



Biovigilance Component Hemovigilance Module Facility Enrollment or Component Activation

Objectives

- ❑ **Provide an overview of the National Healthcare Safety Network (NHSN) and the Hemovigilance Module.**
- ❑ **Learn how to enroll in NHSN for facilities new to NHSN.**
- ❑ **Learn how to activate the Biovigilance Component for facilities already enrolled in NHSN .**
- ❑ **Understand location mapping in NHSN.**

National Healthcare Safety Network

- ❑ **NHSN is a secure, Internet-based surveillance system managed by the CDC's Division of Healthcare Quality Promotion (DHQP).**
- ❑ **The Hemovigilance Module is designed for transfusion services staff in healthcare facilities to monitor recipient adverse reactions and quality control incidents related to blood transfusions.**

Purposes of NHSN

- ❑ **Collect data from a sample of healthcare facilities to permit valid estimations of the:**
 - Magnitude of adverse events
 - Adherence to practices to prevent adverse events
- ❑ **Analyze and report collected data to permit recognition of trends.**
- ❑ **Provide facilities with data that can be used for inter-facility comparisons and local quality improvement activities.**

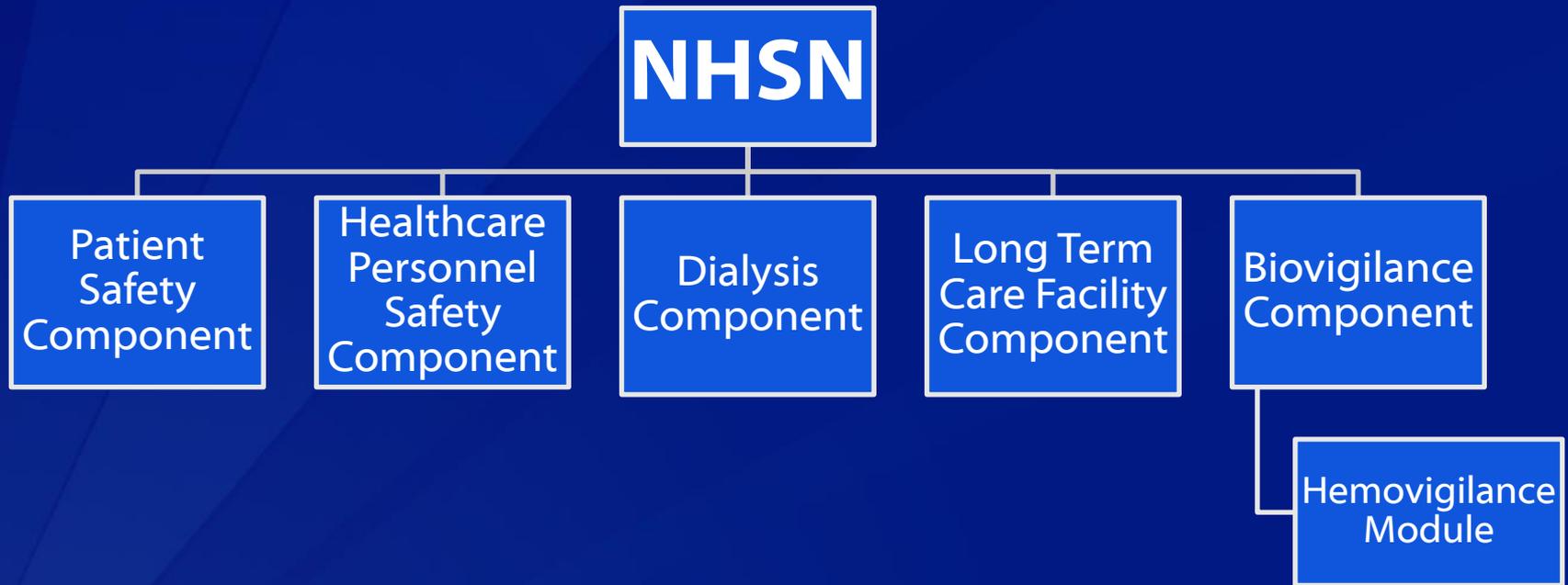
A comprehensive list of purposes can be found on the website:

<http://www.cdc.gov/nhsn/>

Assurance of Confidentiality

- “The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Section 304, 306, and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).”

NHSN Structure



Hemovigilance Module

- ❑ **The Hemovigilance Module requires surveillance from product receipt from suppliers to administration to patients.**
- ❑ **The Hemovigilance Module captures:**
 - Incidents related to the transfusion process
 - Errors and accidents that could lead to adverse reactions in transfusion recipients.
 - Adverse transfusion reactions
 - Undesirable response or effect in a patient temporally associated with a transfusion.
 - Denominators
 - Total number of units and aliquots of specified blood components transfused (each month); total number of discards (each month); and samples collected for type and screen and/or crossmatch.

Key Roles in NHSN

❑ Facility Administrator

- The person enrolling the facility in NHSN.
- Only person who can activate additional components for a facility.
- Has add/edit/delete rights to facility data, users, and users' access.
- Has authority to nominate/join groups for data sharing.
- Only person who can reassign the role of Facility Administrator to another user.

❑ Component Primary Contact

- Someone who is familiar with the facility's transfusion services.
- Interacts most closely with CDC for the component.

❑ Users

- Rights are determined by Facility Administrator: view data, data entry, data analysis.
- May be given administrative rights.

❑ One person may fill multiple roles.

Getting Started in the Hemovigilance Module

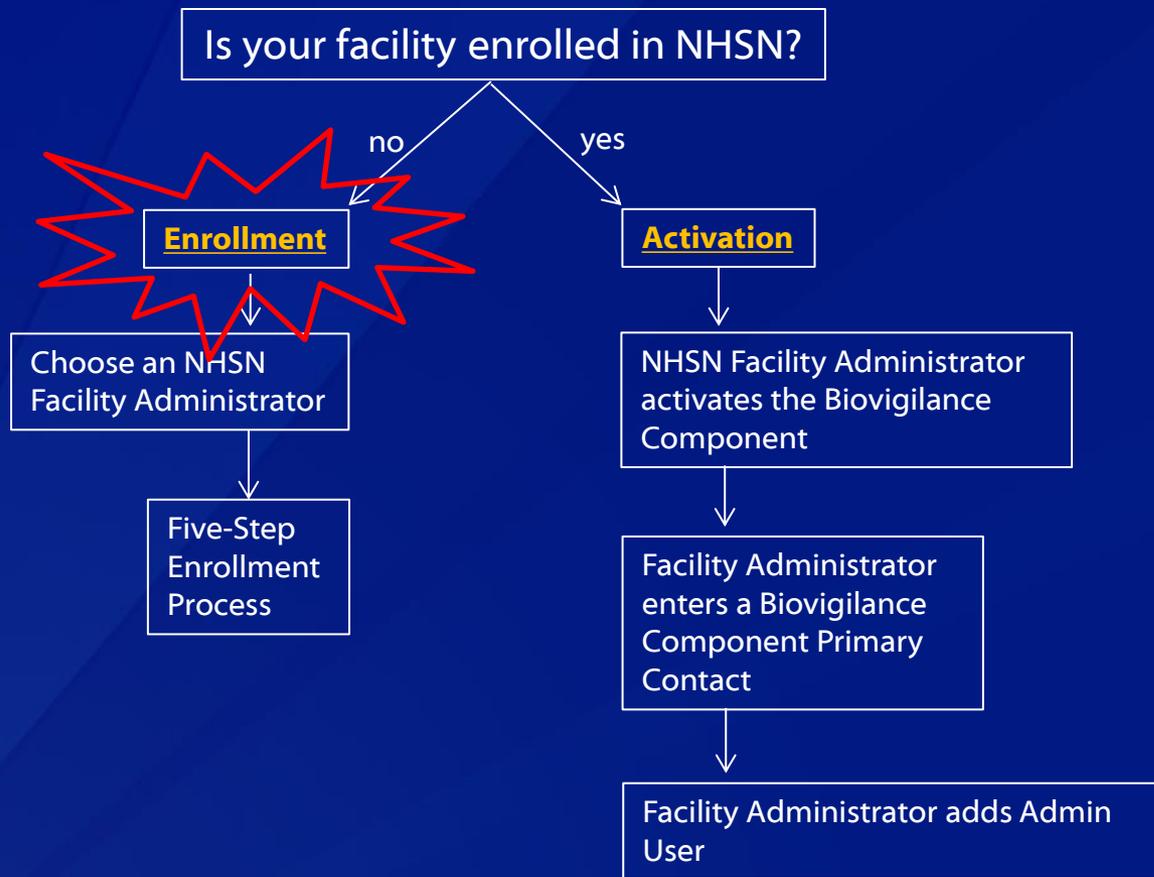
❑ Enrolling in NHSN

- Facilities that are currently not participating in NHSN and wish to participate must **enroll** their facility in NHSN.
 - Please visit <http://www.cdc.gov/nhsn/enrollment/index.html> for more information regarding the enrollment process.
- During the enrollment process, facilities may choose to participate in any of the NHSN components.

❑ Activating the Biovigilance Component

- Facilities that are **already enrolled** in NHSN and wish to participate in the Biovigilance Component must **activate** the component within NHSN.

Getting Started in the Hemovigilance Module



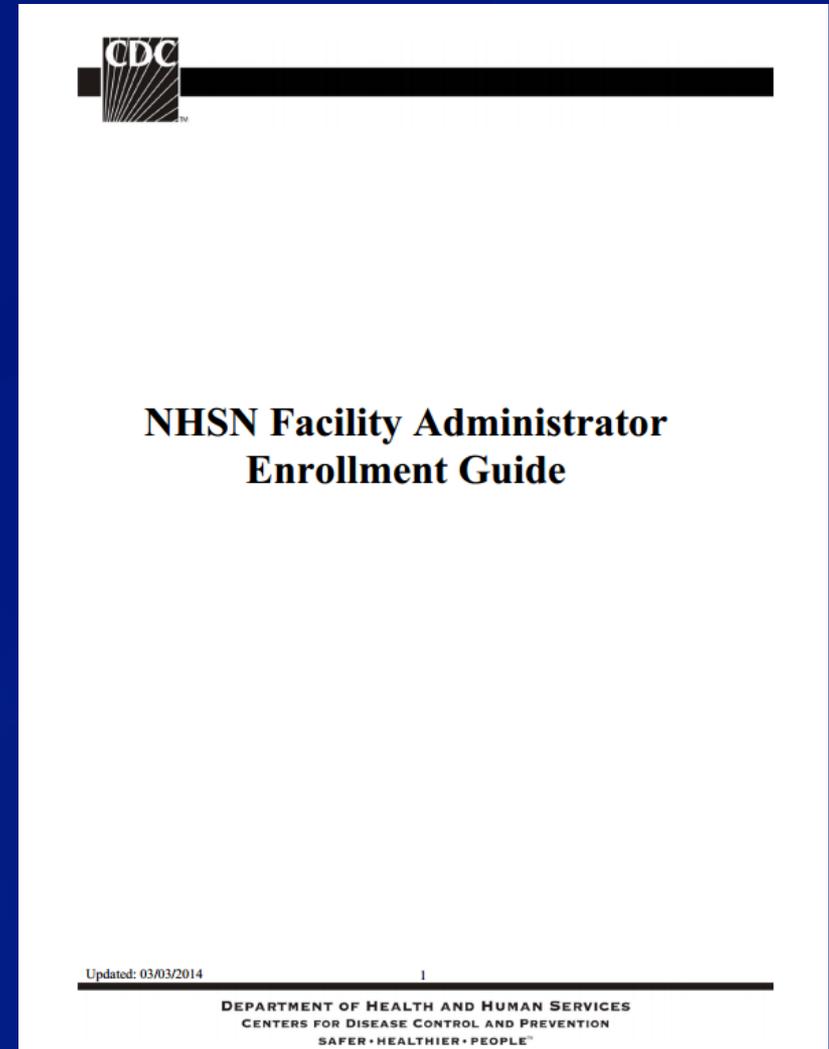
Are you unsure of your facility's status with NHSN?

- Email nhsn@cdc.gov



Enrollment of Facilities in NHSN

- ❑ **Choose an NHSN Facility Administrator**
 - This role should be filled by someone in the facility who has the authority to make decisions regarding facility and patient data.
- ❑ **Read the NHSN Facility Administrator Enrollment Guide.**
 - Available on the website at <http://www.cdc.gov/nhsn/acute-care-hospital/bio-hemo/enroll.html>.
 - Please read this guide before enrollment.



Five-Step Enrollment Process

1. Enrollment Preparation

2. Register for NHSN

3. Register for Secure Access Management Services (SAMS)

4. Submit forms Electronically

5. Sign and Send Consent

Step 1 – Enrollment Preparation

- ❑ **Read the enrollment materials before beginning**
 - “NHSN Facility Administrator Enrollment Guide”
 - “Purposes, Eligibility, Requirements and Confidentiality”
 - “NHSN Rules of Behavior for Facility/Group Administrators”
 - Enrollment materials can be found at <http://www.cdc.gov/nhsn/acute-care-hospital/bio-hemo/enroll.html>
- ❑ **Review the Biovigilance Component-related training materials at <http://www.cdc.gov/nhsn/acute-care-hospital/bio-hemo/index.html>.**
- ❑ **Completing the registration process may require assistance from your IT department.**
 - Update spam-blockers to allow emails from nhsn@cdc.gov and SAMS-NO-REPLY@cdc.gov.
 - Add https://*.cdc.gov to trusted sites and disable all pop-up blockers.

Step 2 – Register for NHSN

- ❑ Go to <http://nhsn.cdc.gov/RegistrationForm/index>.
- ❑ Read and agree to the Rules of Behavior.

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 Department of Health and Human Services
Centers for Disease Control and Prevention

National Healthcare Safety Network (NHSN)

Facility/Group Administrator Rules of Behavior

In order to participate in the NHSN , you must read and agree to abide by the following rules of behavior for safeguarding the system's security. Scroll through the document below and click on Agree or Do Not Agree button. To print a copy of the rules, click on the Print button.

NHSN, a surveillance system of the Centers for Disease Control and Prevention (CDC), allows participating healthcare facilities to enter data associated with healthcare safety, such as surgical site infections, antimicrobial use and resistance, bloodstream infections, dialysis incidents, and healthcare worker vaccinations. NHSN provides analysis tools that generate reports using the aggregated data (reports about infection rates, national and local comparisons, etc). NHSN also provides links to best practices, guidelines, and lessons learned.

NHSN processes and stores a variety of sensitive data that are provided by healthcare facilities. This information requires protection from unauthorized access, disclosure, or modification based on confidentiality, integrity, and availability requirements. These "Rules of Behavior" apply to all users of the NHSN web-based computer system.

Purpose

[Print Version](#)
PDF (87KB/13 pages)

WARNING
This is a U.S. Government computer system, which may be accessed and used only for official government business by authorized personnel. Unauthorized access or use may subject violators to criminal, civil, and/or

Step 2 – Register for NHSN

□ Personal Information

- This is the person who will be the NHSN Facility Administrator.
- The email address must be the same for all steps of the process.

□ Facility Identifier

- Select one and enter the number.

□ NHSN Training Date

- This is the date you completed all the required training.

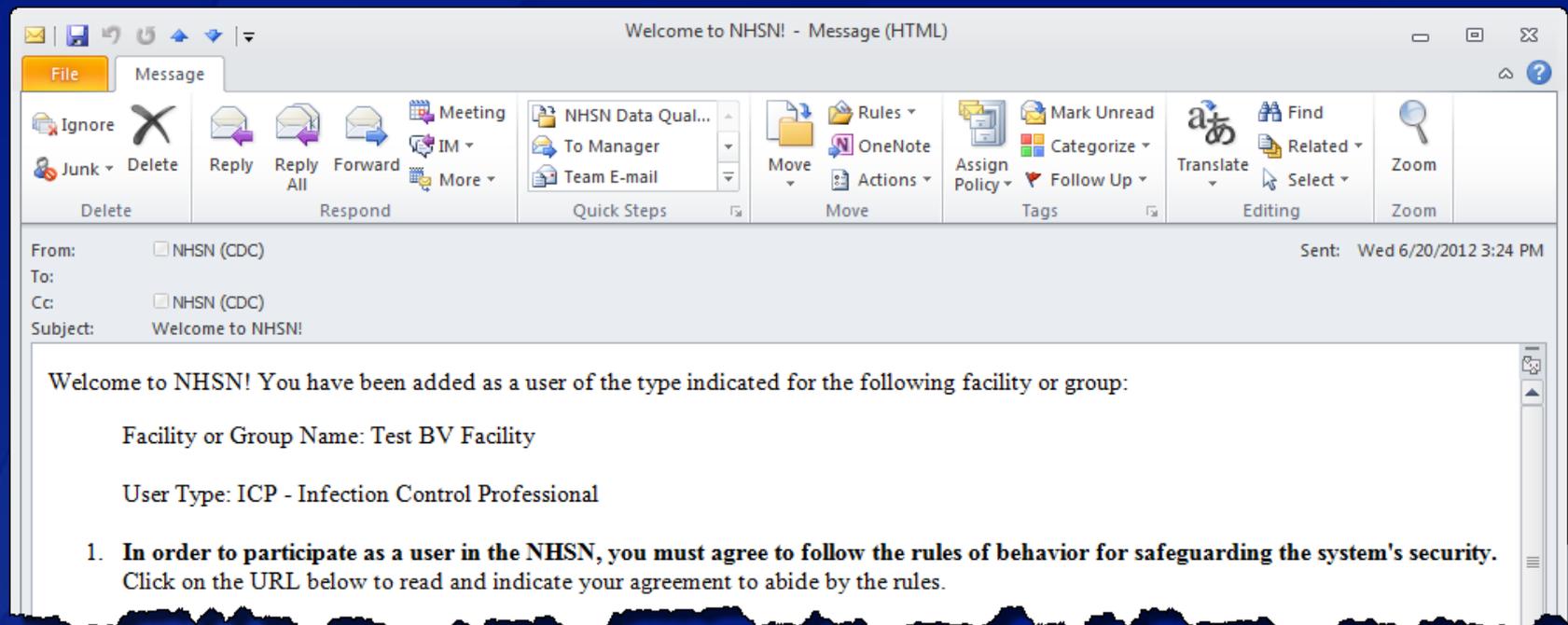
The screenshot displays a registration form with three main sections:

- Personal Information:** Contains four text input fields labeled: *Last name, *First name, Middle name, and *Email address.
- Facility Identifier:** Contains a selection prompt: *Please select a facility identifier: with radio buttons for CCN ID (selected), AHA ID, VA Station Code, CDC Registration ID, and None. Below this is a text input field for *Selected identifier ID.
- NHSN Training Date:** Contains a certification statement: *I certify that I have completed all of the appropriate, required NHSN trainings on: followed by a date picker.

At the bottom right of the form are two buttons: "Reset" and "Save". The "Save" button is highlighted with a red border.

Response from CDC: Welcome to NHSN Email

Following successful registration, you will receive a welcome to NHSN email.



Step 3 – Register for SAMS

- ❑ **The Secure Access Management System (SAMS) provides secure online access to and exchange of information between CDC and public health partners.**
- ❑ **Users receive an invitation to register with SAMS which provides instructions for registration and identify proofing in order to obtain access to CDC applications, including NHSN.**
- ❑ **Registration Approval**
 - During registration the user sets a password which expires every 60 days.
 - The user is also issued a grid card which adds an additional level of security when logging in to the system.

Important Facts SAMS and Email

- ❑ A person cannot obtain SAMS access without first being added as a user, with the exception of a Facility Administrator.
- ❑ Every new user must register with SAMS and provide identity proofing documentation.
- ❑ SAMS is a web-based system so access to NHSN via SAMS is available from any computer.
- ❑ Most communication from CDC to users is by email.
 - You must use the same email address throughout the NHSN enrollment or activation process as well as the registration process for SAMS.
- ❑ For detailed information regarding SAMS, visit <http://www.cdc.gov/nhsn/sams/about-sams.html>.

Step 3 – Register for SAMS

SAMS Homepage

SAMS
secure access management services

CDC

Warning: You are accessing a US Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for US Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following: You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Login Options

Choose one of the three login options.

SAMS Credentials



SAMS Username:

SAMS Password:

[Login](#)

[Forgot SAMS Password?](#)

For users who login with only a SAMS issued UserID and Password.

OR

SAMS Grid Card Credentials



Click login below to login with SAMS Grid Card.

[Login](#)

For users who have been issued a SAMS Grid Card.

OR

HHS PIV Card



Insert your PIV card in your smart card reader before you try to login.

[Login](#)

For users who are CDC staff and have been issued a PIV card.

SAMS Help: For more information and/or assistance, please contact the SAMS Help Desk between the hours of 8:00 AM and 6:00 PM EST Monday through Friday (excluding U.S. Federal holidays) at the following Toll Free: 877-681-2901, Email: samshelp@cdc.gov.

powered by: **miso**

The invitation to register contains the users Username and Password for SAMS registration. At first login, the user will need to accept the Rules of Behavior.

Step 3 – Register for SAMS Registration Page

Secure Access Management Services (SAMS) 

Welcome: Shea Graffo  Logout

Registration

Please provide the following information to register with SAMS, and click Submit. Required fields are marked with a red asterisk (*). Your registration will be routed to a SAMS Application Administrator for approval. You will receive an email notification when your registration has been approved and you have been granted access to SAMS.

User ID

First Name*

Middle Name

Last Name*

Suffix

Email

Home Address

Address Line 1*

Address Line 2

City*

State*

Postal Code*

Country*

After accepting the Rules of Behavior, enter the required registration information and click Submit.

Step 3 – Register for SAMS Identity Proofing

Hello New NHSN User,

Thank you for registering with CDC's SAMS Partner Portal. Your registration information has been received and is currently pending approval.

In order to provide individuals with access to non-public information, U.S. law *requires* the identity of potential users to be verified - this step is critical in helping to protect people's private data and in helping to prevent information misuse. Please be assured that CDC and its Programs have made every effort to keep this necessary process as simple and non-intrusive as possible. Also be assured that your identity information will only be used to help determine your suitability for access and that this data will not be shared outside of CDC programs.

To complete identity verification, please print the form attached to this email message and follow the instructions provided below. The required steps are as follows:

1. Complete the Applicant Section in the attached form - part of the information has been pre-filled for you based on the information you supplied during registration.
2. Take the printed form, along with appropriate photo identity documentation to a Proofing Agent (a person specifically designated by CDC to conduct identity verification or a Notary Public). Have them verify your identity and complete the Proofing Agent / Notary Section. Acceptable forms of identification are listed in the table below:

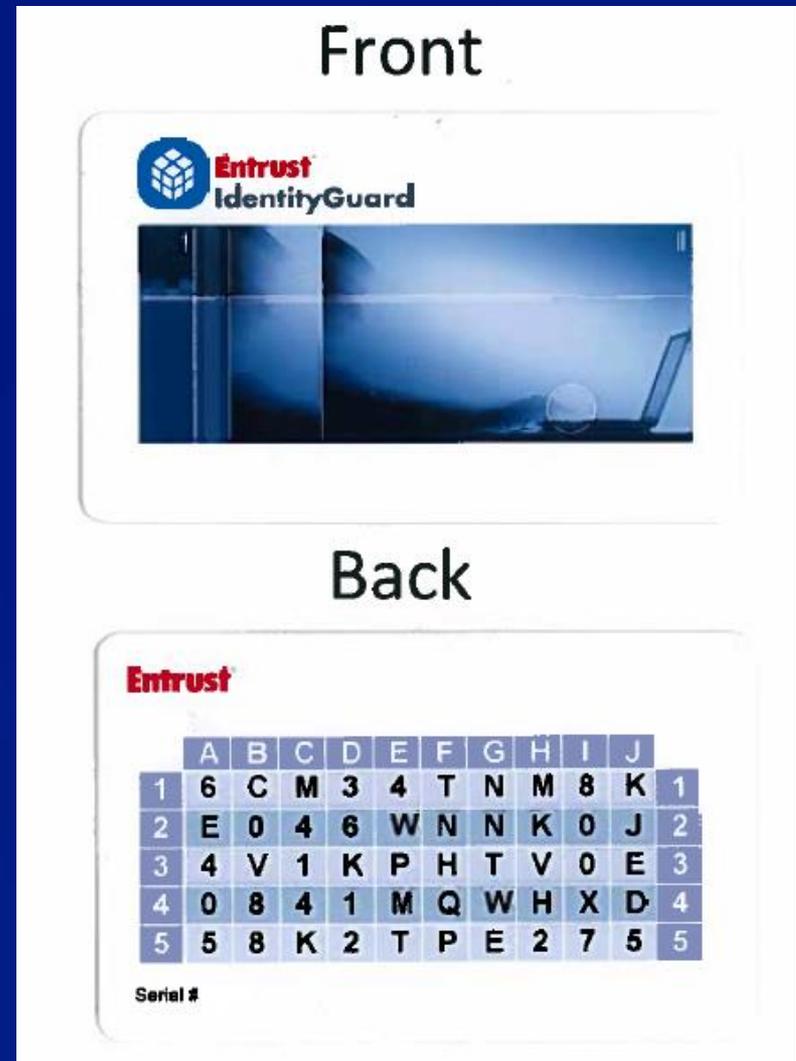
You must provide one (1) unexpired document from List A and one (1) additional unexpired document from List B.

List A - Primary Photo ID	List B - Secondary ID
Driver's license or ID card issued by a state	Driver's license or ID card issued by a state or outlying possession of

Carefully follow the instructions in the email to insure the enrollment process is not delayed.

Step 3 – Register for SAMS SAMS Approval

- Once your identity documentation has been processed, you will receive confirmation of approval for SAMS access.
- You will also be issued a grid card which will be mailed to your home address. The grid card, username, and password are required to log into NHSN.



Access NHSN

Once access is approved and you receive the grid card, you will be able to access NHSN at <https://auth.cdc.gov>.

SAMS
secure access management services

CDC

Warning: This is a U.S. Federal Government system and shall be used only by authorized persons for authorized purposes. Users do not have a right to privacy in their use of this government system. System access, activity, and information stored or transmitted may be monitored for adherence to acceptable use policy. Users of this system hereby consent to such monitoring. Improper or illegal use detected may result in further investigation for possible disciplinary action, civil penalties, or referral to law enforcement for criminal prosecution. This system contains non-public information that must be protected from unauthorized access, disclosure, sharing, and transmission, violation of which can result in disciplinary action, fines, and/or criminal prosecution.

Login Options

Choose one of the three login options.

SAMS Credentials



SAMS Username:

SAMS Password:

Login

Forgot SAMS Password?

For users who login with only a SAMS issued UserID and Password.

OR

SAMS Grid Card Credentials



Click login below to login with SAMS Grid Card.

Login

For users who have been issued a SAMS Grid Card.

OR

HHS PIV Card



Insert your PIV card in your smart card reader before you try to login.

Login

For users who are CDC staff and have been issued a PIV card.

Unsure which login method applies to you?

SAMS Help: For more information and/or assistance, please contact the SAMS Help Desk between the hours of 8:00 AM and 6:00 PM EST Monday through Friday (excluding U.S. Federal holidays) at the following Toll Free: 877-681-2901, Email: samshelp@cdc.gov.

powered by: **miso**

Step 4 – Submit Forms Electronically

Once logged into SAMS, under My Applications, click 'NHSN Enrollment'

SAMS
secure access management services

>Welcome Arty Woodward

SAMS Admin My Profile Logout

Warning: You are accessing a US Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for US Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following: You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Links

- SAMS User Guide
- SAMS User FAQ
- Identity Verification Overview

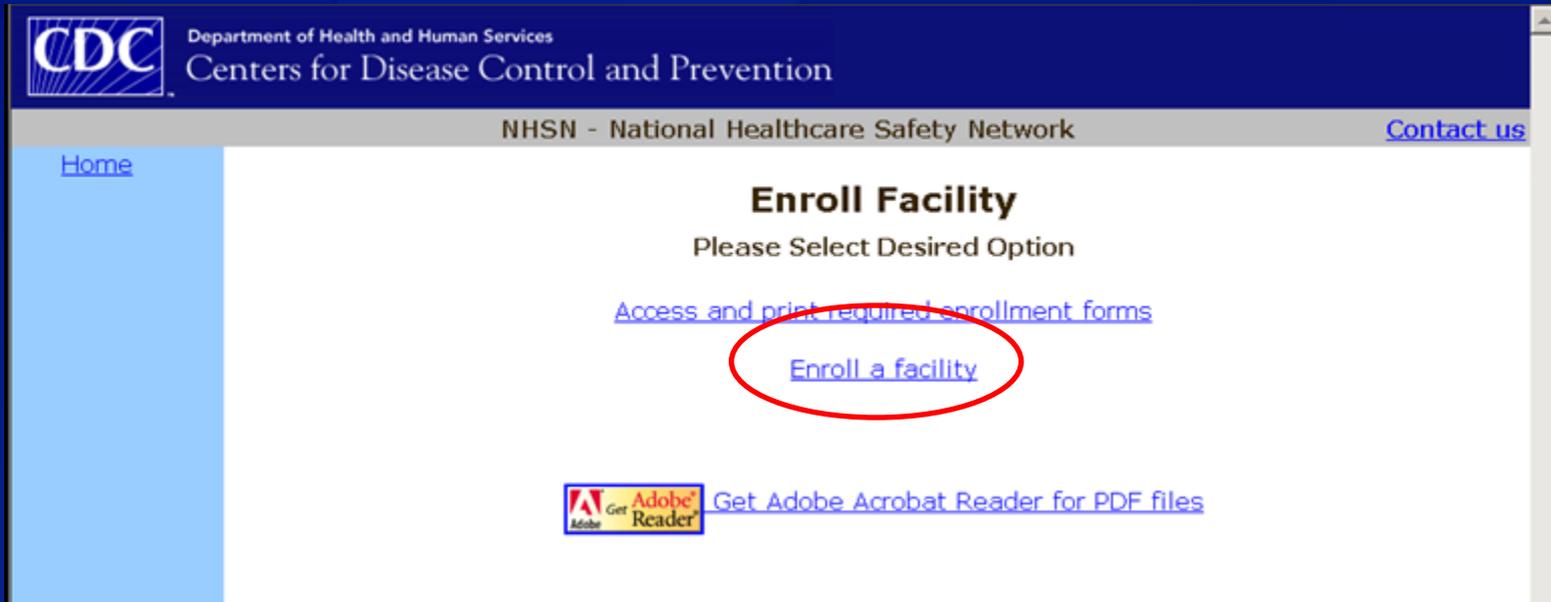
My Applications

National Healthcare Safety Network System

- NHSN Reporting *
- **NHSN Enrollment ***

* Strong credentials required.

Step 4 – Submit Forms Electronically



- ❑ **Click “Enroll a facility”**
 - If you have not completed the required forms, print and fill out the forms before continuing the “Enroll a facility” step by selecting “Access and print required enrollment forms”
- ❑ **The Annual Facility Survey must be completed online during the enrollment process.**

Step 4 – Submit Forms Electronically



Department of Health and Human Services
Centers for Disease Control and Prevention

NHSN - National Healthcare Safety Network

[Contact us](#)

[Start](#)

[Leave Enroll](#)

Enroll Facility

- ✓ The enrollment for facility 'Test Facility' with tracking number 99999 has been completed. The Facility Administrator will receive an email with further instructions.

Once required forms are submitted, the confirmation message will display.

Response from CDC: NHSN Facility enrollment submitted

- ❑ **The email will provide a link to access the “Agreement to Participate and Consent” form.**
 - You have **30 days** to access the consent form.
 - Consent form will open in a .pdf document.
 - Once you have accessed the form, CDC must receive the signed form, by fax or email, within **60 days**.
 - If you do not receive this email, contact the NHSN user support at nhsn@cdc.gov.

Step 5 – Sign and Send Consent

❑ Primary Contacts for Activated Components

- Fill in the contact information for all activated components.
- All signatures **must** be original.

❑ Official Authorization

- This section of the form must be completed by a C-level member of the facility (e.g., CEO, COO, CFO).

❑ The preferred method of returning the form is by fax.

- The fax number can be found at the bottom of page 3 of the form.

Step 5 – Sign and Send Consent

- ❑ 2-3 business days after NHSN receives signed consent form, NHSN will activate your facility.
- ❑ NHSN email notification of facility activation.

From: NHSN (CDC)
Sent: Wednesday, March 17, 2010 4:02 PM
To:
Subject: NHSN enrollment approved

To: NHSN Facility Administrator
From: NHSN
Date: 03/17/2010
Subject: NHSN enrollment approved

Your facility or group has been approved as a new member of NHSN. Welcome!

Facility Name: Alicia's Test Facility
Facility ID #: 00000

As the Facility Administrator, you will now need to access the NHSN application through SAMS by selecting the NHSN Reporting activity. Once in the NHSN application, your first task should be to add those individuals who need to use the application ("users").

Once you add a user, that person will receive an email prompting her/him to register with SAMS.

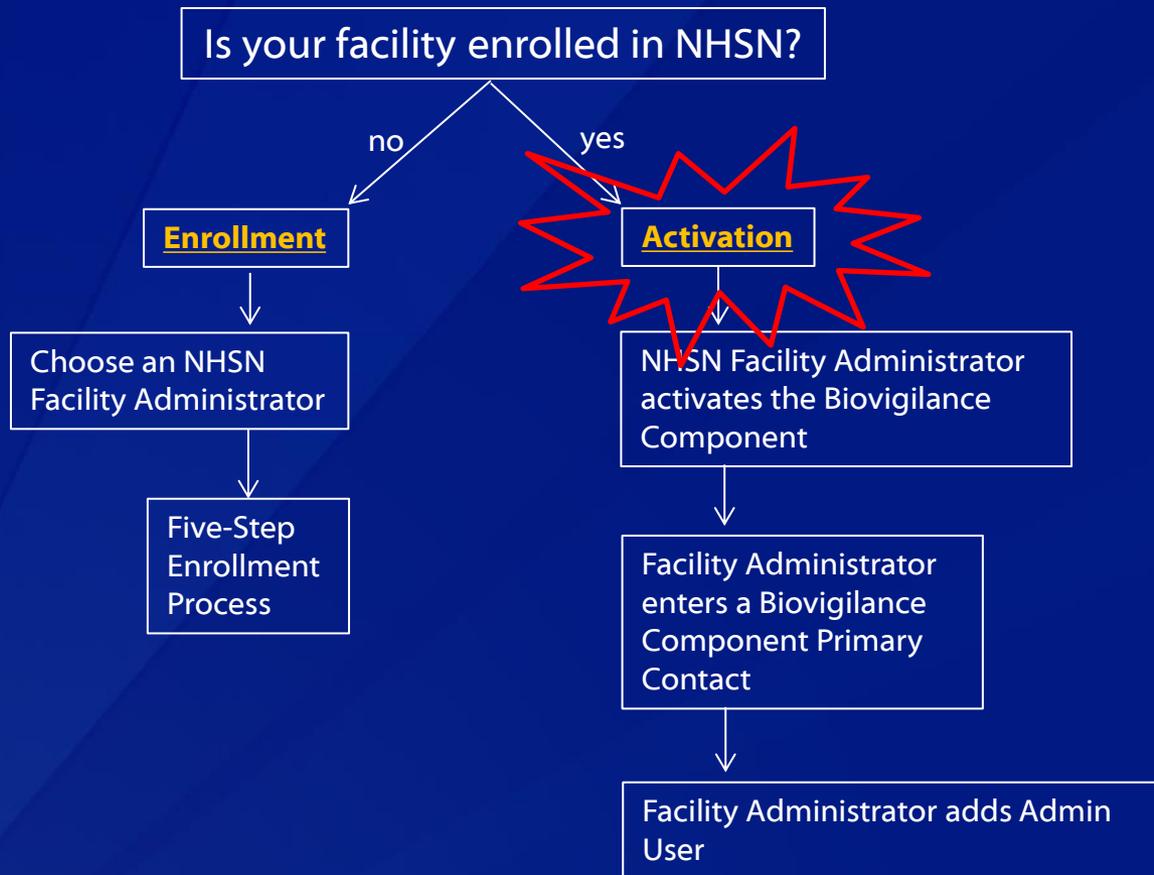
If you have any questions about NHSN, please contact us at nhsn@cdc.gov or <http://www.cdc.gov/nhsn>.

Enrollment is Complete

- ❑ **After enrollment is completed the Facility Administrator can:**
 - Add users and assign user rights
 - Map facility locations
 - Join Groups and share data

- ❑ **Once the Annual Facility Survey has been completed, the facility can enter Monthly Reporting Plans and begin reporting data to NHSN.**

Getting Started in the Hemovigilance Module



- ❑ **Are you not unsure of your facility's status with NHSN?**
 - Email nhsn@cdc.gov



Activating Biovigilance Component for Existing NHSN Facilities

- ❑ **Only the NHSN Facility Administrator can activate a new component.**
 - The Facility Administrator will designate a Primary Contact for the Biovigilance Component, i.e. someone who is familiar with the facility's transfusion services.
- ❑ **Add the Primary Contact as a user and give them Administrative rights to the Biovigilance Component.**
 - Being added as the Primary Contact for a component *does not* automatically add that person as a user.
 - This user with Administrative rights will be able to add additional Biovigilance users and share data using the Group function for the Biovigilance Component.

Activating the Biovigilance Component

- ❑ Facility Administrator logs into <https://auth.cdc.gov>
 - Under 'My Applications' select NHSN Reporting
 - Log into any active component
- ❑ From the Home Page, click "Facility" then "Add/Edit Component"
- ❑ Facility Administrator enters a Biovigilance Primary Contact, adds them as a user, and gives them Administrative user rights.

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NHSN - National Healthcare Safety Network (ISD-CLFT-NHSN1:8081)

Logged into NHSN Test Harvey Memorial (ID 10611) as KOO.
Facility NHSN Test Harvey Memorial (ID 10611) is following the PS component.

NHSN Patient Safety Component Home Page

Use the Navigation bar on the left to access the features of the application.

Assurance of Confidentiality: The voluntarily provided information obtained in this application is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes for which it was collected, and will be disclosed only in accordance with Sections 304, 305, and 306 of the Public Health Service Act, and the corresponding provisions of the Code of Federal Regulations.

NHSN maintenance may occur nightly between 12am and 6am Eastern time.

Get Adobe Acrobat Reader for PDF files

Navigation Bar:

- NHSN Home
- Reporting Plan
- Patient
- Event
- Procedure
- Summary Data
- Import/Export
- Auto CDA Sim
- Analysis
- Surveys
- Users
- Facility**
 - Customize Forms
 - Facility Info
 - Add/Edit Component**
 - Locations
 - Surgeons
- Group
- Log Out

Status:

Components Followed

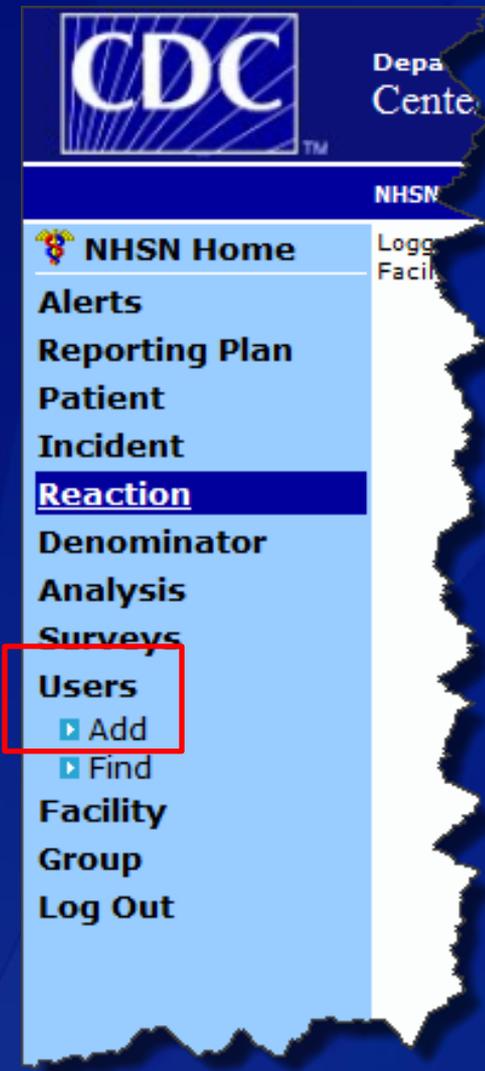
Component	Activated	Deactivated
<input checked="" type="checkbox"/> Biovigilance (Print Survey Form)	02/20/2009	
<input checked="" type="checkbox"/> Healthcare Personnel Safety	11/30/2005	
<input checked="" type="checkbox"/> Patient Safety	11/30/2005	

Contact Information [HELP](#)

Activating the Biovigilance Component

- ❑ **After the Facility Administrator adds the Biovigilance Component, the following must be completed:**
 1. Hemovigilance Module Annual Facility Survey
 - The survey does not have to be completed at activation, but must be completed before data entry

<http://www.cdc.gov/nhsn/acute-care-hospital/bio-hemo/index.html>
 2. Mapping locations
 - Confer with other component Primary Contacts before making changes to locations in NHSN.



Adding Users

- ❑ To add users to your facility, click **“Users”** on the navigation bar, then click **“Add”**.
- ❑ **“Add User”** screen mandatory fields
 - User ID – created by the facility
 - First Name
 - Last Name
 - Email Address – Must be an active/correct address for the user
- ❑ **Any user with administrative rights can add users.**

User Rights

- After saving the new user information, the “Edit User Rights” screen will appear.
- Please be sure to confer the proper rights to users.

CDC Department of Health and Human Services
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NHSN - National Healthcare Safety Network (apt-v-nhsn-test:8081)

Logged into KWC Test Hospital (ID 10976) as KOO.
Facility KWC Test Hospital (ID 10976) is following the BV component.

Edit User Rights

HELPER

User ID: **USER1 (ID 2437)**

Facility List:

Rights	Patient Safety	Healthcare Personnel Safety	Biovigilance
Administrator	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Rights	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Analyze Data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add, Edit, Delete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
View Data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Customize Rights	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Advanced

Effective Rights Save Back

The person assigned as the Primary Contact must be given rights as Administrator

Location Mapping in NHSN

- ❑ **Facility locations are used to stratify data in NHSN.**
- ❑ **Facility location information is shared across components.**
 - Locations used in one component may be used in other components and should not be duplicated or deleted.
 - Confer with other component Primary Contacts before making changes to locations in NHSN.



Location Mapping in NHSN

- ❑ **Locations are defined as physical areas of a facility.**
 - For the Biovigilance Component, locations are defined as any area where patients are transfused, could experience adverse reactions, and/or where products may be handled.
- ❑ **Facility locations must be “mapped” to a standard CDC location code.**
 - A list of CDC location codes, labels and descriptions can be found on the Biovigilance Component website, under the Supporting Materials section.





**Questions or Need Help?
Contact user support**

