

## NSQAP Gude for Participants and Frequently Asked Questions Table of Contents

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## General NSQAP information

### NSQAP program overview

The Newborn Screening Quality Assurance Program (NSQAP) at the Centers for Disease Control and Prevention (CDC) is dedicated to ensuring the quality and reliability of newborn screening (NBS) tests. Here are the key points about NSQAP in the context of NBS:

1. **Purpose:** NSQAP aims to improve the quality of NBS programs across the United States, ensuring that newborns are accurately screened for various genetic, metabolic, and endocrine disorders.
2. **Components:** The program includes proficiency testing (PT) and quality control (QC) measures to assess laboratory performance in conducting NBS tests.
3. **Participation:** Laboratories involved in NBS can participate in the NSQAP to demonstrate compliance with quality standards and enhance their testing processes.
4. **Evaluation:** Participating laboratories are evaluated based on their performance in PT and QC activities, helping to identify areas for improvement and ensuring that screening results are reliable.
5. **Resources and Support:** NSQAP provides resources, training, and guidance to laboratories and public health programs to enhance NBS practices and ensure the timely identification of conditions that can affect a newborn's health.

Overall, NSQAP plays a vital role in safeguarding the health of newborns by ensuring that NBS programs are effective and that any identified conditions are addressed promptly.

## Proficiency Testing (PT) and Quality Control (QC) Programs Serve Different Purposes

### Proficiency Testing (PT)

- **Purpose:** PT programs are designed to assess a laboratory's performance by comparing its test results with those of other laboratories. They help ensure that laboratories produce accurate and reliable results.
- **Process:** In a PT program, laboratories receive a panel of 5 blinded samples with unknown biomarker levels and are required to analyze them as they would as if receiving NBS specimens in the routine workload, then report their results. These results are then evaluated to determine if the laboratory meets established performance criteria.
- **Frequency:** PT is typically conducted at regular intervals (e.g., quarterly or annually) and is often mandated by regulatory bodies or accreditation organizations.

### Quality Control (QC)

- **Purpose:** QC programs focus on the ongoing monitoring of laboratory processes and procedures to ensure that they are functioning correctly and producing valid results. QC helps identify any issues that may arise during routine testing.

- **Process:** QC involves the use of control samples, which are tested alongside patient samples to verify that the testing process is working as intended. Laboratories track the performance of these controls to detect any deviations from expected results.
- **Frequency:** QC is performed continuously or on a daily basis, depending on the laboratory's protocols and the type of tests being conducted.

In summary, PT evaluates a laboratory's overall performance against external benchmarks, while QC ensures the reliability of testing processes within the laboratory itself. Both are essential for maintaining high standards of laboratory quality and accuracy.

## NSQAP Participant Portal

The NSQAP Participant Portal (<https://nbs.dynamics365portals.us/>) is an online platform associated with the Newborn Screening Quality Assurance Program (NSQAP). It is designed to facilitate communication and data management for participants involved in the program. The portal allows users to access resources, submit data, track progress, and engage with program activities related to newborn screening quality assurance initiatives.

## NSQAP Enrollment information

### NSQAP Participation Requirements

The laboratory must be actively engaged in NBS, use the dried blood spot (DBS) matrix, and the laboratory's analyte reference ranges must represent the newborn period of life.

### Application for NSQAP Participation

NEW PARTICIPANTS must complete the Participation Request Form at this link

<https://nbs.dynamics365portals.us/pr/>

*A business street address is required for shipping. We cannot ship to a residential address or a Post Office Box. Tax ID and broker information may be required for laboratories located outside the United States.*

*Enrollment in NSQAP is not guaranteed and is subject to review. Approved applications received before 31 October will ship in January of the upcoming year.*

*Upon enrollment, the applicant will be emailed a time-sensitive invitation to register with CDC's Secure Access Management Service (SAMS). This is a requirement for accessing the NSQAP Participant Portal. Failure to respond within 30 days will result in account inactivation.*

### Cost for Materials and Shipping

There is no cost for DBS materials or shipping for regularly scheduled shipments. **You are responsible for any documents, import permits, fees, taxes, or other costs required by your country for release of your package from customs.** While there is no monetary cost for materials or shipping, results must be reported for all PT and/or QC programs you receive. **Notify NSQAP within 10 days of shipment to inform us of issues with receiving your package that may impact your ability to report results.**

### Requirements for Manufacturer Enrollment

A manufacturer must have at least five NSQAP participants using their product to enroll in our program. We will verify this criterion when we receive your registration request.

## Distributor

A distributor (DIS) is an entity that agrees to receive materials from NSQAP and distribute them to NSQAP participants. The primary role of a distributor is to manage all shipping tasks, ensuring timely and reliable delivery to participating laboratories.

While a distributor may also be a participating laboratory, it must obtain a separate distributor identification code number in the format **DIS-XXXX**, which is distinct from the NSQAP participant laboratory code number in the format **LAB-XXXX**.

Distributors are not authorized to request changes regarding participating laboratories, programs, or accounts unless such requests have been agreed upon and approved by both the NSQAP participating laboratory and the NSQAP team. When contacting the NSQAP team, distributors must reference the LAB ID they represent and include that laboratory in all correspondence.

The establishment of a distributor relationship may be initiated by either the participating laboratory or the distributor; however, both parties must mutually agree to the arrangement, and participation in a distribution group is optional. Laboratories that choose to receive an individual shipment, or are located in areas without an active distribution group, are fully responsible for all import-related activities, including duties, taxes, and any country-specific clearance requirements.

## Laboratory's Responsibility as a Participant

**Maintain SAMS Account** Each participating laboratory must have at least one contact on file with an active SAMS profile.

**Annual Reporting Requirement** To maintain active status in the program(s), participating laboratories must report results for each program at least one time each year to stay active in NSQAP and to continue to receive materials the following year. Failure to report results will result in inactivation from the program(s).

**Repeat Failure-to-Report** Laboratories that enroll in program(s) but subsequently fail to report any data for a cycle of one calendar year, will be deemed ineligible for future enrollment. Continued access to program materials and services will be denied upon reaching this threshold.

## Program Participation Policy

Participation in NSQAP programs is demand-based and subject to approval. Our primary goal is to meet the needs of domestic NBS laboratories.

Participation in NSQAP programs is completely free. Enrollment for upcoming years is **automatic** unless a request for withdrawal is submitted by the laboratory's primary contact or initiated by NSQAP.

If you are already enrolled, the following criteria must be met to maintain your enrollment:

1. Submit results at least once a year for each program in which you are currently enrolled.
2. Provide meaningful data in your submissions. Entries submitted without valid data (i.e., "placeholders" or incomplete information) will be considered non-submissions.

3. Ensure timely receipt of your shipments by working proactively with your customs and border agencies, as well as FedEx.
4. Any report from FedEx indicating refusal to accept even one shipment will result in automatic unenrollment from the program.

### Maximum Number of Laboratories per Country

NSQAP can support up to 50 laboratories per country.

## Program Additions and Account Updates

### Role of Primary Contact

Each participating laboratory can have only one primary contact. This person will:

1. Receives email communication from NSQAP
2. Receives NSQAP packages
3. Responsible for making program changes
  - a. Add/remove users
  - b. Add/remove PT or QC Programs
  - c. Request extra materials
  - d. Contact email addresses
  - e. Laboratory name
  - f. Laboratory physical address
  - g. Laboratory shipping address, etc.

### Add or Remove Proficiency Testing or Quality Control Program

The PRIMARY CONTACT must make this request.

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on HELP in the top black bar
3. Click on HELP on the drop-down
4. Click the "Open a New Request" blue box
5. On next screen, click on "**Modify (Add/Delete) Program**" under the Help Category
6. Type the program(s) to add or delete. *(refer to the list of NSQAP QA Programs on NSQAP Participant Portal)*
7. Click Submit

Enrollment in these programs is not guaranteed and is subject to review. Program changes received between November 1 and October 31 will be reviewed and, if approved, go into effect in January of the upcoming year. Changes received after October 31 will go into effect in January of the following year.

*Example:*

*Changes made between October 31, 2025, and November 1, 2026, will go into effect in January of 2027. Changes made after November 1, 2026, will be effective in January 2028.*

### Request Extra Materials

The PRIMARY CONTACT must make this request.

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on HELP in the top black bar

3. Click on HELP on the drop-down
4. Click the “Open a New Request” blue box
5. On next screen, click on “Extra Materials Request” under the Help Category
6. Type material needed and how material will be used
7. Click Submit

**Note 1:** Requests for extra materials are subject to review and approval by NSQAP. Our primary goal is to ensure adequate inventory and supply availability for upcoming shipment events and domestic program needs.

**Note 2:** For international requests, if your materials are approved, they will be included in the next scheduled shipment. If you need them sooner, you must provide a FedEx account number or prepaid shipping label for off-cycle shipping.

**Note 3:** If you are a manufacturer and NSQAP participant, and requesting materials before the next scheduled shipment, you must provide a FedEx account number or shipping label for early or off-cycle shipping.

## Materials Not Received

If you have not received your materials **within ten days of the shipment date**, submit a HELP REQUEST.

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on HELP in the top black bar
3. Click HELP in the pulldown menu
4. Click the “Open a New Request” blue box
5. Choose “Shipping” under Help Category
6. Type the shipment information
7. Click submit

**Notify NSQAP within 10 days of shipment to inform us of issues with receiving your package that may impact your ability to report results.**

## Update Primary Contact

The current Primary contact must email [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov) with laboratory code number, first name, last name, and email of new primary contact.

NOTE: If the current primary contact has left the organization, the new primary contact must email [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov) and include laboratory code number, first name, last name, and email of new primary contact.

## Update Shipping Address, Telephone Number, Etc.

The PRIMARY CONTACT must email [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov) with laboratory code number and description of updates needed. A contact update form will be provided to document the necessary changes and initiate the process for the requested updates.

## Contact NSQAP for General or Technical Questions

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on HELP in the top black bar
3. Click on HELP on the drop-down
4. Click the “Open a New Request” blue box
5. On next screen, click on “Other” under the Help Category
6. Enter question

7. Click Submit

## NSQAP Portal Access

### Add or Remove User Access

The PRIMARY CONTACT must make this request.

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on HELP in the top black bar
3. Click on Add/Remove Users
4. Select Add User or Remove User in the top field, complete the other fields, and click Submit.

### List of Users with Access

1. Log into the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>
2. Click on Lab Information in the top black bar
3. Click on Lab Information in the pull-down
4. See CONTACTS list

Note: YES next to name indicates portal access

NO next to name indicates no portal access

### Account is Locked, Password is Forgotten, or Password Cannot Be Recovered

The **user** must email NSQAPDMT@cdc.gov. Include your laboratory code number, first name, last name of the locked account. **The email must come from the user's email address associated with the locked account.**

**Every user must have their own login, and sharing login is not allowed as per SAMS policy. See the SAMS User Guide for more information. <https://auth.cdc.gov/sams/SAMSUserGuide.pdf?disp=true>**

### Forgot Password

1. From the NSQAP Participant Portal, click SAMS Login
2. Click Forgot Password under SAMS Credentials section
3. Enter your UserID and click OK
4. Follow instructions to create new password

*Note: If your UserID disappears when you click OK, repeat step 3.*

### **What is the difference between SAMS and the NSQAP Participant Portal?**

*SAMS is an authentication authority that provides central access to applications operated by the CDC.*

*The NSQAP Participant Portal is one of those applications.*

## Data Reporting and Summary Reports

### Shipping Dates and Data Deadlines

The NSQAP event schedule is located on the NSQAP Participant Portal. Scroll down to the bottom of the page and select Calendar: Key Dates and Events. <https://nbs.dynamics365portals.us/>

### Data Entry

All results are reported in the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>

User guides for each program are located by clicking HELP > NSQAP Portal User Guides

### Data Submission

After all results are entered and reviewed, they must be *submitted*. If the submit button is not clicked before the deadline, the results will not be transmitted to NSQAP. Reporting is not complete until the entered results are submitted.

### No Emailed Results Accepted

We do not accept results by email. All results must be reported using the NSQAP Participant Portal <https://nbs.dynamics365portals.us/>

### Data Deadline Extension

We cannot extend the reporting deadline. If you are unable to report results, we suggest you conduct a self-evaluation when the summary reports are released.

### QC Template Upload

To access the QC User guide with template upload instructions:

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on QC in the top black bar
3. Click on QC Information from the pull-down menu

**The ability to upload QC templates will close 15 days before the QC reporting deadline. Manual QC data reporting will be available until the QC reporting deadline.**

### QC Certification Page Location

The QC certification pages can be accessed from the NSQAP Participant Portal under the QC section.

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on QC in the top black bar
3. Click on QC Information from the pull-down menu
4. Click on QC Certification Information icon

### PT Summary Report Location

PT summary report location:

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on Lab Information in the top black bar

3. Click on Reports from the pull-down menu
4. PT summary Reports for all programs are under *View PT Summary Reports*

### PT Evaluation Location

PT Evaluation Location:

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on Lab Information in the top black bar
3. Click on Reports from the pull-down menu
4. Click on RESULTS-LAB-#### under Portal Reports and Documents  
*Note: Click on "Modified" to sort the reports by date*

### PT Interactive Report Location

PT Interactive report location:

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on Lab Information in the black bar
3. Click on Reports from the pull-down menu
4. PT Interactive Reports for all programs are under *View Interactive Reports*

### QC Summary Report Location

QC summary report location:

1. Log into the NSQAP Data Reporting Portal <https://nbs.dynamics365portals.us/>
2. Click on Lab Information in the top black bar
3. Click on Reports from the pull-down menu
4. QC summary Reports for all programs are under *View QC Summary Reports*

### Certificates of Participation

NSQAP **does not issue certificates of participation** for reporting PT or QC results.