responsibility of all IR-4 personnel to ensure that these SOPs meet the needs of the program. If they don't meet the needs of your testing facility please contact the committee.

Review

- Committee will review active SOPs on a 2-year cycle. After review, they will be sent out for retraining. We encourage comments during review process!

Review Process

- When SOPs are created, updated, or on their revision cycle, they will go through IR-4 review
- Each step has a 2-week review period (may be shorter if needed to get out quickly)
- Committee will address comments and send to next review
- After full review, uploaded to eQA. Committee signs off and final signoff from Executive Director



Incorporation at Individual Sites

- As National SOPs are finalized, they are meant to replace site SOPs where applicable.
- Where applicable, those site SOPs should be retired, and a reference to the National SOP included.
- List National SOPs in the site SOP index. At your next revision, update it as new SOPs are added and revisions change.
- Your SOP on SOP should discuss retiring redundant ones.
- There is no longer an SOP 5.8 (eFDB) in the Headquarters SOP. So, if you are referencing it in your facility's SOP, remove it at your next revision.

Key Points in the National SOPs

Key Points

EPA Inspections Procedures (N-01.2)

- A section specifically for Headquarters QA has been added.
- This lists the documents that should be sent to the site in preparation to the EPA inspection on their end.
 - Test Substance Characterization data
 - Cover sheets of QA reports
 - Master Schedules

Key Points

EPA Inspections Procedures (N-01.2)

- Electronic raw data captured in the eFDB system will be printed and certified as a true copy.
- If the Inspector needs access to the eNotebook website, it may be provided by an eStudy administrator. The QA is more than happy to give the EPA a tour of the form layouts.

Key Points

QA Inspections/Audits (N-01.3)

- It is the responsibility of the field researcher to communicate initial dates of application, harvest, etc and update QAU if changes occur.
- Changes to the inspection date due to weather, field events, or application interval should be communicated as soon as possible to the QAU so travel plans can be adjusted.

Key Points

QA Inspections/Audits (N-01.3)

Raw Data Audits

- The FRD will ship paper pages to HQ and notify the SD of the shipment. HQ will let the QAU that the eFDB is available for review.
- Contributing Scientist Reports: The RFC will notify QA that a processing report is available.

Key Points

Electronic Field Data Book Use (N-02.1)

- You must indicate whether the Facility File eFDB will be used in the eFDB. This allows you to reduce the amount of data that you need to add to each trial's eFDB. In Part 2B, indicate your intent on the prompt "Location of Facility Files for this Trial".

8	Location of Facility Files for this Trial	Facility Files eFDB
9	Location of original paper facility files in long-term storage	IR4 headquarters

Key Points

Electronic Field Data Book Use (N-02.1)

- When using the Facility File eFDB, if you are transcribing facility information from another source, you must:
 - Transcribe it in a timely manner
 - Scan the original, upload it to the eFDB
 - Maintain the original as per site SOPs

- Facility Files eFDB must be used exclusively starting in 2027.

Key Points

TS Container Disposal Approval (N-03.1)

- If there is a date listed under “ACT. STUDY COMP” for a trial where the TS was used, it can be disposed of.
- Disposal is not allowed if the TS from the same container was also used in a trial in a different study which has not yet been canceled or completed.

<u>LAB ID#</u>	<u>LAB START</u>	<u>LAB COMP</u>	<u>ACT. STUDY INIT.</u>	<u>EXP. START</u>	<u>EXP. TERM.</u>	<u>ACT. STUDY COMP.</u>
23-ADP04		DISCARD	05/04/22	05/22	11/24	
22-GPR14	08/22	DISCARD	05/04/22	05/22	11/24	
20-FLR05	09/20	11/22	03/18/20	03/20	11/21	04/12/23
22-FLR13	01/23	03/24	05/24/22			
22-FLR13	01/23	03/24				

Key Points

TS Container Disposal Approval (N-03.1)

- When test substance containers are disposed of, document disposal date in the facility chemical inventory.
- Supporting documentation allowing disposal of containers must be maintained in facility records.
Print the Master Schedule and sign, date and maintain it with TS inventory in the test site facility files.



Key Points

Application Types Definitions (N-03.2)

- **Drench Applications:** Calculating the TS rate expressed as per unit area, per number of plants, or per pots in the GH.
- **Drip Applications:** Determining the amount of water applied to the plot by using a known amount in the tank or by collecting output from the emitters.
- **Pre or Post-Application Irrigation:** Calculating the number of acre inches of water to move the chemical into the root zone.

What Lies ahead

- **Advisories will be retired, eventually**
 - Once each Advisory becomes a National SOP, it will be retired and be removed from the Intranet and placed into eQA.
- **Next up Training/Documentation SOP**
- **Potential SOPs (with PMC approval)**
 - Decommissioning sites
 - Amending ASRs
 - Documentation for terminated trials



Questions?

Thank you for your participation!

