How to Get Started in Your Laboratory!

Core Accreditation Program

NIFA

NPDN
NATIONAL PLANT DIAGNOSTIC NETWORK

1 How to Get Started - On Your Mark...

What is Core?

Core is NPDN's laboratory accreditation system that was created based on STAR-D and ISO-17025 standards but was customized to meet plant laboratory needs and, to the extent possible, follow nationally agreed upon standards and procedures. These can be found in the NPDN Core Requirements and Standards document, NPDN-Core-001.

Why Core?

Core was created to provide an assessment of laboratories within the NPDN system. Accreditation through the Core program signifies that a laboratory has met essential requirements and standards which results in a conformity of test results, handling and reporting, regardless of which NPDN laboratory is used for processing.

- ★ Discuss with lab members what activities should be included within your accreditation and define your scope.
- ★ Determine a good time of year when you can dedicate time to begin implementing Core.
- ★ Read system documentation that will help you implement Core in your laboratory. Start with the NPDN Requirements and Standards and the Quality Manual template.

Helpful Hints

- Your lab probably has a system for doing business that is already effective, but maybe informal and undocumented. Take what you already have and organize it following the standards.
- Understanding how certain terms are used within laboratory accreditation systems will help you while implementing your system.

  E.g.
  Should, May, Can = Recommended
  Shall, Must, Will = Required
- Remember to tell yourself often: "We need to start the process and although not every document, form or procedure may be perfect, we are getting started."
- Think of this process and system as an improvement opportunity — once the base system is in place, you should pick an area or two each year to improve.

Goals:

1) Define & write the laboratory's scope by _____ (date). ☐ Completed: _____ (date). ☐

2) Read the NPDN Requirements & Standards (NPDN-Core-001) by _____ (date). ☐ Completed: _____ (date). ☐

3) Schedule a date to begin implementing Core by _____ (date). ☐ Began: _____ (date). ☐

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How to Get Started - Get Set... Go!

- Schedule the first steps of implementing Core in your laboratory.
- Go to the Core web page at www.npdn.org to see what is available to help you prepare and implement the Core program in your laboratory.
- Decide who will perform the Quality Manager functions in your laboratory.
- Review the example checklists so that you and your lab members are aware of the requirements to be accredited.

Helpful Hints

- Give yourself time to really think about the numbering system you will use for your documents.
- When developing the Quality Manual, use the numbering system reflected in the NPDN Core Requirements and Standards document, NPDN-Core-001.
- If a section does not pertain to your laboratory, list the number followed by the wording "NOT APPLICABLE"
- Consider using the same abbreviations and letters used by other NPDN members in their laboratories. For Core documents use Quality Procedure (QP), Work Instruction (WI), and Form. For institution and external documents use Standard Operating Procedure (SOP), External (EXT), and University (UNI).

Goals:

1) Introduce Core to your laboratory members by _____ (date). ☐ Completed: _____ (date). ☐

2) Review the Core web page on the NPDN website by _____ (date). ☐ Completed: _____ (date). ☐

3) Review the example checklists by _____ (date). ☐ Completed: _____ (date). ☐

4) Assign roles and responsibilities & select a Quality Manager by _____ (date). ☐ Completed: _____ (date). ☐

   a) Assign back-up roles to key personnel positions by _____ (date). ☐ Completed: _____ (date). ☐

   b) Specify personnel responsibilities, authorities & inter-lab relationships by _____ (date). ☐ Completed: _____ (date). ☐

5) Review the Quality Manual template; _____ (Name) by _____ (date). ☐ Completed: _____ (date). ☐

_____ (Name) by _____ (date); _____ (Name) by _____ (date). ☐ Completed: _____ (date). ☐

3 How to Get Started - Documents

- Look at example Quality Manuals to see how others interpreted the NPDN Requirements and Standards, and how they modified the Quality Manual template to suit their laboratory.
- Select which laboratory member will have the authority to implement the use of new documents and to approve document changes.
- Decide where you will store electronic versions of your documents. Be sure to choose a place easily accessible by laboratory staff.
- Write your Quality Manual. Look over QP, WI and Form templates, that pertain to section **1.3 Document Control,** decide which you will use.
- Create any needed **1.3 Documents Control** QPs, WIs and Forms.

Helpful Hints

- If you currently have tools that work effectively, keep them. If you already have documents that are effective, add a unique identifier.
- Not every procedure needs to be written down.
- When writing your documents, give yourself lots of flexibility. Do not say "Use a blue pen" when using any color ink will not change the results of the test.
- You will not always need all levels of documentation for every section. Some sections will be completely covered in your Quality Manual (QM), others may be introduced in the QM and specifics given in a QP, and others will need the QM, QP, WI and Forms.
- Include version numbers on each document. Small changes should increase by tenths; big changes may warrant a whole number increase.

Goals:

1) Look at other laboratories' Quality Manuals by _____ (date) ☐ Completed: _____ (date) ; _____ (Location) ☐

2) Assign document approval responsibility by _____ (date) ☐ Completed: _____ (date) ☐

3) Decide where your Core documents will be stored by _____ (date) ☐ Created Current Documents folder: _____ (date) ☐

Created Archived Documents folder: _____ (date) ☐

4) Write your Quality Manual by _____ (date) ☐ Version 1.0 Completed: _____ (date) ☐

5) Create your QPs, WIs, and Forms for documents by _____ (date) ☐ Completed: _____ (date) ☐

4 How to Get Started - Personnel/Training

- Evaluate any system(s) currently in place and ask yourself if it is an effective way of monitoring employee qualifications and competence.
- If a monitoring system is non-existent or inadequate, select a method to be used. Consider using the templates available on the Core web page regarding section **2.2 Personnel**, and ensure that whichever method is selected is readily retrievable.
- Create any needed **2.2 Personnel** QPs, WIs and Forms.
- Ensure you have access to each employee's job description and know their responsibilities, by either referencing the location or physically having a copy on file in your lab or electronically on a computer.
- Ask each staff member for a listing of their past trainings, workshops, and any relevent qualifications.

Helpful Hints

- You may want to use specific terminology for employees that have work experience or education that meets some training requirements. Ex: "John Doe was hired prior to XYZ date (see hired date) and therefore is not required to undergo the training and proficiency evaluations." **OR** "John Doe has been deemed proficient in the following processes based on his past performance."
- Many examples of quality training systems include both a new staff member orientation checklist and an employee training document.
- Learn where your institution keeps job descriptions on file and simply reference this location rather than make a duplicate system in your lab.
- **Key** personnel wording is important — define what constitute a key role.

Goals:

1) Evaluate current personnel qualifications and training monitoring system by _____ (date). ☐ Completed: _____ (date). ☐
2) If needed, select a method of documenting qualifications by _____ (date). ☐ Completed: _____ (date). ☐
3) Create your QPs, WIs, and Forms for personnel by _____ (date). ☐ Completed: _____ (date). ☐
4) Collect solicited staff member training listings by _____ (date). ☐ Completed: _____ (date). ☐
5) Record details in a selected monitoring system by _____ (date). ☐ Completed: _____ (date). ☐

5 How to Get Started - Equipment

Helpful Hints

- Use labels attached to instruments to indicate the need for service or calibration date. Place labels where they can be easily seen by users.
- Conduct all calibrations at the same time each year so that it becomes routine.
- Logs are an important part of your equipment monitoring system. Save time by using templates.

- Evaluate any system(s) currently in place and ask yourself if it is an effective way of tracking equipment purchases and maintenance.
- If non-existent or inadequate, select a method to be used. Consider using the templates available on the Core web page regarding section **2.5 Equipment**.
- Create any needed **2.5 Equipment** QPs, WIs and Forms.
- Inventory the equipment in each section of your laboratory that falls under the scope of your accreditation.
- Record details of the inventory in your selected equipment tracking system. Include unique identifiers, location, and date of significant events. The record should show calibrations and maintenance. Keep these and manuals readily available.
- Create a calibration schedule. Consider using the template available on the Core web page regarding section **2.5 Equipment**.

Goals:

1) Evaluate current system(s) for tracking equipment purchases and maintenance by _____ (date). ☐ Completed: _____ (date). ☐

2) If system(s) are non-existent or inadequate, select a method to be used by _____ (date). ☐ Completed: _____ (date). ☐

3) Create your QPs, WIs, and Forms for equipment by _____ (date). ☐ Completed: _____ (date). ☐

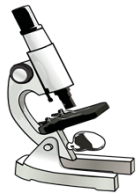
4) Inventory equipment in your laboratory that is under the scope of your accreditation by _____ (date). ☐ Completed: _____ (date). ☐

5) Record details of inventory in your selected equipment tracking system by _____ (date). ☐ Completed: _____ (date). ☐

6) Place equipment logs, manuals and records in a readily available location by _____ (date). ☐ Completed: _____ (date). ☐

7) Create a calibration schedule by _____ (date). ☐ Completed: _____ (date). ☐

6 How to Get Started - Sample Handling



- Evaluate any system(s) currently in place and ask yourself if it is an effective way of handling samples.
- If non-existent or inadequate, select a method to be used. Consider using the templates available on the Core web page regarding section **2.7.2 Sample Handling**.
- Outline how you are accomplishing sample receipt, identification, deviation, protection, storage, retention, transport, and disposal.
- Use the outline **2.7.2 Sample Handling** to create your QPs , WIs and Forms.

Helpful Hints

- Although the sample handling section may seem indistinguishable from the test methods section, there are specific differences. Think of sample handling as how you move samples through the lab from receipt to disposal, and test methods as specific to test protocols.
- In fact, the NPDN SOPs provide instructions for sample handling and test protocols in one document.
- Many labs simply show staff their sample handling process rather than providing them with written documents. This is acceptable if you can provide evidence that staff know all aspects of sample handling.
- Documents such as sample sign-in sheets, sample submission guidelines, sample submission forms, etc. are all part of sample handling.
- In this context, sample deviation refers to the situation when specimens depart from the specified conditions needed for the relevant test method.

Goals:

1) Evaluate current system(s) for handling samples by _____ (date). ☐ Completed: _____ (date). ☐

2) If system(s) are non-existent or inadequate, select a method to be used by _____ (date). ☐ Completed: _____ (date). ☐

3) Outline how you are accomplishing sample receipt, identification, deviation, protection, storage, retention, transport and disposal by _____ (date). ☐ Completed: _____ (date). ☐

4) Create your QPs, WIs, and Forms for sample handling _____ (date). ☐ Completed: _____ (date). ☐

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How to Get Started - CARs and PARs

- **C**orrective **A**ction **R**eports (CARs) and **P**reventive **A**ction **R**eports (PARs) are an important part of any quality management system. Consider using the QP, WI and Form templates on the Core web page regarding section **1.9 Corrective and Preventive Action**.
- This may be a function that you were previously not doing in your laboratory, but you can implement a CARs and PARs system easily.
- Develop a mechanism to document what you do when something goes wrong = corrective action.
- Develop a mechanism to document an employee suggestion for improvement = preventive action.
- Create any needed QPs, WIs, and Forms for **1.9 Corrective and Preventive Action**.

Helpful Hints

- Don't worry about determining if your issue is a corrective or preventive action. As long as you are addressing the issue, the label does not matter.
- When an issue arises that requires a modification to your policies or procedures, take a moment to fill out a CAR or PAR. This is to help mitigate the issue reoccurring.
  Ex. A mistake was made and not caught before-hand
- Schedule time to review your CARs and PARs with your laboratory staff. Used properly, you will soon value this tool.
- Preventive action is a pro-active process.
- Corrective action addresses the root cause of an actual problem (so that it does not get repeated). Versus a correction which is a quick fix of an actual problem.
  Ex. You write a report for the wrong sample number but catch it before it is sent out to the client. No corrective action measure is needed.

Goals:

1) Develop a mechanism to document corrective actions by _____ (date). ☐ Completed: _____ (date). ☐

2) Develop a mechanism to document preventive actions by _____ (date). ☐ Completed: _____ (date). ☐

3) Create your QPs, WIs, and Forms for CARs and PARs by _____ (date). ☐ Completed: _____ (date). ☐
   - You can use the Core templates or create your own

8 How to Get Started - The Rest of the Story

If you completed all the previous sections, you have come a long way towards implementing the Core system. Below are references to the rest of the steps that you must complete before your Core accreditation.

LAB MANAGEMENT REQUIREMENTS		TECHNICAL REQUIREMENTS	
1.4	Review of Request or Agreement	2.3	Accommodation and Environmental Conditions
1.5	Outsourcing of Test Services	2.4	Test Methods
1.6	Purchasing Services and Supplies	2.6	Reference Materials
1.7	Customer Feedback	2.8	Test Results Quality Control
1.8	Control of Nonconforming Testing and Test Results	2.9	Sample Results Documentation, Uploading and Reporting
1.10	Records		
1.11	Assessment		

Reviewing Your Quality Manual

It is important to review the sections of your newly written Quality Manual at a later date in order to ensure that you are actively and accurately following the guidelines you specified in each section.

Schedule a time when you will be able to review the different sections of your Quality Manual. Plan to review that section after you complete all of the activities for each section.

Review section 1.3 Documents by _____ (date). ☐ Completed: _____ (date). ☐

Review section 2.5 Equipment by _____ (date). ☐ Completed: _____ (date). ☐

Review section 2.7 Sample Handling by _____ (date). ☐ Completed: _____ (date). ☐

Review section 1.9 CARs and PARs by _____ (date). ☐ Completed: _____ (date). ☐

Notes

Use this area to jot down improvements and ideas that you think of while implementing the initial steps of the Core accreditation process. You may also run across problems that you cannot address immediately. Be sure to note those here as well.

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This document was made possible with funding from USDA-APHIS-PPQ-CPHST and the Farm Bill.

Special thanks to Kathy Burch, Pat Shiel, Geoffrey Dennis (USDA-APHIS-PPQ-CPHST), Judy O'Mara (Kansas State University), Shouhua Wang (Nevada Department of Agriculture) and Anne Vitoreli (University of Florida). In 2022, Elizabeth Dorman (Michigan Department of Agriculture and Rural Development) and Colette Gabriel (Ohio Department of Agriculture).